DRAFT ENVIRONMENTAL IMPACT ASSESSMENT REPORT

For

"Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility"

At

Plot No. 27 & 28, TANSIDCO Industrial Park,

Village: Pellakuppam Taluk: Tindivanam District: Villupuram State: Tamil Nadu By



M/S. OMEXA FORMULARY PVT LTD

Kalyani towers, 174c, 2nd Avenue, Ashok Nagar, Chennai-600083, Tamil Nadu.

[Project is termed under Schedule 5 (f)-Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates)shall be considered as a Category "B1" since located within TANSIDCO Industrial Park]

Proposal No: SIA/TN/IND3/472326/2024 ToR issued videF.No. 10894 dated:29/06/2024 Baseline Monitoring Period – March to May 2024

EIA Consultant & Laboratory



M/s. HUBERT ENVIRO CARE SYSTEMS (P) LTD

NABET Certificate No & Validity: NABET/EIA/24-27/RA0335, valid up to 31.03.2027 NABL Certificate No: TC-12310 Dated: 25.09.2023 Valid Till 24.09.2025 July 2024



Revision Status

Name of the Client	:	M/s. Omexa Formulory Pvt Ltd
Name of the Project	:	"Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility"
Name of the report	:	Draft EIA report

Project No: H/01/2024/CON/65 Document No: RP003

Notes:

1. In Revision R0 – data request and correction.

Revision details:

No.	No. Date	Details	Prepai	red by	Checl	ked by	Ap	proved by
Rev	Data	Dotoils	Name	Sign	Name	Sign	Name	Sign
R0	03.07.2024	1 st submission to client	Tamil Selvan B	T.	Vamee Krishna Navooru	1.63	J.R. Moses	mular
R1	09.07.2024	2 nd submission	Tamil Selvan B	T.	Vamee Krishna Navooru	1.63	J.R. Moses	mular
R2	15.07.2024	3 rd submission - PH	Tamil Selvan B	Th	Vamee Krishna Navooru	1.63	J.R. Moses	-spulo-



ACKNOWLEDGEMENT

The following personnel are gratefully acknowledged for their fullest support in collection, compilation of needful data regarding the project and kind cooperation in fulfilling the report on Environmental Impact Assessment (EIA) report of "Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Survey No.Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District, Tamil Nadu State

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- 1. Dr. J R Moses (CEO)
- 2. Dr. Raj Kumar Samuel (Director Technical)
- 3. Mr. Vamsee Krishna Navooru (Head Consultant)
- 4. Mr Tamil Selvan B (EIA Coordinator)





Declaration by the Project Proponent

I, Mr. E.Ramanathan-Director, declaration/ undertaking that owing the contents (information and data) of the EIA report preparation has been undertaken in the compliance with Terms of Reference (ToR) for the "Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Survey No.Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District, Tamil Nadu State and the information and content provided in the report are factually correct.

For Omexa Form Pory Pvt. Ltd.

Authorized Signatory

Declaration by the Head of the Accredited Consultant Organization

I, Dr.J.R. Moses, hereby, confirm that the below mentioned experts prepared the EIA/EMP report for "Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Survey No.Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District, Tamil Nadu State. I also confirm that I shall be fully accountable for any misleading information mentioned in this statement.

Signature:

Date: 29.07.2024

Name: Dr.J.R.Moses

Designation: Chief Executive Officer

Name of the EIA Consultant Organization: M/s. Hubert Enviro Care Systems (P) Ltd, Chennai

NABET Certificate No & Validity: NABET/EIA/24-27/RA 0335, valid up to 31.03.2027.

Declaration of Experts contributing to the EIA

I hereby certify that I was involved in the preparation of EIA/EMP for the "Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Plot No. 27 & 28, TANSIDCO Industrial PARK, Pellakuppam village, Tindivanam Taluk, Villupuram District & Tamil Nadu State by M/S. OMEXA FORMULARY PVT LTDas EIA Coordinator with the support of the following Functional Area Experts.

EIA Co-ordinator:			
Name	Mr. Tamil Selvan B		
Signature	gent 2 9/07/2024		
Date	29,07.2024		
Period of Involvement	February 2024 to till date		

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Functional Area Experts:

S. No.	Function	al Areas	Name of the Expert	Involvement (Period & task)	Signature & date
1.	AP	FAE	Mr. Tamil Selvan B	Period:February 2024 to till date Task: Identification of Ambient Air Quality Monitoring locations, collecting secondary data on metorology and ambient air quality, preparing annual windrose, identifying impacts from various industries proposed and suggesting mitigation measures for the project.	Jent 29/07/2024
2.	AQ	FAE	Mr. Tamil Selvan B	Period:February 2024 to till date Task: Collection and developing of micrometeorological data from secondary sources, preparing site specific wind rose pattern, prediction of dispersion of pollutants and incremental pollution levels with air quality modelling. Identification of impacts and proposed the suitable control measures, development of EMP.	April 2024
3.	WP	FAE	Mr. Vamsee Krishna Navooru	Period:February 2024 to till date Task: Based on the type of industries proposed pepared	1-10-1/202

S. No.	Function	ıal Areas	Name of the Expert	Involvement (Period & task)	Signature & date
				the effluent characteristics and finalized the water balance for the project, Identification of surface and ground water quality monitoring locations.	
4.	SHW	FAE	Mr. Vamsee Krishna Navooru	Period:February 2024 to till date Task:Identification and Quantification of municipal solid waste and hazardous waste generated due to the proposed activity. Proposed suitable management methodologies for handling, disposal, treatment and storage of wastes.	2/4/07/2029
5.	SE	FAE	Mr. V. Dhivakar	Period:March 2024 to till date Task:Site visit, and conducted baseline socio-economic surveys. Collection of secondary data, discussion with stake holders and preparation of socio-economic status of the study area. Review of demographic characteristics, and supervision of baseline data collection. Collection and analysis of perception study carried out for the proposed project. Formulation of CER activities/plan for the project.	27/1/2024

S. No.	Functiona	l Areas	Name of the Expert	Involvement (Period & task)	Signature & date
6.	ЕВ	FAE	Mr. Tamil Selvan B	Period:February 2024 to till date Task:Site visit, collection of baseline data from primary and secondary sources on flora and fauna species, and comparing of field data. Compilation of Ecology and bio diversity data and their impact assessment on the study area, preparation of conservation plan, greenbelt development plan and environmental management plan for biological environment.	22/07/2024
7.	НG	FAE	Mr. PVRS Surendra	Period:March 2024 to till date Task: Identification of ground water potential of the study area, Collection of secondary data and preparation of report with respect to Hydrogeological condition in and around the study area.	Pres Surando 201/2004
8.	Noise & Vibration (NV)	FAE	Mr. Vamsee Krishna Navooru	Period:February 2024 to till date Task: Collected the ambient noise data through secondary sources, identification of noise monitoring locations and suggesting Noise pollution control measures during both phases of project.	1. Jan 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2

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S. No.	Function	ıal Areas	Name of the Expert	Involvement (Period & task)	Signature & date
9.	LU	FAE	Mr. Venkateshwaralu Rachala	Period:March 2024- May 2024 Task: Development of landuse maps of study area using GIS / related tools, site visit for ground reality survey, finalization of landuse maps and marking the ecologically sensitive details in the study area per Topo map and Gazette notifications	R. Venkatantus
10.	RH	FAE	Dr. J. R. Moses	Period:February 2024 to till date Task: Identification of hazards materials, Fire accidents and & Disaster management plan along with the preparation of risk forthe proposed project and development of EMP.	24/7/24

EIA Team Members:

S.No	Name	Role
1.	PVRS Surendra	TM for WP
2.	Abraham Abishek Moses	TM for AP & WP
3.	Pravina Rachel Moses	TM for WP & EB
4.	B Tamil Selvan	TM for WP
5.	Raj MP	TM for LU & WP
6.	Kannan Annamalai	TM for EC
7.	Dr Ramrajan S	TM for EB
8.	Praveenkumaar R	FAA for LU
9.	Mahadevi T	FAA for AP & AQ
10.	M Prabu	TM for SHW

AP - Air pollution monitoring, prevention and control

WP - Water pollution monitoring, prevention and control

SHW - Solid and hazardous waste management

SE - Socio-economics

EB - *Ecology and biodiversity*

HG - *Hydrology*, *ground* water and water conservation

Geo - Geology

NV - Noise & Vibration

LU - Land use

RH - Risk assessment and hazards management

SC – Soil conservation

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LIST OF ACRONYMS

AAQM-Ambient Air Quality Monitoring

CPCB-Central Pollution Control Board

CPHEEO- Central Public Health and Environmental Engineering Organisation

CTE-Consent to Establish

CTO-Consent to Operate

CSR-Corporate Social Responsibility

CER-corporate environmental responsibility

EIA-Environmental Impact Assessment

EMC- Environmental Monitoring Cell

EMP-Environmental Management Plan

ETP -Effluent Treatment Plant

GLC -Ground Level Concentration

KLD -Kilo Liters per Day

MoEF& CC-Ministry of Environment, Forests and Climate Change

MSDS-Material Safety Data Sheets

NAAQs- National Ambient Air Quality Standards

NABET-National Accreditation Board for Education & Training

OHSAS-Occupational Health and Safety Administration Series

PPE-Personal Protective Equipment

RO-Reverse Osmosis

SMS-Safety Management System



SPCB -State Pollution Control Board

STP-Sewage Treatment Plant

SIPCOT-State Industries Promotion Corporation of Tamil Nadu

SEZ- Special Economic Zone

TNPCB-Tamil Nadu Pollution Control Board

TANGEDCO-Tamil Nadu Generation and Distribution Corporation

VOC-Volatile Organic Compounds

ZLD-Zero Liquid Discharge



Executive Summary



EXECUTIVE SUMMARY

1. Project Description

M/s. Omexa Formulary Private Limited has proposing new manufacturing facility of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/ Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The total project site area is 3.743 Acres.

According to the EIA Notification, 2006 and its amendment issued by MoEF & CC under Environmental Protection Act - units located inside the notified industrial area/estate are listed under schedule no. 5(f) Category 'B1'.

Accordingly ToR application was submitted vide Proposal No: SIA/TN/IND3/472326/2024 dated: 06.06.2024 and ToR was issued vide F.No. 10894 dated: 29/06/2024. Baseline monitoring for the proposed project was undertaken from March to May 2024. As per the issued ToR, Draft EIA report has been prepared and submitted for conducting Public Hearing (PH). After completion of Public Hearing, the Final EIA report along with action plan for Public concerns by the project proponent will be submitted to TNSEIAA for further appraisal of the project and obtaining the Environmental Clearance (EC).

The project site does not come under Comprehensive Environmental Pollution Index (CEPI) of Critically Polluted Area. Also, this project does not come under National Clean Air Programme.

2. Project Location

The proposed project has planned to establish new manufacturing facility of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. National Highway NH-77 (Tindivanam-Krishnagiri)/ NH179B (Chennai-Tindivanam-Harur)~0.37 km (S). Venmaniyattur village is located ~ 1.16 km, N. The nearest town is Tindivanam ~ 2.0 km, ESE.

2.1 Site Salient features

Table 1 Salient features of the project site and surrounding features

S. No	Particulars	Details
1	Geographical Location	Centroid(12°15'10.79"N,79°37'5.11"E)
2	Present Land Use	Industrial use Zone as per site located in TANSIDCO Industrial



		Park, Pellakuppam Village District	e, Tindivan	ıam Talu	ık, Villupuraı
3	Nearest Railway Station	Nearest Railway Station - Tindivanam ~4.31 km (ESE)			
4	Nearest Airport	Puducherry Airport ~37.48 km	(SSE)		
5	Nearest Highway	NH-77(Tindivanam-Krishnagiri)/NH179B(Chennai-Tindivanam-Harur)~0.37 km (S)			
		Villages	~Dist	Dire	Population
		Hamlet(Periyar Ninaivu Samathuvapuram-Pattanam)	0.74km	NE	240
6	Nearest habitation	Venmaniyattur	1.16km	N	1,350
-	/Village	Pelakuppam	1.39km	SSE	1,610
		Vempundi	1.47km	SSW	1,843
		Pattanam	1.53km	ENE	2,896
		Tindivanam Nearest Town: Tindivanam ~ 2	2km	ESE	72,796
8	Densely populated	Tindivanam(Pop~72,796) ~2 kr	n (ESE)		
0	area			(1)	D:
9	area Inland water bodies	Sensitive places	~Dist ((km)	Direc
9		Sensitive places Water	~Dist (`	
9		Sensitive places	~Dist (`	Direc ESE
9		Sensitive places Water	~Dist (9	
9		Sensitive places Water Pelakuppam Lake	~Dist (9 9	ESE
9		Sensitive places Water Pelakuppam Lake Pattanam Lake	~Dist (rbodies 0.9 1.5	9 9 3	ESE NNE
9		Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake	~Dist (rbodies 0.9 1.5 2.1	9 9 3 6	ESE NNE SSE
		Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake	~Dist (rbodies 0.9 1.5 2.1 2.2	9 9 3 6 1	ESE NNE SSE SW
9	Inland water bodies	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3	9 9 3 6 1	ESE NNE SSE SW NE
	Inland water bodies Reserved Forests/	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake Avaiyurkuppam Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3 7.3	9 9 3 6 1 6 5	ESE NNE SSE SW NE SW
	Inland water bodies Reserved Forests/	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake Avaiyurkuppam Lake Kodiyam Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3 7.5	9 9 3 6 1 6 5 7	ESE NNE SSE SW NE SW N
	Inland water bodies Reserved Forests/	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake Avaiyurkuppam Lake Kodiyam Lake Saram Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3 7.5 7.9	9 9 3 6 1 6 5 7	ESE NNE SSE SW NE SW N ENE
	Inland water bodies Reserved Forests/	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake Avaiyurkuppam Lake Kodiyam Lake Saram Lake Vilukkam Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3 7.5 7.9 8.2	9 9 3 6 1 6 5 7	ESE NNE SSE SW NE SW N ENE
	Inland water bodies Reserved Forests/	Sensitive places Water Pelakuppam Lake Pattanam Lake Buderi Lake Vempundi Lake Melpakkam Lake Avaiyurkuppam Lake Kodiyam Lake Saram Lake Vilukkam Lake Elamangalam Lake	~Dist (rbodies 0.9 1.5 2.1 2.2 4.3 7.5 7.9 8.2 8.6	9 9 3 6 1 6 5 7 1 5	ESE NNE SSE SW NE SW N ENE W WNW



		Olakkur Lake	10.75	NE
		Sankaraparani R/Varaha N	10.85	WSW
		Etanemali Lake	10.98	NW
		Ongur Channel	14.05	ENE
		Nallur Lake	14.68	N
		Reserved Fo	orest (RF)	
		Sevur RF	12.39	Е
11	Defense Installations	Nil within 15 km radius	,	
	Archeologically	Monument	~Dist	Direc
12	Important places/	Pallava Rock-cut shrine	7.79km	N
13	Interstate/ National Boundaries	Nil within 15 km radius		
14	Notified Wildlife Sanctuary/ Notified national parks/ Ecologically sensitive areas	Nil within 15 km radius		

2.2 Magnitude of operation

The proposed project will involve manufacturing of Monoclonal antibodies with Capacity of 520 kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month. The list of proposed products and their respective quantities are given in Table 2

Table 1 List of Proposed products with quantity

Monoclonal antibodies (drug substances)

Sl.No	Product	CAS No.	Kg Per annum	Used to Treat
1	Pembrolizumab	1374853-91-4	100	Lung cancer, head and neck cancer, melanoma and cervical cancer.
2	Denosumab	615258-40-7	20	Treatment of osteoporosis. It is also used to treat bone loss in men with prostate cancer and in women with breast cancer
3	Ustekinumab	815610-63-0	20	Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis,



4	Bevacizumab	216974-75-3	10	Colon cancer, lung cancer, ovarian cancer, glioblastoma, and renal-cell carcinoma.
5	Adalimumab	331731-18-1	20	Spondylitis, rheumatoid arthritis, psoriasis,
6	Aflibercept	862111-32-8	10	Metastatic colorectal cancer.
7	Apixaban	503612-47-3	50	Stroke prevention · Deep vein thrombosis · Pulmonary embolism
8	Trastuzumab	180288-69-1	20	Breast and Stomach Cancer
9	Olaratumab	1024603-93-7	10	Solid Tumors
10	Omalizumab	242138-07-4	10	Moderate to severe asthma
11	Palivizumab	188039-54-5	10	Respiratory syncytial virus (RSV) infections
12	Panitumumab	339177-26-3	10	Colon and rectum Cancer
13	Tocilizumab	375823-41-9	10	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and other inflammatory disease
14	Trastuzumab emtansine	1018448-65-1	10	Breast Cancer
15	Infliximab	170277-31-3	10	Rheumatoid arthritis Ankylosing spondylitis Psoriasis
16	Eculizumab	219685-50-4	10	Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS),
17	Etanercept	185243-69-0	10	Rheumatoid arthritis · spondylitis · Psoriasis
18	Ziv-aflibercept	862111-32-8	10	Colorectal Cancer
19	Rituximab	174722-31-7	10	Rheumatoid arthritis, blood cancer
20	Ramucirumab	947687-13-0	10	Lung Cancer, Stomach Cancer and Rectum
21	Raxibacumab	5655451-13-0	10	Prophylaxis and treatment of inhaled anthrax.
22	Sarilumab	1189541-98-7	10	Severely active rheumatoid arthritis
23	Inotuzumab ozogamicin	635715-01-4	10	Acute lymphoblastic leukemia
24	Brodalumab	1174395-19-7	10	Inflammatory diseases.
25	Abatacept	332348-12-6	10	Rheumatoid arthritis
26	Abciximab	143653-53-6	10	Blood Clots
27	Agalsidase beta	104138-64-9	10	Genetical Disorders
28	Alemtuzumab	216503-57-0	10	Blood cancer (Chronic lymphocytic leukemia) · Multiple sclerosis (MS)
29	Alglucosidase alfa	420784-05-0	10	Treatment of Pompe disease (Glycogen storage disease type II)
30	Alirocumab	1245916-14-6	10	High cholesterol in Adults



31	Cetuximab	205923-56-4	10	Meta static Colorectal Cancer, Head & Neck Cancer
32	Pertuzumab	380710-27-5	10	Metastatic HER2 positive Breast cancer
33	Somatropin	12629-01-5	10	Growth Factors
34	Tenecteplase	191588-94-0	20	Prevents Thrombosis
Total		520		

Formulation products (drug products)

Filling Format	Quantity (Numbers per Month)
Prefilled Syringes	1,00,000
Vials	40,000
Lyophilised Vials	24,000

2.2.1 Land Requirement

The total land area is 15147.40 Sq.m. The land area break-up details are provided in **Table 3** and builtup area is given in **Table 4**.

Table 3 Land Area Breakup

Items	Area in Sq.m	Area in Acres	%
Ground coverage (plinth)	6472.00	1.599	42.73
Greenbelt	5011.40	1.239	33.08
Open Space	144.00	0.036	0.95
Road & Parking	3520.00	0.869	23.24
Total	15147.40	3.743	100

Table 4 Tentative Builtup Area

Items	Area in Sq.m
Manufacturing block	13370.00
R&D Block	1950.00
Admin/QC/QA block/reception	2400.00
Pilot plant + Dining	3875.00
Security Block	42.00
Creche, OHC & Utilities	600.00
Total	22237.00



2.3 Raw materials

All the raw materials required in manufacturing are procured from local markets. The raw materials and finished products are transported by road. All chemicals used in the process were stored in a designated area with proper labels in the warehouse.

2.4 Water Requirement

2.4.1 Construction phase:

About 40 KLD of water (for labour 1.4 KLD & Construction activities 38.6 KLD) will be required during the peak construction phase and it will be sourced through Private tankers.

2.4.2 Operation phase:

Total water requirement for the project is 132.4 KLD. Fresh water is 70.4 KLD and Recycled water is 62 KLD. Source of fresh water is TANSIDCO. Details of water requirement for the proposed project are given in **Table 5**

Table 5 Water Requirements-Proposed

Description	Fresh water (KLD)	Recycle water (KLD)	Total Water (KLD)
Pre-Treatment System for process & Lab	65	0	65
Cooling tower	0	37	37
Boiler	0	7	7
Greenbelt	0	18	18
Domestic	5.4	0	5.4
Total (KLD)	70.4	62	132.4

2.5 Power Requirement

Power requirement will be met from TANGEDCO. Two (2) DG set will be installed as back-up power requirement during power failure. The power and energy requirement details are provided below.

Table 6 Power and Energy Requirement

Details	Quantity	Source
Power Requirement (kVA)	1745.64	TANGEDCO
Back-up (kVA)	2x600	DG Sets
Boiler (kg/hr)	1x1500	For steam
Fuel Requirement:		
HSD (KLD) for Boiler	2.509 I	Local Supply such as HP, BHP & IOC



HSD for DG set (KL/Hr)	0.12	
` ,		

Note: *In ToR application, DG sets capacity - 2x350 kVA.

2.6 Manpower Requirement

Total Manpower requirement Breakup is given below.

Table 7 Manpower Requirements

S.No	Manpower	Construction Phase	Operation Phase
1	Contract	30	30
2	Permanent	0	90
	Total	30	120

Additional employment opportunity for product dealers and distributors, and transport sectors for product movement will increase the employment opportunity indirectly.

2.7 Project Cost

Estimated project cost is INR. 95 Crores

2.8 Municipal Solid waste generation and management

Municipal Solid waste generation and management for the proposed projectare given in Table 8

Table 8 Municipal Solid Waste Generation

S.No	Waste	Proposed (kg/day)	Total (kg/day)	Method of disposal
Opera	tions Phase (120 No	os)		
1	Organic	32.4	32.4	To Local TANSIDCO bins
2	Inorganic	21.6	21.6	To TNPCB Authorized Recyclers
3	STP Sludge	0.6	0.6	Used as a manure for greenbelt.
Total	1	54.6	54.6	-
Construction Phase (30 Nos): 13.5 Kg/day (Disposal through local TANSIDCO bins)				

Note: As per CPHEEO norms - 0.45kg/capita/day



2.9 Hazardous Waste generation and management

The details of hazardous waste generation and handling/Management are given in Table-9.

Table 9 Hazardous waste details

S.No	Description of Waste	Category as per HWM Rules 2016	QTY/Annum	Storage method	Method of disposal
1	Used /Spent Oil	5.1	1 KL		Will be collected and disposed through TNPCB Authorised recycler
2	Waste or residues containing oil	5.2	1 Ton	All the generated Hazardous	Will be collected and disposed through TNPCB Authorized TSDF
3	Discarded Containers/Bags	33.2	4 Ton	waste will be stored on Concrete	Will be collected and disposed through TNPCB Authorised recycler
4	MEE salt	37.3	16.5 Ton (50 kg/day)	platform in leak Proof	
5	ETP Sludge	35.3	3.3 Ton (10 kg/day)	Barrels in designated	Will be collected and
6	Off Specification Products (Doesn't Met by Specifications or standards)	28.3	2 Ton	areas	disposed through TNPCB Authorized TSDF
7	Expiry Products/Chemicals	28.5	1.5 Ton		

3. Description of the Environment

3.1 Meteorological Environment

The baseline study was carried out during March to May 2024.

Table 10 Micrometeorological data during study period

S. No	Parameter	Observation
		Max. Temperature: 41°C
1	Temperature	Min. Temperature: 24°C
		Avg. Temperature: 31.15°C
2	Average Relative Humidity	73.36%
3	Average Wind Speed	3.61m/s



4 Predominant Wind Direction South East	4	Predominant Wind Direction		
---	---	----------------------------	--	--

3.2 Ambient Air Quality

The ambient air quality has been monitored at 8 locations as per NAAQS, 2009 within the study area. The results obtained are summarized as below:

- The average baseline levels of PM₁₀ vary from 36.27 to $50.05 \mu g/m^3$.
- The average baseline levels of PM_{2.5} vary from 21.42 μ g/m³ to 27.88 μ g/m³.
- The average baseline levels of SO₂ vary from 8.50μg/m³ to 10.49 μg/m³.
- The average baseline levels of NO₂vary from 19.42 μ g/m³ to 21.81 μ g/m³

3.3 Noise Environment

8 locations under the study constitute of 7 locations in residential areas and 1 in industrial area. It was observed that within the Residential areas, noise levels (Day and Night) are well within the standards prescribed by CPCB.

- In Industrial area (Project site), day time noise level was about 54.6 dB (A) and 49.3 dB(A) during night time, which is within prescribed limit by CPCB for Industrial area (75 dB(A) Day time & 70 dB(A)Night time).
- In Residential area day time noise levels varied from 45.4 dB (A) to 54.6 dB (A) and night time noise levels varied from 40.4 dB(A) to 43.6 dB(A) across the sampling stations. The field observations during the study period indicate that the ambient noise levels in Residential area are within the limit prescribed by CPCB for Residential area (55 dB (A) Day time & 45 dB(A) Night time).

3.4 Surface water quality

Surface water sample results are discussed below:

- Water sampling results are compared with Surface water standards IS 2296:1992.
- pH in the collected surface water samples varies between 7.34to7.74which is within the limit of IS 2296:1992.
- The Total Dissolved Solids (TDS) value of collected surface water sample ranges from 395mg/l to 473mg/l.
- The Total hardness value of the collected surface water sample ranges between 175 mg/l to 265 mg/l.
- BOD value of surface water varies from 2 mg/l to 5 mg/L
- COD value of surface water varies from 10 to 22 mg/l.



3.5 Ground water quality

A summary of analytical results are presented below:

- The pH of the collected ground water sample ranges from 6.91-7.6
- The concentrations of Chloride in the collected ground water sample ranges from 146 to 206 mg/l.
- Total Dissolved Solids (TDS) value of the collected ground water sample varies from 650 mg/l to 750 mg/l.
- Total hardness of the collected ground water sample ranges from 226 mg/l to 243 mg/l.

3.6 Soil quality

Summary of analytical results

- The pH of the soil samples ranged from 6.55 to 7.56.
- Conductivity of the soil samples ranged from 276 to 346 μ S/cm.
- Nitrogen content ranged from 83.5 to 116.8 mg/kg.
- Phosphorous ranged from 3.6 to 5.3 mg/kg.
- Potassium content ranges from 37.5 to 50.3 mg/kg.

3.7 Biological Environment

A detailed biological survey of the core zone (Project site) and 10 km radius (Buffer zone) from periphery of the proposed project) was carried out based on secondary sources giving details of flora and fauna.

As Per Indian Wild Life (Protection) Act, 1972 as amended on 17th January 2003 is an Act to provide for the protection of wild animals, birds and plants and for matters connected therewith or ancillary or incidental thereto with a view to ensuring the ecological & environmental security. Indian Wild Life (Protection) Act, 1972 protects some of the sighted fauna.

While many birds are included in Schedule IV except Brahminy Kite (*Haliastur indu*) which comes under in Schedule I. Suitable measures and conservation plan was prepared for Brahminy Kite.

3.8 Socio economic status

The Socioeconomic profile of the study area shows that the majority of people in the study area work in non-agricultural sector, however in rural area majority of the people in the rural area depends on agricultural sector. They have good educational infrastructures and the people in the study area are well connected to the educational infrastructures. The average literacy rate of the study area is 71.54 %. The people in the study area are well connected to Government primary health centres and Primary health subcentres.



Table 11 Socio- economic indicators of study area

S.No	Particulars	Study area	Unit
1	Number of villages in the Study Area	59	Nos.
2	Total Households	38642	Nos.
3	Total Population	162540	Nos.
4	Children Population (<6 Years Old)	17309	Nos.
5	SC Population	46608	Nos.
6	ST Population	1971	Nos.
7	Total Working Population	70465	Nos.
8	Main Workers	56966	Nos.
9	Marginal Workers	13499	Nos.
10	Cultivators	10205	Nos.
11	Agricultural labours	25509	Nos.
12	Household Industries	1479	Nos.
13	Other Workers	33272	Nos.
14	Literates	116282	Nos.

Source: census 2011

4. Impact on Air environment

Air quality modelling was done using AERMOD software to identify the ground level concentration due to operation of proposed industries. The details on the type of fuel proposed, emissions are given in Chapter-4 of the EIA report. Based on the modelling done, the total ground level concentrations from point source and line source are given in below:

Table 12 Total Maximum GLCs from the Stack Emissions

Pollutant	Max. Base line Conc. (μg/m3)	Estimated Incremental Conc. (μg/m3)	Total Conc. (μg/m3)	NAAQ standard (μg/m3)
PM	59.48	0.056	59.536	100
SO2	12.46	0.048	12.508	80
NOx	25.92	0.832	26.752	80
СО	720	1.497	721.497	4000

Table 13 Total Maximum GLCs from the Vehicular Emissions

Pollutant	Max. Base line Conc. (μg/m3)	Estimated Incremental Conc. (µg/m3)	Total Conc. (μg/m3)	NAAQ standard (μg/m3)
PM	59.48	0.03	59.51	100
NOx	25.92	0.87	26.79	80



Table 14 Total Maximum GLCs from the cumulative Emissions

Pollutant	Max. Base line Conc. (μg/m³)	Estimated Incremental Conc. (μg/m³)	Total Conc. (μg/m³)	NAAQ standard (μg/m³)
PM10	59.48	0.05	59.53	100
SO2	12.46	0.04	12.5	80
NO _x	25.92	0.87	26.79	80
СО	720	22.16	742.16	4000

Air pollution control measures will be taken and the following will be adopted:

- 1. There are no process emissions from the proposed manufacturing facility.
- 2. Wet scrubber with stack height of 3.0 m (AGL) will be provided for QC lab vent.
- 3. Utilities stacks are provided with adequate height for DG Sets-30m for 2x600 KVA and also 30m for 1x1.5TPH boiler.
- 4. Adequate Green belt area will be provided

5. Alternate site consideration

No Alternative site was selected since the Omexa selected the plot at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State

Specific Site Selection Criteria of the Unit have been given below:

- 1. It is allocated within Notified TANSIDCO industrial Park.
- 2. Site is well connected by road (~0.37km, S), railways (~4.31 Km, ESE) and Airway (~37.48 km,SSE)
- 3. Sufficient land is available within the TANSIDCO IP.
- 4. 100% assurance of water & power supply by TANSIDCO.

6. Environmental Monitoring Programme

A monitoring schedule with respect to Ambient Air Quality, Water & Wastewater Quality and Noise as per CPCB/MoEF&CC/Tamil Nadu Pollution Control Board (TNPCB) shall be maintained.

7. Public Hearing

The Draft EIA report is being submitted to TNPCB for conducting Public hearing.



8. Rehabilitation and Resettlement

R&R is not applicable; since site is located within TANSIDCO industrial area

9. Environmental Management Plan

9.1 Air Environment

- 1. There are no process emissions from the proposed manufacturing facility.
- 2. Wet scrubber with stack height of 3.0 m (AGL) will be provided for QC lab vent.
- 3. Utilities stacks are provided with adequate height for DG Sets-30m for 2x600kVA and also 30m for 1x1.5TPH boiler.
- 4. Adequate Green belt area will be provided.

9.2 Noise Environment

As a preventive measure for the noise reduction the following will be adopted:

- 1. Acoustic measure for all the DG set, air compressor and feed water pumps etc.
- 2. Greenbelt development and maintenance will attenuate the noise levels.
- 3. The designed equipment with noise levels not exceeding beyond the requirements of Occupational Health and Safety Administration Standard will be employed.
- 4. Personal protective Equipments (PPE) will be provided to the workers who are working in high noise areas.
- 5. Speed restrictions will be provided to the vehicles in the plant premises.

9.3 Water Environment

Total waste water is separated into sewage and Trade effluent.

Table 12 Liquid waste management

S. No	Description	Proposed Quantity KLD)	Final Disposal Points	
		Con	struction Phase	
1	Sewage	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development	
	Operation Phase			
1	Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.	



			Will be treated through packaged STP (6 KLD) and
2	Sewage	4.6	treated sewage will be reused for Greenbelt development.
			STP Sludge will be used as a manure for greenbelt.

No disposal of wastewater outside the plant premises and Zero Liquid Discharge (ZLD) concepts will be implemented. Technical Specification of STP and ETP is attached as an **Annexure-5a** and **Annexure-5b**.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- ➤ Chemical dosing system
- \triangleright Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.



Online monitoring System: All pollution generating stream will be connected to server of OCMS, TNPCB. So it will be continuously monitored.

9.4 Solid & Hazardous waste:

- 1. STP is proposed for treating the sewage generated and treated sewage will be used for green belt development within the industry.
- 2. ETP with ZLD scheme is proposed to treat the effluent. Hence there will be no discharge of treated/untreated wastewater outside the project premises.
- 3. Municipal Solid Wastes generated will be segregated to organic and inorganic wastes. The organic wastes (33 kg/day) will be disposed to TANSIDCO Bins and inorganic waste (21.6 kg/day) will sell to TNPCB authorized vendors.
- 4. Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant.
- 5. Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental Clearance from SEIAA, Tamil Nadu.

9.5 Greenbelt Development

The total land area is 15147.40 Sq.m and Greenbelt area is 5011.40 Sq.m (33.08%). Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted as calculated below:

S.No	Description	Unit	Proposed Greenbelt within project site
1	Total area of project site	На	1.5147
2	Total Area of Green Belt	На	0.5011
3	Percentage of total project area		33.08
_	the MoEF&CC Requirement, No. ring 80% survival rate	of tree sap	olings to be planted as per guidelines(2500 tree/Ha)
4	As per MoEF&CC requirement	Nos	1503
5	Actual No. of plants present	Nos.	-
5	No of plants to be planted	Nos.	1503
6	Fund Allotted	Lakhs	6.00
7	Status of Implementation	-	Within 3 year



Table 13 Recommended Species for Proposed Green Belt Development in project site

S.No	Scientific Name	Common Name	No of Trees	Yearwise	
1	Pongamia pinnata	Pungai	300	1 st Year	
2	Thespesia populnea	Poovarasu	300	2 nd Year	
3	Albizis lebback	Vaagai	150	2 1 ear	
4	Cassia fistula	Sarakondai	150	3 rd Year	
5	Lagestroemia Speciosa	Poo marudhu	150	s year	
6	Pterocarpus Marsupium	Vengai	150		
7	Aegle Marmelos	Vilvam	150	4 th Year	
8	Madhuca longifolia	Iluppai	153		
	Total		1503		

9.6 Risk Assessment

Risk assessment is an indispensable part of Process Safety Management (PSM). PSM must be invariably invoked when involved in handling, using, storing, moving, or manufacturing of highly hazardous chemicals. The M/s.Omexa Formulary Pvt Ltd is planning to manufacture of bulk drugs & intermediates & formulation products, handles some solvents which pose health and flammability hazard. Thus, the risk associated with production facility was assessed and to be elaborated in this report. The Risk Assessment study has been performed as dictated by the IS15656:2006 "HAZARD IDENTIFICATION AND RISK ANALYSIS - CODE OF PRACTICE" to give crucial insights on the hazards involved in the facility line of production.

Based on the available studies & plant layout, the potential scenarios which can cause significant consequences like Dispersion of vapour cloud, fire and explosion scenarios were identified. The purpose of the study includes the following:

- > To identify those hazards that pose health and flammability risks as per NFPA rating.
- ➤ To eliminate or reduce to As Low As Reasonably Practicable (ALARP) the risk to human health, risk of injury, risk of damage to plant, equipment and environment, business interruption or loss etc.
- > To Suggest On-site Mitigation Measures

9.7 Budgetary provisions for EMP

The capital cost of EMS is Rs 456.0 lakhs and recurring cost will be Rs. 42.2 Lakhs, this includes cost of APCM, ETP, STP, Solid and Hazardous waste management, Safety equipments and greenbelt development as well third party monitoring, maintainace and membership cost



Table 14 Budget for Environmental Management Plan

S. No	Particulars	Proposed Capital Investment (Rs in lakhs)	Recurring Cost per Annum (Rs in Lakhs)
Enviro	nment Management Plan		
Water	Pollution Control		
1	ETP	350	20
2	MEE/ATFD and RO	330	20
3	STP	8.5	2
Air Po	llution Control		
4	DG & Boiler Stack/ Wet scrubber	60	3
Enviro	nmental Monitoring		•
5	Environmental Monitoring by third party	0	4.4
Solid W	Vaste Management		•
6	Solid Waste Management	2	3
Greenb	elt		•
7	Greenbelt Development	7	2
Hazard	ous Waste Management		•
8	Hazardous Waste Management	2	5
Storm '	Water and Rain water harvesting managemen	t	
9	Storm Water and Rain water harvesting management	26	2.6
10	OHC Expenses	1.5	0.2
	Total	456.0	42.2

10. CER Cost:

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost ie., (INR 1.9 crores) will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing

11. Project Benefits

 Presently, 120 persons are expected to be employed for the skilled, semi skilled and unskilled category for the proposed project.



- The preference will be given to local populations for employment in the semi skilled and unskilled category, this will increase the employment opportunity in the surrounding area.
- Secondary jobs and indirect employment are also bound to be generated to provide day to day needs and services to the work force and industrial activity.
- This will also increase the demand for essential daily utilities in the local market.
- The employed people will be benefited financially. This financial gain will fulfill their monetary requirements which in turn will increase their standard of living.



CHAPTER – 1 INTRODUCTION



1 INTRODUCTION

1.1 Purpose of the Report

M/s. Omexa Formulary Private Limited has proposed a new manufacturing unit of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Prefilled Syringes &Vials and Lyophilized vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State.

The total project site area is 3.743 Acres. The land document (Allotment letter) is attached as Annexure-1a. The proposed project comes under the notified industrial area since SIPCOT obtained the EC for development of industrial park at Tindivanam over an extent of 291.60.5 Ha under Schedule 8(b), Category B1 is attached as **Annexure** – **1b**. Subsequently Office Order signed between SIPCOT and TANSIDCO for the development of industrial Park over an extent of 113.00 Acres is attached as an **Annexure-1c**. The proposed project falls under schedule no. 5(f), Synthetic organic chemicals Category 'B1' located within the notified industrial area, as per EIA Notification, 2006 and its amendment issued by MoEF & CC.

The project site does not come under Comprehensive Environmental Pollution Index (CEPI) of Critically Polluted Area. Also, this project does not come under National Clean Air Programme.

Accordingly ToR application was submitted vide Proposal No: SIA/TN/IND3/472326/2024 dated: 06.06.2024 and ToR was issued vide F.No. 10894 dated: 29/06/2024 which is provided as an Annexure-2.

The purpose of this EIA study is to study the baseline environmental condition of the area, assess the environmental impact of plant operations and to suggest mitigationary measures to address the same. The EIA study has been carried out in line with approved Terms of References.

> Baseline monitoring for the proposed project was undertaken from March to May 2024.

As per the issued ToR, Draft EIA report has been prepared and submitted for Public Hearing (PH). After completion of Public Hearing, the Final EIA report along with action plan for commitment by the proponent will be submitted to TNSEIAA for further appraisal of the project and obtaining Environmental Clearance.



1.2 Identification of Project & Project Proponent

About Project: M/s. Omexa Formulary Private Limited is proposed to setup a new unit at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State for manufacture of Monoclonal antibodies & formulations. The Monoclonal antibodies and Formulation products details are given in **Table 1-1** and **Table 1-2**.

Table 1-1Monoclonal antibodies Product details

Sl. No.	Description	Proposed
1	No of Products	34
2	Quantity of product (kg/Annum)	520

Table 1-2Formulations product details

Sl. No.	Description	Proposed in Nos/Month
1	Prefilled Syringes	100000
2	Vials and Lyophilized vialis	64000
Total		164000

About Project proponent: Omexa Formulary Private Limited is at the forefront of biosimilar innovation, dedicated to producing high-quality alternatives to brand-name biologics, through scientific excellence, unwavering commitment, and technological innovation, we aim to empower healthcare providers and reach patients worldwide, ensuring they receive dependable, effective, and cost-efficient therapies.

Our mission is to enhance patient access to vital treatments while ensuring safety, efficacy, and affordability. Harnessing advanced technologies and rigorous scientific methodologies, we bridge the future of healthcare with today's needs. Omexa's vision is to be the global benchmark in biosimilar healthcare, where every patient has access to sustainable, state-of-the-art, and affordable treatments, fostering a world where quality healthcare knows no boundaries.

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Tamil Nadu

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1.3 Brief description of the project

1.3.1 Nature

M/s. Omexa Formulary Private Limited has proposed a new manufacturing facility of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Prefilled Syringes &Vials and Lyophilized vialis) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. This is a New Greenfield project.

1.3.2 Size

The total project site area is 15147.40 Sq.m (3.743 acres) and tentative builtup area is 22237.00 Sq.m.Available land area will be utilized for building, plant, road and pavement and green belt. Allotment letter issued by TANSIDCO is attached as an **Annexure-1a**.

1.3.3 Location

The Site is located within the Notified TANSIDCO Industrial Park. The land document (Allotment letter) is attached as **Annexure -1a.** The Site is located atPlot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The site is located about ~0.37 km (S) from NH-77(Tindivanam-Krishnagiri)/NH179B (Chennai-Tindivanam-Harur). The nearest railway station is Tindivanam RS ~4.31 km (SE). Nearest Airport: Puducherry Airport ~37.48 km (SSE).

1.3.4 Importance to the Country and Region

India moves to increase the import substitution by way of "Make in India", this growth is likely to sustain for a long period justifying bigger API & API Intermediates Plants like the proposed unit. The average growth of the API industry is about 12 % per annum over the last 10 years. And this growth is likely to sustain for the next five to ten years.

Proposed project is needed to serve the increasing demand of Monoclonal antibodies from local & export market. The proposed project to Manufacture various Mab's are based on the market surveys.

Omexa intends to manufacture the monoclonal antibodies to treat cancer patients at an affordable cost and also export to global market from India. This will contribute to nation vision to become India as a global supplier of biological products and also generates local employment and skills set development in the field of Biotechnology.



1.3.4.1 Demand and Supply gap

M/s. Omexa Formulary Private Limited will leverage the strength of fermentation technology to develop a wide port folio of generic biologicals, Monoclonal antibodies and Therapeutic Proteins. As some of the key biological products patents are going to expire soon an opportunity is set to meet the market demand at lower prices, which will help the patients.

1.3.4.2 Import vs Indigenous Production

The products are developed in house generic bio pharmaceutical products through biotechnological processes.

1.3.4.3 Export Possibility

Products manufactured from the proposed facility will be exported to cater the requirement of international market.

1.3.4.4 Domestic/ Export Markets

The products are meant to bed is tribute to all the existing and new customers across the world.

1.4 Scope of the Study& Methodology Adopted

In addition to the Terms of Reference issued we have included the following scope:

- To ensure environmental considerations are explicitly addressed and incorporated into the development of decision-making process.
- To anticipate and avoid, minimize or offset the adverse significant biophysical, social and other relevant effects of the above project proposal.
- To protect the productivity and capacity of natural systems and the ecological processes which maintain their respective functions.
- To promote development that is sustainable and optimizes resource use as well as management opportunities.

And fully recognizing the scope and requirements of the TOR and comply with the same.

1.4.1 Objectives of the EIA Report

- To ensure environmental considerations are explicitly addressed and incorporated into the development decision-making process.
- To anticipate and avoid, minimize or offset the adverse significant biophysical, social and other relevant effects of the above project proposal.
- To protect the productivity and capacity of natural systems and the ecological processes which maintain their respective functions.



- To promote development that is sustainable and optimizes resource use as well as management opportunities.
- To fully recognize the scope and requirements of the ToR and comply with the same.

1.4.2 Scope of Work

The scope of the study has been based on EIA notification 2006, **APPENDIX I** Generic Structure of Environmental Impact Assessment Document& issued ToR. Work mentioned includes an assessment study of proposed expansion and their impact on the region. This study puts forward the most effective ways to protect the environment from increasing pollution caused by the burgeoning industrial development and recommendations for environmental-friendly development initiatives in the region.

This EIA report presents the existing baseline scenario and the assessment and evaluation of the environmental impacts that may rise during the construction and operational phases of the project. The Environmental Monitoring Program during construction operation phases of the project also highlighted in the report and the post project monitoring program. In terms of the EIA Notification of the MoEF&CC dated 14th September 2006 and subsequent amendments the generic structure of the EIA document will be as under:

Chapter 1: Introduction

Introductory information is presented in this Chapter. The introduction chapter provides background to the project, project proponent and describes the objective of this document. The purpose and organization of the report is also presented in this chapter.

Chapter 2: Project Description

This Chapter includes Project Description and Infrastructure Facilities delineating all the industrial and environmental aspect of the industry of M/s. Omexa Formulary Limited operation phase activities as well as process details of proposed products.

Chapter 3: Description of the Environment

This Chapter provides baseline environmental status of Environmental Components (Primary data) delineating meteorological details of the project site and surrounding area.

Chapter 4: Anticipated Environmental Impacts & Mitigation Measures



This Chapter presents the analysis of impacts on the environmental and social aspects of the project as a result of establishment of plan and there by suggesting the mitigation measures.

Chapter 5: Analysis of Alternatives (Technology and Sites)

This chapter includes the justification for the selection of the project site from Environmental point of view as well as from economic point of view so that the technology will be affordable to the member units of the industrial area.

Chapter 6: Environmental Monitoring Program

This chapter will include the technical aspects of monitoring, the effectiveness of mitigation measures which will include the measurement methodologies, frequency, location, data analysis, reporting schedules etc.

Chapter 7: Additional Studies

This chapter will detail about the Public Consultation sought regarding the project (if applicable). It will also identify the risks of the Project in relation to the general public and the surrounding environment during construction and operation phases of the plant and thereby presents Disaster Management Plan. Social impact assessment and R&R action plans and any other studies carried out for the project as specified in the ToR.

Chapter 8: Project Benefits

This Chapter deals with improvement in physical and social infrastructures, employment potential and other tangible benefits.

Chapter 9: Environmental Cost Benefit Analysis

This Chapter summarizes the cost benefit analysis if it is available in scoping stage.

Chapter 10: Environmental Management Plan

This is the crucial Chapter of the report and describes the mitigation plan, includes the institutional and monitoring requirements to execute environmental mitigation measures and to estimate their adequacy while project implementation.

Chapter 11: Summary and Conclusion



This chapter summarizes the information given in Chapters in this EIA/EMP report and the conclusion based on the environmental study, impact identification, mitigation measures and the environmental management plan.

Chapter 12: Disclosure of the Consultants

Names of consultants engaged in the preparation of the EIA/EMP report along with their brief resume and nature of Consultancy rendered are included in this Chapter.

1.4.3 Detailed Methodology adopted for the EIA Study

The Environmental Impact Assessment (EIA) report has been prepared based on the methods and guidelines suggested by MoEF&CC to address all the conditions stipulated in the Terms of Reference issued by SEIAA, Tamil Nadu.

The EIA study team, headed by an accredited EIA Coordinator, along with the approved FAE's, undertook detailed baseline monitoring studies as per the issued ToR, from **March to May 2024.**

Micro-meteorological data comprising hourly readings of wind direction, wind speed, relative humidity, rainfall and temperature was measured by planting an onsite meteorological station near the Project site. For the period of three (03) months, hourly readings were collected. By using Micro-meteorological data, Wind rose diagrams were generated and also GLC due to the proposed project emission will be predicted. Ambient Air Quality (AAQ) was measured at eight locations within the projectstudy area as per the methods and procedures recommended by Central Pollution Control Board. Air quality sampling was undertaken for periods of 12 weeks - total of 24 samples per site were taken as per the MoEF&CC guidelines. Stipulated criteria pollutants such as Particulate Matter size less than 10 microns (PM₁₀), Particulate Matter size less than 2.5 microns (PM_{2.5}), Sulphur Dioxide (SO₂), Nitrogen Dioxide (NO₂), Carbon monoxide (CO) and Ozone (O₃) were analysed at all the locations. The measured data'swere compared with that of the prevailing NAAQs and this will also form the basis for predicting the cumulative air quality scenario due to the operation of the proposed facility.

Hydro-geological status was collected based on the secondary published long-term data. Data on subsurface soil profile and also bore-log data (in study area) was obtained. In additional, a preliminary study on the regional and local aquifer status was collected based on primary and secondary data.



Ground water samples from 8 locations were analysed as per the terms of reference for all the designated parameters. Assessed values were compared with drinking water standards. Secondary data on the regional ground water status was also collected from the CGWD and SGWD.

Surface water samples from eight locations were analyzed as per the 'ToR' for all the designated parameters. All seasonal streams, rivers, and water bodies located within the study area was mapped through the latest remote sensing data under land use and land cover study. From local village offices and district census data, Major cropping patterns and irrigation methods, etc were collected. Details of the surface water quality in the study area were also collected and analyzed for designated physicochemical, elemental, and biological parameters.

Land use and land cover was mapped using remote sensing satellite imagery. The data was processed using selective software models and level-II land use classification within 10km radius was developed.

Soil samples were also collected at eight locations and all relevant parameters such as pH, texture, nutrients, heavy metals etc, were analysed.

Study of Flora and Fauna was undertaken in the study area and all spotted ecological and biological aspects were mapped. Bio-diversity density and abundance were estimated.

Socio-economic survey in the study area was undertaken to capture the socio-economic conditions, major occupation, drinking water and sanitation facilities, transportation and other amenities in the study area, with reference to the villages.

In addition to the above, detailed analysis on the socio-economic aspects of study area were done through district level census data published by National Informatics Centre (NIC). Based on the socioeconomic survey, a need based Community Development Plan under CSR and CER was suggested. Since the site is under the procession of PP, R&R is not applicable.

Typical reviews on the various pollution control systems, proposed details of wastes and discharges that are envisaged from the proposed project were also undertaken. Such inputs are adopted while predicting various environmental impacts due to facility operation and also to suggest an appropriate Environmental Management Plan and environmental monitoring plan.

As a part of the EIA study, an attempt was made to predict the possible and likely impacts on background environment. Likely air quality impacts due to release of emissions within the stacks were modelled using AERMOD model.



Ground Level Concentration (GLC) of criteria pollutants such as PM, SO_x, and NO_x were estimated using MoEF&CC approved AERMOD model. Hourly meteorological data collected from IMD data, at the Project site was adapted to assess Ground Level Concentrations. Maximum Ground Level Concentrations were predicted and concentration isopleths of the above mentioned pollutants were plotted.

Predicted GLC of the respective pollutants were added to the prevailing baseline concentrations of the designated pollutants to assess the likely cumulative post project scenario. Such values were compared with the NAAQ Standards.

Noise generating sources and expectednoise levels were estimated. Impacts due to utilisation of treated wastewater for greenbelt/utilities applications were also studied.

In addition to the above aspects, the positive environmental benefits arising from community development plans under CSR and CER programme, ecological and biodiversity enhancement aspects due to green-cover development in the project site were also studied.

Based on a detailed EIA study, a comprehensive report on the environmental management plan was developed covering the following aspects: air quality management plan, noise and water quality (surface & ground) management plan, wastewater treatment, reuse, recycling and disposal programme, rainwater harvesting plan, socio-economic and community development plan and ecological and biodiversity enhancement plan. An outline of the proposed environmental management systems, environmental cell and environmental monitoring programme are also presented in this report.

Although the proposed project utilises the limited quantities of flammable and combustible materials below the stipulated quantities under Hazardous Materials Handling Rules, a preliminary risk assessment study and Disaster Management study, wasundertaken to assess the residual risks, if any, due to storage and handling of combustible materials. Wherever applicable, quantitative methods were adopted to establish the heat radiation levels due to accidental fires at storage facilities.

CPCBguidelines on risk assessment methods were adopted and CPR 18(E) guidelines were used for estimating the consequences of fire accidents. Based on the risk assessment study, a preliminary fire safety and occupational health management plan was suggested. A road map for onsite emergency and disaster management plan was suggested based on the preliminary information available at this stage.

1.4.4 EIA Process

EIA process is composed of the following stages:

- Detailed study of Project and Process.
- Screening & Scoping environmental pre-feasibility study & application for approval of ToR.



- Collection of detailed project management plan/report.
- Baseline monitoring data collection.
- Impact identification, Prediction and Evaluation.
- Mitigation measures and delineation of EMP.
- Risk assessment and safety and disaster management plan.
- Review and finalization of EIA Report based on the ToR requirements.
- Submission of EIA report for implementation of mitigation measures & EMP as well as necessary clearances from relevant Authority.



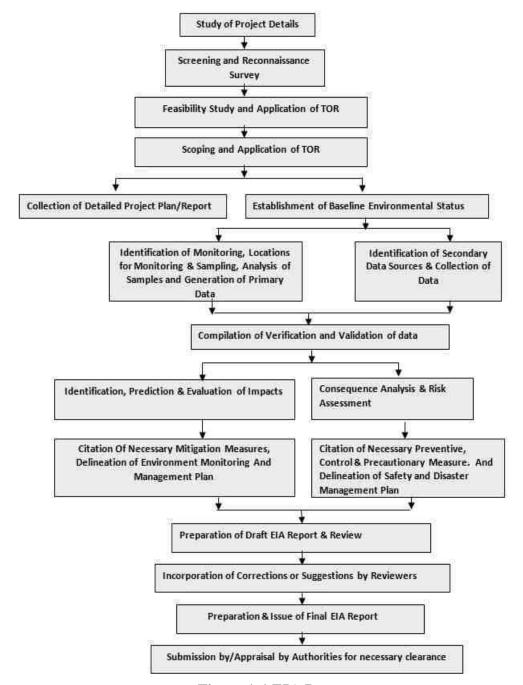


Figure 1-1 EIA Process

1.4.5 Objectives of the Study

The major objective of this study is to prepare a detailed Environmental Impact Assessment Study within the study area i.e. 10 km radius from the project.



1.5 Applicable Regulatory framework

The following are applicable acts and rules related to the proposed project. Details of acts and rules with applicability to the proposed project are given below:

Table 1-3Details of Acts and Rules with applicability to the proposed project

	Table 1-3Details of Acts and Rules with applicability to the proposed project				
S. No.	Act/Rules	Purpose	Applicable Yes/No	Reason for Applicability	Authority
1	The Environment Protection Act of 1986	Improve & Protect the Overall environment	Yes	Since the project is new, it Attracts this Act	MoEF&CC.GoI CPCB;SPCB
2	Environmental Impact Assessment Notification 14 th Sep 2006 and subsequent amendments time to time	To provide Environmental Clearanceto new development/Expansion/ Modernization activities following Environmental Impact Assessment	Yes	The project falls under Schedule-5(f) Category B1 as per the notification 2006. It is New project.	SEIAA, Tamil Nadu
3	The National Environment Appellate Authority Act (NEAA) 1997	Address Grievances regarding the Process of environmental clearance.	Yes	Grievances if any will be dealt with, within this act.	NEAA
4	The Land Acquisition Act 1894 & 1989	Set out rule for acquisition of land by government	No	Since land is allotted to PP by TANSIDCO	SIPCOT
5	The Air (Prevention and Control of Pollution) Act of 1981	Prevention, control and abatemento fair pollution	Yes	During Operation-Air Pollutants from the unit to be managed as per theAct.	MoEF&CC
6	The Water Prevention And Control of Pollution) Act of 1974 And amended on1988	Prevention and control of water. Pollution and also maintaining or Restoring the wholesomeness ofwater	Yes	Water Pollutants generated from the unit will be treated as per Prescribed standards	MoEF&CC
7	The Noise Pollution (Regulation and Control) Act 1990	Standards for noise during day & night have been publicized by the MoEF&CC for various land uses.	Yes	This act will be applicable to all noise generating sources including traffic for design necessary control measures for future.	MoEF&CC
8	Environmental (Protection) rules, 1986 (Amendments in 1999, 2001, 2002, 2002, 2002, 2003, 2004)	Protection and Improvement of the Environment.	Yes	As all environmental notifications, rules and Schedules are issued under this act.	MoEF &CC
9	Hazardous Waste (Management and Handling) Rules,1989 amended 2000 and 2016	Management&Handling of Hazardous wastes from proposed project	Yes	Hazardous wastes generated from the unit will be managed as per the Rules	CPCB,SPCB
10	Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules of 1989	Regulate themanufacture, storage and import of Hazardous Chemicals	Yes	The facility will handle HSD fuel for operation. Thus, associated fire and explosion hazards will	MoEF&CC, CPCB, SPCB, Chief Inspector of Factories,



	& amended on 2000			attract these rules.	Chief Controller of Explosives, District Collector or District Emergency Authority
11	Chemical Accidents (Emergency Planning, Preparedness and Response) Rules,1996	Emergency Planning Preparedness and Response to chemical accidents	Yes	The facility will handle HSD fuel for operation. Thus, associated fire and explosion hazards will attract these rules.	CCG, SCG, DCG, LCG and MAH Units
12	The Public Liability Insurance Act, 1991 Amended 1992	To provide immediate relief for persons affected by accident involving hazardous substances	Yes	Protect the staff working in the Industry due to use of Hazardous Substances	District Collector
13	The Factories Act, 1948	Control of work place environment, and providing for good health and safety of workers	Yes	All the industries to be established attract the Act.	Ministry of Labour, DGFASLI and Directorate of Industrial Safety and Health/Factories Inspectorate
14	The Petroleum Act, 1934	Regulate the import, transport, storage, production, refining and blending of petroleum	Yes	Since petroleum products are stored, it attracts the Act.	Ministry of Petroleum & Natural Gas
15	ThePetroleumRules,200	Regulate the import, transport, storage, production, refining and blending of petroleum	Yes	Since petroleum products are stored, it attracts the Act.	Ministry of Petroleum and Natural Gas, Ministryof Environment, Forests & Climate Change or SPCB Chief Controller of Explosives, district authority
16	The Static and Mobile Pressure Vessels (Unfired) Rules,1981	Regulate the import, manufacture, design, installation, transportation, handling, use and testing of mobile and static pressure vessels (unfired) with a view to Prevent accidents	Yes	Since the industry uses boiler, it attracts the Rules.	Ministry of Commerce and Industry and Chief Controller of Explosives, collector, DGCA, DC, DM, Police (sub- inspector to commissioner)



1.6 ToR Compliance

S. No	Term of References	Compliance		
SEA	C Conditions- Site Specific			
	1. Every industry located in the SIPCOT	Noted,		
	shall be served individual notices regarding	Public Hearing notice (regarding Public hearing schedule) will be issued to all industries within SIPCO		
	the schedule of public hearing	TANSIDCO.		
		Project proponent will explore the possibilities of implementing the following:		
		Water consumption will be minimized by recirculation and reusemethod. The treated water will be sent to		
		gardening and Utilities.		
		Zero Liquid Discharge (ZLD) system will be adopted.		
	2. The PP shall furnish the roadmap for	STP system will be provided with MBBR technology.		
	achieving Net Zero waste	100% utilization of wastewater within the unit.		
1		 100% renewable energy by 2030 and avoid use of fossil fuel such as HSD in future. 		
		Attain Water and carbon neutrality by 2030		
		Encourage the employees and vendors to use the electric vehicles instead of standard diesel units.		
		Not applicable, Since our entire process is based on Mammalian Cell culture Process. It is:		
		"Mammalian Expression system is Chinese Hamster Ovary (CHO) cells and theprocess time considered is 20		
	3. EIA shall contain stoichiometric material	days/batch. In the manufacturing of biopharmaceuticals from mammalian cells consists of two stages those are		
	balance indicating any by -products, solid	upstream and downstream processes"		
	waste, etc	There will be no by- products from the production process.		
		> Effluent from the process will send to ETP followed by MEE/ATFD. All salt (solid waste) from ATFD will		
		be send to TSDF (50 kg/day).		



	Noted	,							
4. The proponent shall conduct the EIA	>	As per ToR issued,	draft EIA rep	ort will be	prepared an	nd same wil	l be submitted	to TNPCE	3 for Public
study and submit the EIA report for the		Hearing.							
entire project area	>	After incorporation	of Public hear	ing proceed	lings, Final 1	EIA report v	vill be submitte	ed to TNSE	IAA/SEAC
		for Environmental C	learance.						
5. The proponent shall ensure the proposed	Noted								
industrial shed meets green building norms		, iildings proposed withi	n the project s	ite will be a	decianed in a	such a way t	hat it will com	nly the IGE	C Standard
and shall obtain a minimum of IGBC Gold		rug regulatory of India	1 0	ite will be t	aesigned in s	such a way t	nat it will com	pry the roll	oc Standard
ranking	and D	rug regulatory of mula	•						
6. The PP shall furnish action plan for	>	Proponent proposed	to install Solar	r panel on r	oof top and	obtain 100 k	VA through So	lar energy.	
harnessing 50% solar energy or shall	>	Remaining 775 kV	A will be source	ced from re	newable gre	en energy v	endors who ar	e authorize	d by TNEB
purchase 50% renewable green energy from	and Agreement will be made them after all statutory Approvals obtained.								
TNEB to meet the energy requirement.	Layou	t plan of the project sit	e showing the	solar panel	for 100 kV	A is attached	as an Annexu	re-3.	
	Sl. No.	Raw materials	Approx Quantity per annum (In Kgs)	Type of Package	Source	Storage Tempera ture	State (Solid/Liqui d/Gas)	Chemic al properti es	Mode of transport
	Mon	oclonal products (Drug	g substances)-	for EC pro	ducts				
7. The physical and chemical characteristics of all the chemicals shall be listed in the EIA report	1	Sodium chloride	1800	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	colourle ss & Odourle ss	Road
	2	Potassium Chloride	10	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourle ss	Road
	3	Sodium phosphate	60	Bag /Drum	Domestic / Imported	20- 25 deg C	Power Solid	White & Odourle ss	Road



	4	Potassium phosphate	10	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourle ss	Road
	5	Citric acid	500	Bottle /Box	Domestic / Imported	20- 25 deg C	Small beads (crystal)	White & Odourle ss	Road
	6	Sodium Citrate	1150	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourle ss	Road
	7	Tris Buffer	2300	Bag /Drum	Domestic / Imported	20- 25 deg C	Liquid	Clear & Odourle ss	Road
	8	Sodium Acetate	600	Bag /Drum	Domestic / Imported	20- 25 deg C	Crystallline (solid)	white	Road
	9	Sodium Hydroxide	1500	Bag /Drum	Domestic / Imported	20- 25 deg C	Pellets (solid)	White & Odourle ss	Road
	10	Glucose	400	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourle ss	Road
	11	Sodium bicarbonate	200	Bag /Drum	Domestic / Imported	20- 25 deg C	Power Solid	White & Odourle ss	Road
	12	Pluronic F68	100	Bag /Drum	Domestic / Imported	2- 8 deg C	Liquid	NA	Road



ell Culture Media Glutamine	2200	Bag /Drum Bottle /Box	Domestic / Imported Domestic	2- 8 deg C	Dry powder (solid)	NA	Road
	30		Domestic /	2- 8 deg			
orbitol			Imported	C	NA	NA	Road
·	200	Bottle /Box	Domestic / Imported	20- 25 deg C	Solid	White & Odourle ss	Road
hanol	100	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Clear & Odourle ss	Road
nosphoric Acid	60	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Clear	Road
cetic Acid	40	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Odourle ss	Road
ydrochloric acid	150	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Light yellow & pungent	Road
Total	11410	-	-	-	_	-	-
Fo	rmulation pr	oducts (dru:	g products) -	- for Non EC	nroducts		
nosphoric Acid	60	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Clear	Road
cetic Acid	2200	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Odourle ss	Road
			D			Light	
10	Total Fo osphoric Acid	Total 11410 Formulation prosphoric Acid 60	Total 11410 - Formulation products (drugosphoric Acid 60 Bottle /Box Bottle /Box Bottle /Box Bottle /Box	Total 11410 Formulation products (drug products) - Sphoric Acid 60 Bottle /Box Imported Bottle /Box Domestic / Imported Bottle /Box Imported Bottle /Box Imported Domestic / Imported	Total	Total	



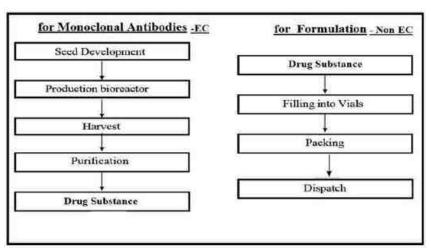
- 8. Necessary supporting documents including latest patta copy and land documents pertaining to all the subdivided S.F.Nos, approval from Competent Authority for supply of fresh water & drinking water shall be furnished
- > The entire site is located within Notified TANSIDCO Industrial park, Pellakuppam Village, Tindivanam Taluk, Villupuram Village and Tamil Nadu State.
- Land allotment order given by TANSIDCO for the plot no: 27 (1.883 Acres) & plot no: 28 (1.863 Acres) is attached as an **Annexure-1a**.
- As per land allotment order, water will be supplied by TANSIDCO and agreement will be made between TANSIDCO and Omexa after EC.
- 9. The PP shall furnish the drone video of the entire project site

Noted,

Drone video of the entire project site will be presented during presentation (TNSEAC)

General Manufacturing Process flowchart:

10. The process flow diagram should include quantity of various items, the effluents air emissions / hazardous waste generated including the quantity and their characteristics. Appropriate pollution control measures contemplated for controlling each category of pollution, the pollutants getting discharged into the environment including the quantity as well as the characteristics



Process flow diagram including quantity of various items, the effluents air emissions / hazardous waste generated including the quantity and their characteristics along with Pollution control measures and treatment process is

		detailed in Chapte	er-2, section 2	.6.1 of EIA re	eport.		
		Project Activity	Likely Pollutants	Surround ing Environm ent	Media	Likely Impacts	Probable Mitigation Measures
		Fuel storage, handling in stock yard & raw materials & finished product transportation	Dust		Air	 Degradation of surrounding air quality. Health hazards to local inhabitants. Reduced growth of vegetation that gets 	 Providing controlled excess air to ensure complete fuel combustion Provision of adequate APCM before stack. Raw materials & finished
	11. The EIA should cover the possible impacts starting from unloading of	Emission from process & utility Stack	PM, SO ₂ ,NOx, CO	- Industrial		coated with dust. Reduction in soil fertility due to pollutant deposition.	products will be kept covered during transportation.
	chemicals, storage, process and finally letting into the environment	Water Usage		& Agricultur	Water	Resource Depletion	Maximize the usage of treated water and reduced fresh water consumption.
		Treatment of wastewater from project activity		- al	Water & Soil	 Degradation of water quality of receiving water bodies. Land degradation due to percolation. 	 Designing the efficient water water treatment systems and reusing the treated water based on its quality within the plant. Maintain ZLD facility.
		Storage area runoff	water		Water & Soil	 Land degradation due to percolation. Degradation of water quality of receiving water bodies 	Suitable plant layout and provision of run off collection system



Due to Manufacturing Process, Transportation & storage of Products and	Odour	Air/ water/ solid	 Health hazards due to hazardous chemical handling 	 Odor masking Authorized transportation system (TREM Card), Public liability insurance
Products and Raw materials				T done hability insurance

Process emission: There are no process emissions from the proposed manufacturing facility since it is biological process (Mammalian Cell culture Process).

Control measures:

• Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.

Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. Adequacy/Performance of Air Pollution Control measures shall be reviewed.

12. The EIA should concentrate on specific pollutants emanated from the industry in addition to the normal pollutants which are dealt with in EIA study

Other emission:

Boilers and DG sets are the two main sources that contribute to emissions from the plant. Industry is proposed 1.5 TPH HSD fired boiler. Particulate matter (PM), Sulfur dioxide (SO2), Carbon monoxide (CO) and Oxides of Nitrogen (NOx) will be the major pollutants. Stack height of 30 m is proposed to meet the CPCB guidelines. Diesel about 0.12 KL/hr will be used at full operation load in the DG sets. Proposed DG sets are of 2 x 600 kVA DG set will be used as stand by during power failure.

Proposed Stack emission details

C		Fue	Fuel		Sta	ick Deta	ails			Emis	sions	
S. N O.	Source	l Typ e	Quant ity (KL /	No. of Stac	Heig ht (m)	Tem p (°C)	Dia (m)	Exit Velo city	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)



				Day)	k				(m/s				
	1	DG-600 kVA*	HS D	2.00	1	30	200	0.2	9.5	7.43 E-03	6.93 E-03	1.05 E-01	2.26 E-02
	2	DG-600 kVA*	HS D	2.88	1	30	200	0.2	9.5	7.43 E-03	6.93 E-03	1.05 E-01	2.26 E-02
	3	Boiler 1.5 TPH	HS D	2.509	1	30	210	0.3	10	3.41 E-03	4.70 E-04	6.62 E-02	1.66 E-02
			1	Т	otal	1	1			1.83 E-02	1.43 E-02	2.76 E-01	6.17 E-02
		<i>In ToR applica</i> I Measures	tion, D	G sets cap	acity - 2	x350 kV	VA.						
	 Stack height of 30 m is proposed for boiler. 30m stack height will be provided for DG sets. 												
13. Details on how the reactors are cleaned and how the residues are collected and disposed shall be elaborated		gle Use Biorea d (Solid Waste)			•			•	Ū		oreactor	bags are	e Sanitiz
	•	Sanitized solu	tion fro	m the Sing	le used	bioreac	tor sent t	o ETP.E	Effluent	from pro	cess cle	aning (6	KLD) a
14.Any washing of reactor with water is		Water for inje	ctable (2	22.5 KLD)	will be	treated	in ETP v	with cap	acity of	70 KLD	along w	ith utilit	ty efflue
done such waste water shall be considered		(8 KLD).											
as effluent and the same shall be sent to the	•	Treated efflue	nt from	ETP will b	e passe	d throug	gh RO fo	llowed b	oy MEE	ATFD.			
ETP. Accordingly, the project proponent	• RO permeate and MEE Condensate will be reused for utilities and greenbelt.												
shall design the ETP	•	ATFD salt wil	l be sen	d through	TSDF.								
	Technic	al Specification	of ET	P ia attache	ed as an	Anney	ure-5h						
		1			ou us un	IMILICA	ui C Sb						

will be a major problem. The project proponent should formulate measures to monitor and control the odour appropriately and submit the details in the EIA report

There is no odour from the process since it is done through closed environment only. Possible source of odour will be from ETP and STP area only.

Mitigation Measures

- The entire QC lab vent will be routed through wet srubber connected with stack of 3.0m.
- Aromatic Plants such as Ocimum americanum (Local Name: Nai thulasi), Ocimum basilicum (local name: Karpura thulasi & Thiruneetrupatchai), Ocimum gratissimum (Local Name: Elumichanthulasi) & Ocimum tenuiflorum (local Name: Thulasi) etc., will be planted to minimize Odour generated from STP and ETP area.

The main source of hazardous waste generation from manufacturing process will be discarded in bags/drums/barrels, used oil, ETP sludge and evaporation residue.

16.Hazardous waste generated shall be clearly identified and shall be disposed to TNPCB authorized recyclers. The project proponent shall fumish the proposal for Hazardous waste management

Hazardous waste details

S.No	Description of Waste	Category as per HWM Rules 2016	Qty/Annum	Storage method	Method of disposal
				All the	Will be collected and
1	Used /Spent Oil	5.1	1 KL	generated	disposed through
1	Osed /Spent On	3.1	1 KL	Hazardous	TNPCB Authorised
				waste will be	recycler
				stored on	Will be collected and
2	Waste or residues containing	5.2	1 Ton	Concrete	disposed through
	oil	3.2	1 1011	platform in	TNPCB Authorized
				leak Proof	TSDF

3	Discarded Containers/Bags	33.2	4 Ton	Barrels in designated areas	Will be collected and disposed through TNPCB Authorised recycler
4	MEE salt	37.3	16.5 Ton (50 kg/day)		
5	ETP Sludge	35.3	3.3 Ton (10 kg/day)		Will be collected and disposed through
6	Off Specification Products (Doesn't Met by Specifications or standards)	28.3	2 Ton		TNPCB Authorized TSDF
7	Expiry Products/Chemicals	28.5	1.5 Ton		

Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant. Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental Clearance from SEIAA, Tamil Nadu.

There will be chance of fugitive emission due to raw material handling, transportation and Manufacturing activity. The details of fugitive emissions and its control measures are given below:

Details of Fugitive emission and its control measures

17.Fugitive emissions generated from the
other activities shall be collected through
adequate ducting system and provided with
wet scrubbers.

Source	Probable pollutant parameter	Control Measures
Loading/unloading and storage of raw materials and finished products	VOC & PM	 Loading/unloading of liquid material will be done through pipeline. It will be done in a closed system. Local Exhaust ventilation will be provided.
Raw material storage	VOC	 Carry out work place area monitoring to find out concentration level in ambient air. Closed transfer system will be provided.

		•	Unit will carry out regular workplace monitoring.
Handling of raw Material in bags storage area	PM	•	Provision of exhaust ventilation in plant area. Provision of PPE. Job rotation to reduce exposure.
Warehouse storing drums and bags	VOC&PM	•	Spillages will be strictly prevented by proper handling of equipment. SOP will be followed.

Control Measures

- There are no process emissions from the proposed manufacturing facility since entire process will be in closed condition.
- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.

Greenbelt development:

The total land area is 15147.40 Sq.m (3.743 Acres). Greenbelt area is 5011.40 Sq.m (33.08%). Around **1503** numbers of tree (2mx2m spacing for each trees) will be planted (by considering 80% survival rate) in that around 50 trees was already planted.

Tentative Proposed green belt Species

S.No	No Scientific Name Common Name		No of Trees	Yearwise	
1	Pongamia pinnata	Pungai	300	1 st Year	
2	Thespesia populnea	Poovarasu	300	2 nd Year	
3	Albizis lebback	Vaagai	150	2 Year	
4	Cassia fistula	Sarakondai	150 3 rd Year		
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year	
6	Pterocarpus Marsupium	Vengai	150		
7	Aegle Marmelos	Vilvam	150	4 th Year	
8	Madhuca longifolia	Iluppai	153		
Total			1503		

(Note: The plant species proposed are based on the guidelines for developing green belt by CPCB- March 2000)

18.Green belt development and CSR activities should be as per norm



		Layout plan of the project site showing greenbelt area is attached as an Annexure-6 .
		CSR Activities: The company is aware of the obligations towards the society and to fulfill the social obligations, company will
		employ semi-skilled and skilled labour from the nearby villages as much as possible and also try to generate
		maximum indirect employment in the nearby villages by appointing local contract workers.
		Will give Scholarship to local students of the community which would enable them to educate and skill
		themselves for a healthy life ahead.
		Will provide Mobility Aids & Equipments for the Disabled people in the nearby villages.
		Periodical health check-up will be conducted for all the employees and all the reports will be recorded and
		maintained, once the plant is operational.
		The health check-ups will be conducted once in six months and the reports will be recorded.
	19.Details of the procedures to be adopted	The medical health check-up will be fitment for job, which includes eye examination, colour blindness, tuberculosis,
	for the regular health check-ups for the staff	skin and other contagious diseases.
	shall be famished.	In case a person is found affected by any contagious disease during the medical check-up, those employee will not
		be allowed to work and will be advised for further medical treatment.
		After the completion of the necessary treatment the employee will be allowed to resume their work after obtaining
		medical fitness certificate from the qualified doctor.
-	20.Details of extra safety standards against	To protect against anticipated exhaust and exposures, in Omexa, the following safety standards will be followed:
	anticipated exhaust and exposures by the	Hazard communication : All chemicals used in the industry will be properly labeled and workers shall be trained on
	project proponent to be famished and its	the hazards associated with each chemical. This includes information on the proper handling, storage, and disposal
	impact on workers including disorders and	of hazardous substances.
	disabilities to be listed	Ventilation: Proper ventilation should be provided to control the release of hazardous substances into the work

Eme

environment. This may include local exhaust ventilation systems and general ventilation systems.

Engineering controls: Additional engineering controls, such as fume hoods and chemical storage cabinets, may be required to control exposure to hazardous substances.

Monitoring: Regular monitoring of the work environment for hazardous substances will be essential to identify potential risks and take necessary precautions.

Emergency preparedness: An emergency plan will be in place in case of accidental release of hazardous chemicals. Workers should be trained on emergency procedures, including evacuation and decontamination.

21. Will exposures have any impact on workers? Can it cause disorders and disabilities?

Training: Workers should be trained on the proper handling and use of hazardous substances, including how to properly wear and maintain PPE.

Periodical Medical Check-up: Periodical heath check-up will be conducted for the employees and recorded.

Personal Protective Equipment (PPE): Workers should wear appropriate PPE, such as gloves, lab coats, goggles, and respirators, to protect against exposure to hazardous chemicals. The type of PPE required will depend on the specific chemical will be handled and the potential hazards associated with it.

Compliance with regulatory standards: Employers should comply with local, state, and national regulations on handling hazardous substances, including proper storage, labeling, and disposals.

This is proposed new industry and all the above pro-active measures will be continued always.

Layout plan showing the location of fire hydrant and Hose and Fire tank is attached as an Annexure-13

22. Impact of anticipated vapours on the migratory birds and other bio-diversity and its harmful effect

There will be no anticpitaed impact of vapour on migratory birds and other bio-diversity due to following points:

- **Process emission**: There are no process emissions from the proposed manufacturing facility since its is biological process (Mammalian Cell culture Process).
- Apart from above, Other utilities emission from DG and boiler is within limits of NAAQ stanadard

	 There is no national park, Eco sensitive zone, Protected/reserved forest within 10 Km radius from the project site boundary. 	
23. Can anticipated seepages if any, cause disturbances to soil, micro flora and to plantations including agriculture and biodiversity	 There will be no impact of Seepage from the project site to soil, micro flora and to plantations including agriculture and bio-diversity due to following points: There is no seepage from the project since ZLD will be maintained and frequent monitor will be done to check any issue through Standard SOP. Project site is located within the Notified TANSIDCO which is extending over the Area of 113.00 acres. Previous TANSIDCO part was under the procession of SIPCOT for which they obtained the EC for development of industrial park at Tindivanam over an extent of 291.60.5 Ha under Schedule 8(b), Category B1. 	
24. Proper disaster management plan considering the worst-case scenario shall be famished	The risk assessment of the project site which covers the disaster management plan considering the worst-case scenario shall be scenario is attached as an Annexure-7 .	
25. Details of litigations, if any pending against the project shall be furnished along with supporting documents	 Nil, The total project site area is 3.743 Acres. The land document (Allotment letter) for the Plot No. 27 & 28 is attached as Annexure- 1a. The proposed project comes under the notified industrial area since earlier SIPCOT obtained the EC for development of industrial park at Tindivanam over an extent of 291.60.5 Ha under Schedule 8(b), Category B1 is attached as Annexure – 1b. After that, Office Order signed between SIPCOT and TANSIDCO for the development of industrial Part over an extent of 113.00 Acres is attached as an Annexure-1c. The company assures that there are no pending cases and the affidavit for No Litigation has been attached a Annexure-14. 	
26. The proponent shall furnish the detailed	Liquid waste Management:	
sewage treatment technology available and		



furnish the design details of the STP treatment system. Adequacy report for ETP &STP for the proposed project obtained from any reputed Government institution such as IIT, Anna University, NIT shall be furnished.

	S. No	Description	Proposed Quantity (KLD)	Final Disposal Points			
C	Construction Phase						
1		Sewage	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development			
0	Operation Phase						
1		Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.			
2		Sewage	4.6	Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt.			

Technical Specification of STP (6 KLD) is attached as an **Annexure-5a** and Technical Specification of ETP (ZLD) is attached as an **Annexure-5b**.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steel piping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no



flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- > Chemical dosing system
- \triangleright Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.

Adequacy Report:

Adequacy report for ETP &STP from reputed Government institution will be submitted in Final EIA report.

27. The proposal to construct a pond of appropriate size in the earmarked OSR land in consultation with the local body. The pond should be modelled like a temple tank with parapet walls, steps, etc. The pond is

1.OSR (Open Space Reserve):

Not applicable, since SIPCOT already maintain the separate OSR for entire IP (since TANSIDCO is formed from SIPCOT only) and it is maintained as Greenbelt.

2. Stormwater management

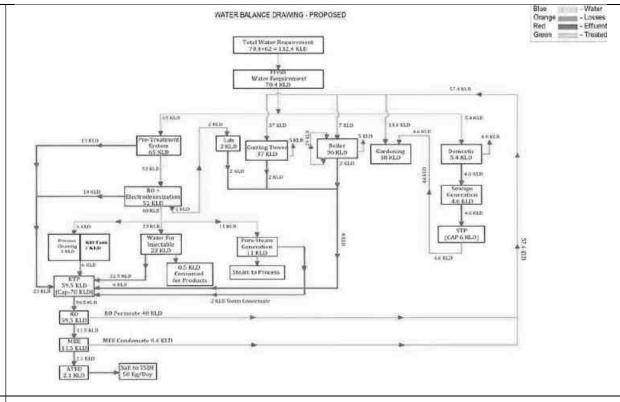
meant to play three hydraulic roles, namely (1) as a storage, which acted as insurance against low rainfall periods and also recharges groundwater in the surrounding area, (2) as a flood control measure, preventing soil erosion and wastage of runoff waters during the period of heavy rainfall, and (3) as a device which was crucial to the overall eco-system

Collected Rain water is used as an insurance against low rainfall periods and also recharges groundwater in the surrounding area. It also helpful in flood control measure, preventing Soil erosion and wastage of runoff waters during the period of heavy rainfall. Excess storm water will be collected and discharge into TANSIDCO drain.

28. The treated/untreated sewage water shall not be let-out from the unit premises accordingly revised water balance shall be incorporated

Noted, treated sewage of 4.6 KLD will be reused for the greenbelt development and there will be no outfall outside the plant.

Water balance chart:



29. As per G.O. Ms. No. 142 approval from Central Ground Water Authority shall be obtained for withdrawal of water and furnish the copy of the same, if applicable

30. Commitment letter from competent authority for supply of water shall be

Not applicable.

Fresh water will be sourced from the TANSIDCO only and Agreement will be made between TANSIDCO and Omexa before Consent order from TNPCB.

Fresh water will be sourced from the TANSIDCO only and Agreement will be made between TANSIDCO and Omexa before Consent order from TNPCB.



furnished.							
	The Building is designed as NBC to ensure that required staircases and emergency doors are made available. There						
31. Detailed Evacuation plan during	will be P	ublic address system in	nstalled to communicate the	evacuation activit	y during emergency. There will be a		
emergency/natural disaster/untoward	assembly	point identified for all	personnel to assemble post	evacuation for fur	ther instruction and safe exit from the		
accidents shall be submitted	premises	as required. Required l	Fire rated doors with rating o	of minimum 90 mii	n will be provided.		
	Detailed	Evacuation plan during	g emergency/naturaldisaster/	untoward accidents	s is attached as an Annexure-7 .		
32. The space allotment for solid waste	The space	e allotment for solid wa	aste disposal and sewage trea	atment plant is give	en below:		
disposal and sewage treatment plant shall be	•	Solid waste Disposal- 1	00 Sq.m				
furnished.	• STP and ETP – 68 Sq.m+ UG equalisation tank of 100 Sq.m						
	Municipal Solid waste Municipal Solid Wastes generated will be segregated to organic and inorganic wastes. The organic wastes will be disposed to TANSIDCO Bins and inorganic waste will be sent to TNPCB authorized Recyclers.						
	Municipal Solid Waste Generation						
	S.No	Waste	Proposed (kg/day)	Total (kg/day)	Method of disposal		
33. Details of the Solid waste management	Operations Phase (120 Nos)						
plan shall be prepared as per Solid Waste	1	Organic	32.4	32.4	To Local TANSIDCO bins		
Management Rules, 2016 as amended and shall be furnished.	2	Inorganic	21.6	21.6	To TNPCB Authorized Recyclers		
	3	STP Sludge	0.6	0.6	Used as a manure for greenbelt.		
	Total		54.6	54.6	-		
	Construction Phase (30 Nos): 13.5 Kg/day (Disposal through local TANSIDCO bins)						
	Note: As	per CPHEEO norms -	0.45kg/capita/day				
	Paper/Ca	ard Board, dry leaves,	grass, Dustbin collection, 1	Metal scrap & wo	oden scrap will be recycled/ sent		

authorize dealer.

Item Name	Proposed (MT/year)	Mode of disposal
Cartons, Paper and stationary scrap	0.5	To scrap vendors

E-waste: Tentative e-waste generated from the project site will be mainly from Admin block, Production Blocks, Engineering, Warehouses, Administration, and Toilets etc. It is mainly:

- 1. Fans
- 2. Light
- 3. Electrical items.
- 4. Defective equipments etc.

It will be stored in separate place and disposed through TNPCB authorized E-Waste recyclers

34. Details of the E-waste management plan shall be prepared as per E-waste Management Rules, 2016 as amended and shall be furnished.

35. Details of the Rain water harvesting system with cost estimation should be furnished.

36. A detailed storm water management plan to drain out the storm water entering the premises during heavy rains period shall be prepared including main drains and subdrains in accordance with the contour levels of the proposed project considering the water bodies around the proposed project site & the surrounding development. The storm water drain shall be designed in accordance with the guidelines prescribed

1. Rainwater harvesting calculation

8								
Description	Area (m²)	Run off Coefficient	Intensity of rainfall-I (m/day)	Total Discharge-Q(m3/day)				
Ground coverage (plinth)	6472	0.8	0.073	377.96				
Greenbelt	5011.4	0.2	0.073	73.17				
Open Space	144	0.7	0.073	7.36				
Road & Parking	3520	0.7	0.073	179.87				
Total	15,147.40	0.00	0.00	638.36				

Formula:

Discharge, $Q = CIA (m^3/day)$

Where,

Q= Discharge (in m^3/day)

C=Coefficient of Runoff

I= Intensity of rainfall (in mm/day) (Max Flood in 12.11.2022- 73.79 mm as per IMD Villupuram)

A= Area (in Sq.m)

by the Ministry of	Urban Development.
--------------------	--------------------

Runoff calculation:

- ightharpoonup Total runoff Load = 638.36 m³/day
- ightharpoonup Total runoff load per hour =638.36/24 = 26.60 m3/hr.
- ➤ RWH pits of 1.5m dia and 4.0 m depth, capacity of each pits= 3.53 m3 and we considered 50% percolation so the capacity of RWH pit is 1.77 m3.
- \triangleright No. of RWH pits proposed = 26.60/3.53 = 15.02 Say 15 Nos.

15 no. of rainwater harvesting pits are proposed Storm water will be collected in RWH pitsthrough storm water drains and only eccess storm water will be let into TANSIDCO Drain. Layoutwith storm water drain is attached as an **Annexure -8.**

2.Cost Estimation for Rainwater harvesting:

Description	Nos	Amount (INR. Lakhs)
Rain water harvesting pits (in Cu.m)	15	10
Storm water drain (in R.m)	-	16
Total	-	26.0

37. The OSR area should not be included in the activity area and not be taken in to account for the green belt area.

OSR (Open Space Reserve):

Not applicable, since SIPCOT already maintain the separate OSR for entire IP (since TANSIDCO is formed from SIPCOT only) and it is maintained as Greenbelt.

38. As per the MoEF&CC Office Memorandum F.No.22-65/2017-lA.llldated: 30.09.2020 and 20.10.2020, the proponent shall furnish the detailed EMP mentioning all the activities as directed by SEAC in the CER and furnish the same.

Environmental Management Plan Budget (tentative):

S. No	Particulars	Capital Investment (Rs in lakhs) Proposed	Recurring Cost per Annum (Rs in Lakhs)				
Environ	nent Management Plan						
Water Po	Water Pollution Control						



1	ETP	250	20					
2	MEE/ATFD and RO	350	20					
3	STP	8.5	2					
Air Pollution Control								
4	DG & Boiler Stack/ Wet scrubber	60	3					
Environ	nmental Monitoring							
5	Environmental Monitoring by third party	0	4.4					
Solid W	aste Management							
6	Solid Waste Management	2	3					
Greenb	elt							
7	Greenbelt Development	7	2					
Hazard	ous Waste Management							
8	Hazardous Waste Management	2	5					
Storm V	Storm Water and Rain water harvesting management							
9	Storm Water and Rain water harvesting management	26	2.6					
10	OHC Expenses	1.5	0.2					
	Total	456.0	42.2					

CER activities:

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost (INR 1.9 crores) ie., will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing.



39. The company shall have a well laid down environmental policy duly approved by the Board of Directors



ENVIRONMENT POLICY:

- To take account of environmental consideration in planning and decision making.
- To monitor the impact of all the company activities upon the environment and to ensure that it is maintained.
- To pay special regards to the environment protection of the communities in which its
 operations are located.
- To conduct periodical audits to ensure implementations of the company environmental policy.
- That environmental regulations laid down by the government and public authorities are treated as minimum standard to be improved upon wherever practicable.
- That the company works closely with appropriate authorities in seeking to improve its environmental performance.



Kalyani tower, 174C 2nd Avenue, Ashok ragar Chennal - 600083 Contact No. +91 8428424699. E-mail - Contact No. +91 8428424699.

- 40. Land requirement for the facility including its break up for various purposes, its availability and optimization.
- 41. Details of proposed layout clearly demarcating various activities such as security.

The total land area is 15147.40 Sq.m. The layout is attached as Annexure 9.

Land Area Breakup

Items	Area in Sq.m	Area in Acres	%
Ground coverage (plinth)	6472.00	1.599	42.73
Greenbelt	5011.40	1.239	33.08
Open Space	144.00	0.036	0.95
Road & Parking	3520.00	0.869	23.24
Total	15147.40	3.743	100



	Tentative Built	up Area	
	Items	Area in Sq.m	
	Manufacturing block	13370.00	
	R&D Block	1950.00	
	Admin/QC/QA block/reception	2400.00	
	Pilot plant + Dining	3875.00	
	Security Block	42.00	
	Creche, OHC & Utilities	600.00	
	Total	22237.00	
	Collection and transportation of wastes to the disposal poi	nts:	
	Hazardous waste will be collected and disposed through TNPCB Authorized Recyclers and TSDF (TNW)		
42. Details on collection and transportation	gummidipoondi) through GPS enable vehicles/Trucks only.		
of wastes to the disposal points, etc.	Number of vehicles and feature of vehicles:		
	Monthly once, 1 no of lorry will come to collect the Hazar	dous waste. It is fully closed to prevent any leak on	
	ground while transit.		
43. The PP shall furnish the compliance status of the directions/guidelines issued by competent authority with respect to pharmaceutical manufacturing units Yes. The facility shall be designed and operated as per Schedule M guidelines for current Good Manufacturing with CDSCO which is the governing body to approve the Pharma manufacturing in India"			
44. Details on fuel requirement for incineration/combustion	 There is no Incineration process adopted in the proposed project. So there is no fuel requirement for that. However, kill tank will be installed to kill all kinds of microorganisms before sending to treated effluent tank. 		

➤ HSDwill be used as a fuel for DG Sets and Boiler.

Proposed Stack emission details:

FUEL			S	Stack Details			Emissions					
SL. NO	SOURC E	FUEL TYPE	QUANT ITY (KL / Day)	No. of Sta ck	Hei ght (m)	Dia (m)	Exit Veloci ty (m/s)	Tem p (°C)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
1	DG-600 kVA*	HSD				0.2	9.5	200	7.43E- 03	6.93E- 03	1.05E- 01	2.26E- 02
2	DG-600 kVA*	HSD	2.88	1	30	0.2	9.7	200	7.43E- 03	6.93E- 03	1.05E- 01	2.26E- 02
3	Boiler 1.5 TPH	HSD	2.509	1	30	0.3	10	210	3.41E- 03	4.70E- 04	6.62E- 02	1.66E- 02
	Total							1.83E- 02	1.43E- 02	2.76E- 01	6.17E- 02	

45. Details on flue gas emissions discharge through stack analysis of toxic pollutants and proposed pollution control technologies.

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Control Measures

- Stack height of 30 m is proposed for boiler.
- 30m stack height will be provided for DG.
- Adequate Green belt area will be provided.

Process Emission:

There are no process emissions from the proposed manufacturing facility.

Control Measures

- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.
- Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. Adequacy/Performance of Air Pollution Control measures shall be reviewed.

- 46. Details on residue/ash generation and management.
- There is no ash management Since HSD is used as a fuel for DG and boiler.
- > Sludge from ETP and salt from MEE will be collected and stored on Concrete platform in leak Proof Barrels in designated areas. Same will be disposed through TNPCB Authorized TSDF.

Fire Hydrant System

Fire hydrant will be placed across the plant & required firefighting equipments like extinguishers, Fire safety alarms, fire buckets etc will be provided where ever required. Trained people will be allotted to mitigate the fire during emergency and regular mock drills will be conducted to enrich the knowledge of the people.

List of safety Equipments Proposed

		V 1 1 1		
	S. Io.	Safety And Fire Fighting Equipments Description	Qty	Capacity
1	1.	Underground static water tank	1 No	300 KL
2		Fire water pumps (as per NBC guidelines and Tamil Nadu Fire and Rescue services guideline)	1 No	130 Cum/Hr
3	3.	Jockey pumps	1No's	40 Cum/Hr
4		Note: Deluge valves, Manual Call Points, Hand Siren, Gas Monitoring System, Foam trolley, Fire Hydrant Lines, MVW Sprinkler etc.,	will be pi	ovided as per ailed design

47. Details of the proposed overall safety and health protection measures

List of Fire Extinguishing proposed for the project site with count

S. No.	Type of Fire Extinguishers	Capacity	Unit	Quantity
1	CO_2	4.5	Kg	10
2	DCP	9.0	Kg	50
3	Foam	50.0	Litres	10

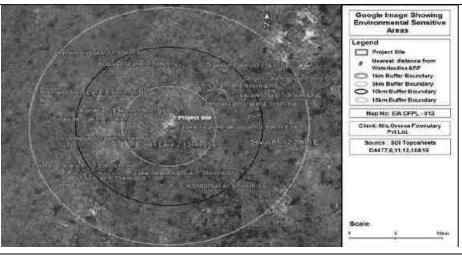
Preliminary Layout plan showing the location of fire hydrant is attached as Annexure-13.

2. Health Protection Measures:

The unit will have total 3 number of Emergency cupboards, in that one at Production Block, Storage area and another at Utility Area / Boiler Room. Each Emergency Cupboard will have the following items;



	Self Contained Breathing Apparatus (SCBA)
	Nose Mask
	Helmet-Provided to individuals
	Ear Plug
	Safety Glass -10 & Face Shield – to individuals
	Gum boot - to individuals
	Safety Belt - in safety department
	Manila Rope/Life Safety Rope
	• Fire Axe
	Fire Proximity Suit
	Safety Ladder
	Emergency Flame proof Torches
	Hand gloves
48. Details of the existing access	The entire site will have a peripheral road of minimum 6 m wide for movement of vehicles and people. There will be
	demarcated pathways for people movement across the site. For building to building access on GF, required pathway
road(s)/walkways to the designed	with pavers or RCC roads are provided. As part of the design, the outside road levels are also matched for smootl
operations in the site and its layout.	movement of people and vehicles taking in to account, the water drainability from site to avoid flooding
49. Land use map based on satellite imagery	
including location specific sensitivities such	Satellite Imagery showing the specific sensitivities such as water bodies, reserved Forest, national parks / wildlife
as national parks / wildlife sanctuary,	sanctuary etc.,. within 15Km radius is shown below:
villages, industries, etc.	



50. Surface water quality of nearby water bodies

Summary of Surface water sample results are discussed below:

- Water sampling results are compared with Surface water standards IS 2296:1992.
- pH in the collected surface water samples varies between 7.34to7.74which is within the limit of IS 2296:1992.
- The Total Dissolved Solids (TDS) value of collected surface water sample ranges from 395mg/l to 473mg/l.
- The Total hardness value of the collected surface water sample ranges between 175 mg/l to 265 mg/l.
- BOD value of surface water varies from 2 mg/l to 5 mg/L
- COD value of surface water varies from 10 to 22 mg/l.

Surface water quality of nearby river and other surface drains at eight locations as per CPCB/ MoEF&CC guidelines are collected & analyzed and the details are provided in the **Chapter 3**, **Section 3.8.2**.

51. Details on proposed groundwater monitoring wells, locations, frequency of monitoring, parameters, etc

Frequency of monitoring: one time during premonsoon season i.e., March –May 2024.

Ground water monitoring locations and parameter are given below:

S.No	Location	LocationCode	Distancein ~Km	Direction
1	ProjectSite	GW1	0.57	Е



2	Ural	GW2	3.05	NNE
3	Tindivanam	GW3	3.10	ESE
4	Pelakuppam	GW4	1.65	SSE
5	Kollar	GW5	2.35	WSW
6	Gudisaippalaiyam	GW6	2.25	WNW
7	Kattuvisiri	GW7	3.14	NW
8	Venmaniyathur	GW8	1.31	N

Parameters:

SL No	Parameters	Unit
1	Colour	Hazen
2	Turbidity	NTU
3	pН	-
4	Electrical Conductivity	μS/cm
5	Total Dissolved Solids	mg/l
6	Total suspended solids	mg/l
7	Total Alkalinity as CaCO ₃	mg/l
8	Total Hardness as CaCO ₃	mg/l
9	Sodium as Na	mg/l
10	Potassium as K	mg/l
11		
12	<u> </u>	
13		
14	1	
Nitrate as NO ₃		mg/l
16	Phosphate as PO ₄	mg/l
17	Fluorides as F	mg/l
18	Cyanide	mg/l
19	Arsenic as As	mg/l
20	Boron as B	mg/l
21	Cadmium as Cd	mg/l
22	Chromium as Cr	mg/l



23	Copper as Cu	mg/l
24	Lead as Pb	mg/l
25	Manganese as Mn	mg/l
26	Mercury	mg/l
27	Nickel as Ni	mg/l
28	Selenium as Se	mg/l

Environmental Monitoring Programme - Operation Phase

S. No	No Monitoring Stations		Frequency of Sampling	Parameters to be Analyzed
1.	Water	One surface and ground water sample near the site	Once in 6 months through NABL labs	All the parameters as per IS 10500:2012

Greenbelt Development

The total land area is 15147.40 Sq.m and Greenbelt area is 5011.40 Sq.m (33.08%). Around 1503 numbers of tree(2mx2m spacing for each tress) will be planted as calculated below:

52. Action plan for the greenbelt development in accordance with CPCB published guidelines. The PP shall no fruit bearing trees developed as part of green belt

S.No	S.No Description		Proposed Greenbelt within project site					
1	1 Total area of project site		1.5147					
2	2 Total Area of Green Belt		0.5011					
3	Percentage of total project area	%	33.08					
As per the MoEF&CC Requirement, No. of tree saplings to be planted as per guidelines(2500								
tree/Ha)	considering 80% survival rate	tree/Ha) considering 80% survival rate						
-								
4	As per MoEF&CC requirement	Nos	1503					
5	As per MoEF&CC requirement Actual No. of plants present	Nos Nos.	1503					



6	Fund Allotted	Lakhs	6.00
7	Status of Implementation	-	Within 3 year

Recommended Species for Proposed Green Belt Development in project site (as per CPCB guidelines for greenbelt development)

S.No	Scientific Name	Common Name	No of Trees	Yearwise
1	Pongamia pinnata	Pungai	300	1 st Year
2	Thespesia populnea	Poovarasu	300	2 nd Year
3	Albizis lebback	Vaagai	150	2 Year
4	Cassia fistula	Sarakondai	150	3 rd Year
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year
6	Pterocarpus Marsupium	Vengai	150	
7	Aegle Marmelos	Vilvam	150	4 th Year
8	Madhuca longifolia	Iluppai	153	
	Total		1503	

Budget for greenbelt development is INR. 7.0 lakhs

Note: No fruit bearing trees was considered for the development of green belt.

Pollution control measure (for Air pollution):

- Stack height of 30 m is proposed for boiler.
- 30m stack height will be provided for DG
- There are no process emissions from the proposed manufacturing facility.

Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.

Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. Adequacy/Performance of Air Pollution Control measures shall be reviewed.

53. Details on pollution control technologies and online monitoring equipments

Pollution control measure (for water pollution):

Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- Chemical dosing system



	➤ Transfer pumps – 1 working + 1 standby
	The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent
	mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.
	The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles,
	agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.
	Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified
	concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste
	As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump
	recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary
	treatment to the centralized effluent treatment as a regular process liquid waste.
	Online monitoring System: All pollution generating stream will be connected to server of OCMS, TNPCB. So is
	will be continuously monitored.
54. Details of the emergency preparedness	Details of the emergency preparedness plan and on-site & off-site disaster management plan was given in
plan and on-site & off-site disaster	Annexure-7.
management plan.	Allicative-7.
55. The proponent shall conduct Socio-	The proposed project is located in a notified industrial area of TANSIDCO. Secondary data has been collected from
economic and health survey	government sources and details are provided in Section 3.11 of Chapter-3.
56. A detailed incinerator design needs to	
be submitted on the likelihood of emission,	Not applicable, since there is no incinerator proposed within the site.
possible types of gases coming out of the	
process and its measures and mitigation.	
57. The proponent shall furnish SOP for the	Detailed Standard Operating Procedure (SOP) for the production process is given in Annexure -10 .
process	Detailed Standard Operating Procedure (SOF) for the production process is given in Annexure -10.



	Baseline study was conducted for the period of 3 months (March - May 2024) and their observation are given as
59. The proposent shall conduct a detailed	following:
58. The proponent shall conduct a detailed	> Air Environment- Section 3.6 of Chapter-3.
study on water, land and Air quality.	> Water Environment-Section 3.8of Chapter-3.
	> Soil Environment- Section 3.9 of Chapter-3.
59. Proponent shall furnish the letter	
received from DFO concerned stating the	Request letter submitted to PCCF regarding the details of Reserved Forests, Protected Areas, Sanctuaries, Tiger
proximity details of Reserve Forests,	
Protected Areas, Sanctuaries, Tiger reserve	reserve etc., up to a radius of 25 km from the proposed site. Acknowledgement copy for the Same is attached an
etc., up to a radius of 25 km from the	Annexure-11.
proposed site	
	Detailed Bio diversity study was conducted by HECS. Study is detailed below:
	Floral Study
	❖ Plants species were identified based on their specific diagnostics characters of family, genus and species
	using available floral, other related literature.
60. The Proponent shall carry out Bio	* Besides the identification of plant species, information was collected on the vernacular names and uses of
diversity study through reputed Institution	plants made by local inhabitants.
and the same shall be included in EIA	Faunal Study
Report.	Secondary information collected from published government data etc.
	List of the endangered and endemic species as per the schedule of The Wildlife Protection Act, 1972.
	* Emphasis is given to identify avifauna and mammals to determine the presence and absence of Schedule-1
	species, listed in The Wildlife Protection Act 1972, as well as in Red List of IUCN.
	Floristic composition within the study area



For secondary information based on a total 80 species under 32 family found in the study area. The detailed list of plant species found in each quadrat provided below:

Checklist of floral diversity in and around the area

S.No	Species	Family	Common Name	Habit	IUCN
1.	Abrus precatorius	Fabaceae	Kundumani	Shrub	NA
2.	Abutilon indicum	Malvaceae	Perun thuthi	Shrub	NA
3.	Acacia nilotica	Mimosaceae	Karuvelam	Tree	LC
4.	Acacia planifrons	Mimosaceae	Kodaivelam	Tree	NA
5.	Acalypha indica	Euphorbiaceae	Kuppaimeni	Herb	NA
6.	Acanthospermum hispidum	Compositae		Herb	NA
7.	Achyranthes aspera	Amaranthaceae	Nayurivi	Herb	NA
8.	Aegle marmelos	Rutaceae	Vilvam	Tree	NA
9.	Aerva lanata	Amaranthaceae	Sirupeelai	Shrub	NA
10.	Aerva persica	Amaranthaceae	Perumpeelai	Shrub	NA
11.	Aeschynomene aspera	Fabaceae	Thakkai	Shrub	NA
12.	Ageratum conyzoides	Compositae	Poom pillu	Herb	NA
13.	Alloteropsis cimicina	Poaceae		Grass	NA
14.	Alternanthera sessilis	Amaranthaceae	Ponnanganni	Herb	NA
15.	Anisomeles indica	Labiatae		Herb	NA
16.	Annona squamosa	Annonaceae	Seetha	Tree	NA
17.	Arachis hypogaea	Fabaceae	Verkadalai	Herb	NA
18.	Argemone mexicana	Papaveraceae	Braman Thandu	Herb	NA
19.	Aristida adscensionis	Poaceae		Grass	NA
20.	Aristida hystrix	Poaceae		Grass	NA
21.	Aristolochia bracteolata	Aristolochiaceae	Aduthinnappalai	Herb	NA
22.	Barleria acuminata	Acanthaceae	Vellai kurinji	Shrub	NA



23.	Barleria longiflora	Acanthaceae		Shrub	NA
24.	Barleria noctiflora	Acanthaceae	Barleria	Shrub	NA
25.	Boerhavia diffusa	Nyctaginaceae	Mookarattai	Herb	NA
26.	Carissa carandas	Apocynaceae	Kalaa, Perun kala	Shrub	NA
27.	Cassia fistula	Caesalpiniaceae	Kondrai	Tree	NA
28.	Celosia argentea	Amaranthaceae	Pannai keerai	Herb	NA
29.	Cissus quadrangularis	Vitaceae	Pirandai	Shrub	NA
30.	Citrullus colocynthis	Cucurbitaceae	Peikkumatti	Herb	NA
31.	Citrus aurantifolia	Rutaceae	Elumichai	Tree	NA
32.	Cleome viscosa	Capparidaceae	Nai kadugu	Herb	NA
33.	Coccinia grandis	Cucurbitaceae	Kovai	Climber	NA
34.	Croton bonplandianum	Euphorbiaceae	Rail poondu	Herb	NA
35.	Cyperus bulbosus	Cyperaceae	_	Sedge	NA
36.	Eclipta prostrata	Compositae	Karisaalai	Herb	NA
37.	Euphorbia antiquorum	Euphorbiaceae	Sadura-kalli	Tree	NA
38.	Evolvulus alsinoides	Convolvulaceae	Vishnukarandi	Herb	NA
39.	Ficus benghalensis	Moraceae	Aala maram	Tree	NA
40.	Ficus religiosa	Moraceae	Arasu	Tree	NA
41.	Indigofera linnaei	Fabaceae		Herb	NA
42.	Indigofera tinctoria	Fabaceae	Avuri, Neeli	Herb	NA
43.	Ipomoea pes-caprae	Convolvulaceae	Kudhirai Kulambu	Creeper	NA
44.	Jatropha gossypifolia	Euphorbiaceae	Kaatu-amanakku	Shrub	NA
45.	Justicia adhatoda	Acanthaceae	Adathodai	Shrub	NA
46.	Justicia simplex	Acanthaceae		Herb	NA
47.	Lagenaria siceraria	Cucurbitaceae	Surakkaai	Climber	NA
48.	Lantana camara	Verbenaceae	Unnichedi	Shrub	NA
49.	Leucaena leucocephala	Mimosaceae	Soundil	Tree	NA



50.	Merremia hederacea	Convolvulaceae		Herb	NA
51.	Nyctanthes arbor-tristis	Nyctanthaceae	Parijaatham	Tree	NA
52.	Ocimum americanum	Labiatae	Ganjaankorai	Herb	NA
53.	Phyllanthus amarus	Euphorbiaceae	Kizha-nelli	Herb	NA
54.	Pongamia pinnata	Fabaceae	Punga maram	Tree	NA
55.	Portulaca oleracea	Portulacaceae	Kari keerai	Herb	NA
56.	Prosopis juliflora	Mimosaceae	Velikkaathaan	Tree	NA
57.	Rhynchosia viscosa	Fabaceae		Climber	NA
58.	Ricinus communis	Euphorbiaceae	Amanakku	Shrub	NA
59.	Rivea hypocrateriformis	Convolvulaceae	Boodhikeerai	Climber	NA
60.	Ruellia tuberosa	Acanthaceae		Herb	NA
61.	Senna auriculata	Caesalpiniaceae	Avaram	Shrub	NA
62.	Senna occidentalis	Caesalpiniaceae	Peiyavarai	Tree	NA
63.	Sida acuta	Malvaceae	Malai thangi	Herb	NA
64.	Sida cordata	Malvaceae	Pazhampaasi	Herb	NA
65.	Sida cordifolia	Malvaceae	Nilatutthi	Herb	NA
66.	Solanum americanum	Solanaceae	Manatakkali	Herb	NA
67.	Solanum torvum	Solanaceae	Chundai	Shrub	NA
68.	Solanum trilobatum	Solanaceae	Thoodhuvalai	Climber	NA
69.	Spermacoce hispida	Rubiaceae	Nathaichoori	Herb	NA
70.	Tamarindus indica	Caesalpiniaceae	Puliya maram	Tree	NA
71.	Tectona grandis	Verbenaceae	Thekku	Tree	NA
72.	Tephrosia purpurea	Fabaceae	Kozhinji	Undershrub	NA
73.	Terminalia catappa	Combretaceae	Badam	Tree	NA
74.	Thespesia populnea	Malvaceae	Poovarasu	Tree	NA
75.	Tinospora cordifolia	Menispermaceae	Seenthilkodi	Climber	NA
76.	Tridax procumbens	Asteraceae	Vettukayapoonduthalai	Herb	NA



77.	Vitex negundo	Verbenaceae	Nochi	Tree	NA
78.	Waltheria indica	Sterculiaceae	Chempoodu	Herb	NA
79.	Wrightia tinctoria	Apocynaceae	Vetpaalai	Tree	NA
80.	Ziziphus mauritiana	Rhamnaceae	Illandhai	Tree	NA

Source:

- 1. Flora of Tamil Nadu. Botanical survey of India.1983.
- 2. IUCN Status: https://www.iucnredlist.org/

Fauna Diversity

A checklist faunal species such as birds, reptiles, amphibians and butterfly species based on secondary information. As per the Wild Life Act (1972) those animals, which have been enlisted in the schedules of the Wildlife Act, have been presented below. The schedules are based on the species namely, rare, endangered, threatened, vulnerable etc. According to the threat of extinction, Schedule-I contains those species which need topmost priority, while II, III, IV and V have lesser degree of threat. Most of the avi-fauna has been listed in Schedule-IV. As per the list of avifaunal species, these are mostly local migrant species only. Secondary information for Fauna diversity were collected to cross check with relevant literatures (Smith 1933-43, Ali and Ripley 1983, Daniel 1983, Prater 1993, Murthy and Chandrasekhar 1988).

Faunal diversity IUCN status

S.No	Scientific Name	Common Name	Family	IUCN	WPA
1.	Acridotheres tristis	Common Myna	Sturnidae	LC	Sch IV
2.	Anthus rufulus	Paddyfield pipit	Motacillidae	LC	Sch IV
3.	Apus affinis	House Swift	Apodiformes	LC	Sch IV
4.	Ardea alba	Great Egret	Ardeidae	LC	Sch IV
5.	Ardea cinerea	Grey Heron	Ardeidae	LC	Sch IV
6.	Ardeola grayii	Indian Pond Heron	Ardeidae	LC	Sch IV
7.	Bubulcus ibis	Cattle Egret	Ardeidae	LC	Sch IV
8.	Calidris minuta	Little Stint	Scolopacidae	LC	Sch IV
9.	Centropus sinensis	Greater Coucal	Cuculidae	LC	Sch IV



10	. Ciconia episcopus	Asian Woolly-necked Stork	Ciconiidae	NT	Sch IV
11		Purple Sunbird	Nectariniidae	LC	Sch IV
12	•	Eurasian Marsh-Harrier	Accipitridae	LC	Sch IV
13	. Columba livia	Rock Pigeon	Columbidae	LC	Sch IV
14	Copsychus saularis	Oriental Magpie Robin	Muscicapidae	LC	Sch IV
15	Coracias benghalensis	Indian roller	Coraciidae	LC	Sch IV
16	. Corvus splendens	House Crow	Corvidae	LC	Sch IV
17	. Cyornis tickelliae	Tickell's blue flycatcher	Muscicapidae	LC	Sch IV
18	. Dendrocygna javanica	Lesser Whistling-Duck	Anatidae	LC	Sch IV
19	Dicaeum erythrorhynchos	Pale billed flowerpecker	Dicaeidae	LC	Sch IV
20	Dicrurus macrocercus	Black Drongo	Dicruridae	LC	Sch IV
21	. Egretta garzetta	Little Egret	Ardeidae	LC	Sch IV
22	. Elanus caeruleus	Black-winged Kite	Accipitridae	LC	Sch IV
23	Eudynamys scolopaceus	Asian Koel	Cuculidae	LC	Sch IV
24	. Euodice malabarica	Indian silverbill	Estrildidae	LC	Sch IV
25	. Fulica atra	Eurasian Coot	Rallidae	LC	Sch IV
26	Gallinula chloropus	Eurasian Moorhen	Rallidae	LC	Sch IV
27	. Haliastur indus	Brahminy Kite	Accipitridae	LC	Sch I
28	. Halcyon smyrnensis	White-throated kingfisher	Alcedinidae	LC	Sch IV
29	Lonchura punctulata	Scaly-breasted Munia	Estrildidae	LC	Sch IV
30	Merops orientalis	Green Bee-eater	Meropidae	LC	Sch IV
31	. Microcarbo niger	Little cormorant	Phalacrocoracidae	LC	Sch IV
32	. Milvus migrans	Black Kite	Accipitridae	LC	Sch IV
33	. Motacilla maderaspatensis	White browed Wagtail	Motacillidae	LC	Sch IV
34	. Mycteria leucocephala	Painted Stork	Ciconiidae	NT	Sch IV
35	Nycticorax nycticorax	Black-crowned Night-Heron	Ardeidae	LC	Sch IV
36	Orthotomus sutorius	Common tailorbird	Cisticolidae	LC	Sch IV
37	Ortygornis pondicerianus	Grey francolin	Phasianidae	LC	Sch IV
38	Passer domesticus	House Sparrow	Passeridae	LC	Sch IV
39	Pelecanus philippensis	Spot-billed Pelican	Pelecanidae	NT	Sch IV



40	. Phalacrocorax carbo	Great Cormorant	Phalacrocoracidae	LC	Sch IV
41	. Phalacrocorax fuscicollis	Indian Cormorant	Phalacrocoracidae	LC	Sch IV
42	. Plegadis falcinellus	Glossy Ibis	Threskiornithidae	LC	Sch IV
43	. Prinia inornata	Plain prinia	Cisticolidae	LC	Sch IV
44	. Prinia socialis	Ashy Prinia	Cisticolidae	LC	Sch IV
45	. Pseudibis papillosa	Red-naped Ibis	Threskiornithidae	LC	Sch IV
46	. Psittacula krameri	Rose-ringed Parakeet	Psittaculidae	LC	Sch IV
47	. Pycnonotus cafer	Red-vented Bulbul	Pycnonotidae	LC	Sch IV
48	. Saxicoloides fulicatus	Indian Robin	Muscicapidae	LC	Sch IV
49	. Sterna hirundo	Common Tern	Laridae	LC	Sch IV
50	. Sternula albifrons	Little Tern	Laridae	LC	Sch IV
51	. Streptopelia chinensis	Spotted Dove	Columbidae	LC	Sch IV
52	. Streptopelia decaocto	Eurasian collared dove	Columbidae	LC	Sch IV
53	. Streptopelia senegalensis	Laughing Dove	Columbidae	LC	Sch IV
54	. Sturnia pagodarum	Brahminy Starling	Sturnidae	LC	Sch IV
	. Tachybaptus ruficollis	Little Grebe	Podicipedidae	LC	Sch IV
56	. Thalasseus bengalensis	Lesser Crested Tern	Laridae	LC	Sch IV
57	. Threskiornis melanocephalus	Black-headed Ibis	Threskiornithidae	NT	Sch IV
58	. Tringa erythropus	Spotted Redshank	Scolopacidae	LC	Sch IV
59	. Vanellus indicus	Red-wattled Lapwing	Charadriidae	LC	Sch IV
60	. Vanellus malabaricus	Yellow-wattled Lapwing	Charadriidae	LC	Sch IV
Mamn	nals				
S.No	Common Name	Scientific Name	Family	IUCN	WPA Schedule
1	Five striped Palm squirrel	Funambulus pennantii	Sciuridae	LC	Sch IV
2	Field Rat	Rattus argentiventer	Muridae	LC	Sch V
3	Indian hare	Lepus nigricollis	Leporidae	LC	Sch V
4	Wild boar	Sus scrofa	Suidae	LC	Sch V
Butter	flies				



1	Baronet	Euthalia nais	Nymphalidae	NT	Schedule IV
2	Blue tiger	Tirumala limniace	Nymphalidae	LC	Schedule IV
3	Pioneer	Belenois aurota	Pieridae	LC	Schedule IV
4	Common crow	Euploea core	Nymphalidae	LC	Schedule IV
5	Common Emigrant	Catopsilia pomona	Pieridae	NT	Schedule IV
6	Common evening brown	Melanitis leda	Nymphalidae	LC	Schedule IV
7	Common grass yellow	Eurema hecabe	Pieridae	LC	Schedule IV
8	Common jezebel	Delias eucharis	Pieridae	NT	Schedule IV
9	Common leopard	Phalanta phalantha	Nymphalidae	LC	Schedule IV
10	Common lime	Papilio demoleus	Papilionidae	NT	Schedule IV
11	Common mormon	Papilio polytes	Papilionidae	NT	Schedule IV
12	Danaid eggfly	Hypolimnas misippus	Nymphalidae	LC	Schedule I
13	Great eggfly	Hypolimnas bolina	Nymphalidae	NT	Schedule I
14	Grey pansy	Junonia atlites	Nymphalidae	NT	Schedule IV
15	Lemon pansy	Junonia lemonias	Nymphalidae	NT	Schedule IV
16	Mottled Emigrant	Catopsilia pyranthe	Pieridae	NT	Schedule IV
17	Pale Grass Blue	Pseudozizeeria maha	Lycaenidae	NT	Schedule IV
18	Peacock pansy	Junonia almana	Nymphalidae	LC	Schedule IV
19	Plain tiger	Danaus chrysippus	Nymphalidae	LC	Schedule I
Repti	les				
1	Oriental Garden lizard	Calotes versicolor	Agamidae	LC	Schedule I
2	Indian Rat Snake	Ptyas mucosa	Colubridae	LC	Schedule II
3	Russels Viper	Daboia russelii	Viperidae	LC	Schedule II
4	Peninsular Rock Agama	Psammophilus dorsalis	Agamidae	LC	Schedule IV
5	Checkered keelback	Xenochrophis piscator	Colubridae	LC	Schedule II

Conservative measures are given in section 3.10.23, Chapter-3 of EIA report.

61. The Project Proponent shall conduct the hydro-geological study considering the

- ➤ Proposed project site is located within Notified TANSIDCO industrial park
- > Fresh water will be supplied by TANSIDCO so there will no extraction of ground water for the proposed



contour map of the water table detailing the number of ground water pumping & open wells, and surface water bodies such as rivers, tanks, canals, ponds etc. within 1 km (radius) along with the collected water level data for both monsoon and non-monsoon seasons from the PWD / TWAD so as to assess the impacts on the wells due to proposed activity. Based on actual monitored data, it may clearly be shown whether working will intersect groundwater. Necessary data and documentation in this regard may be provided.

project.

- List of water bodies within 15 km radius is given in **Table 3-1** of **chapter-3**.
- Contour profile of study area is given in Figure 3-10 of chapter-3.

Hydrogeology study is in progress and same will be submitted during final EIA report.

62. The Proponent shall furnish the baseline data for the environmental and ecological parameters with regard to surface water/ground water quality, air quality, soil quality & flora/fauna including traffic/vehicular movement study

Baseline study was conducted for the period of 3 months (March - May 2024) and their observation are given as following:

- > Air Environment- Section 3.6 of Chapter-3.
- > Noise Environment- Secion 3.7 of Chapter-3.
- ➤ Water Environment-Section 3.8 o f Chapter-3.
- > Soil Environment- Section 3.9 of Chapter-3.
- **Biodiversity Study-Section 3.10 of Chapter-3.**
- > Impact due to traffic movement-Section 4.1.3.2. of Chapter-4

63. The Proponent shall carry out the

The study area of 10km radius around the project site is taken as buffer zone. The impacts of existing development

Cumulative impact study due to project activity specifically with reference to the specific environment in terms of soil health, biodiversity, air pollution, water pollution, climate change and flood control & health impacts. Accordingly, the Environment Management plan should be prepared keeping the proposed site and the surrounding habitations in the mind.

were already considered in the baseline monitoring study for the period of March - May 2024.

Air Pollution:

Air quality modelling was done using AERMOD software to identify the ground level concentration due to operation of proposed industries.

Total Maximum GLCs from the cumulative Emissions

Pollutant	Max. Base line Conc. (μg/m³)	Estimated Incremental Conc. (µg/m³)	Total Conc. (μg/m³)	NAAQ standard (μg/m³)
PM10	59.48	0.05	59.53	100
SO2	12.46	0.04	12.5	80
NO _x	25.92	0.87	26.79	80
CO	720	22.16	742.16	4000

Based on above modeling, air emission from project is well within limit. So there is no impact on air.

Cumulative impact due to the proposed project (including Point source-DG sets and line source-vehicle) is given in

Chapter-4.

Water pollution:

The proposed project will implement Zero Liquid Discharge concepts and no effluent /waste water will be discharged outside the plant premises. Recycle and reuse concepts will be implemented in the plant and entire wastewater will be reused within the plant for greenbelt and utilities. Hence no impact on water.

Biodiversity:

Detailed Bio-diversity assessment has been carried out during March-may 2024. Details are provided in Section 3.10 of Chapter-3 of EIA report. Mitigation measures along with budget for protection of Schedule-1 Fauna are given in 3.10 of Chapter-3 of EIA report.



The proponent has proposed a sum of Rs. 5,35,000/-for the conservation plan under the following heads:

S.N	Work or Activity	Approximate Cost. Rs.					
0	Work of Activity	Year 1	Year 2	Year 3	Year 4	Year 5	
1	Monitoring birds	105,000/-	105,000/-	52,500/-	-	-	
2	Birds monitoring tools	1,00,000/-	-	-	-	-	
3	Environmental awareness programme	24,000/-	24,000/-	24,000/-	24,000/-	24,000/-	

(Not including water supply, grass seed collection and plantation)

There is no impact on ecology& biodiversity due to the proposed project due to the following:

- 1. ZLD system will be adopted
- **2.** Segragation of waste will be in place and waste will be disposed according to the guidelines.
- **3.** Hazardous waste wil be segregated and disposed through TSDF

Soil health:

Soil samples have been collected within 10km radius of study area. Details are provided in **section 3.9 of chapter-3.** There is no impact on soil health due to the proposed project due to the following:

- 1. ZLD system will be adopted
- 2. Segragation of waste will be in place and waste will be disposed according to the guidelines.
- 3. Hazardous waste wil be segregated and disposed through TSDF.

Climate change:

The proposed project will not generate any process emissions. The whole process operations will be in a closed condition. The emission from utilities will be controlled by APC measures. Emissions will be monitored by continuous online monitoring systems and same will be connected to CPCB/TNPCB servers. Hence there is no



impact on climate change due to the proposed project.

Flood control:

There is no major river in the study area hence project site is safe from inundation.

Health impact:

1. For Local Public:

Proposed project is manufacturing of monoclonal antibodies which will be used to treat disease such as cancer etc.

All statutory compliance will be followed and monoclonal antibodies will be manufactured as per the FDA/USA norms under closed environment. Hence no impacts on local public.

2. For Workers:

There is no impact on the workers due to the proposed project since all Personal Protective Equipments will be provided to workers. Health status of workers will be monitored for every six months as per rules.

Occupational Health Centre (OHC):

Omexa will have agreement signed with nearby hospital for their valuable service during emergency along with 24/7 ambulance facility. Unit will provided Occupational Health Centre within their premises with facilities like bed and O₂ Generator. Cost estimation for OHC is given in below:

Cost Estimation for OHC

S. No.	Description	Capital cost (in lakhs)	Recurring cost / Month (in lakhs)
1	OHC Expenses	1.5	0.2
	Total	1.5	0.2

Environmental management plan is provided in **Chapter 10** and tentative budget for Environment Management Plan is provided in **Table 10-7**.



64. Rain water harvesting management with

recharging details along with water balance

(both monsoon & non-monsoon) be

Rain water harvesting management with recharging details:

Description	Area (m²)	Run off Coefficient	Intensity of rainfall-I (m/day)	Total Discharge-Q(m3/day)
Ground coverage (plinth)	6472	0.8	0.073	377.96
Greenbelt	5011.4	0.2	0.073	73.17
Open Space	144	0.7	0.073	7.36
Road & Parking	3520	0.7	0.073	179.87
Total	15,147.40	0.00	0.00	638.36

Formula:

Discharge, $Q = CIA (m^3/day)$

Where,

Q= Discharge (in m³/day)

C=Coefficient of Runoff

I= Intensity of rainfall (in mm/day) (Max Flood in 12.11.2022- 73.79 mm as per IMD Villupuram)

A= Area (in Sq.m)

Runoff calculation:

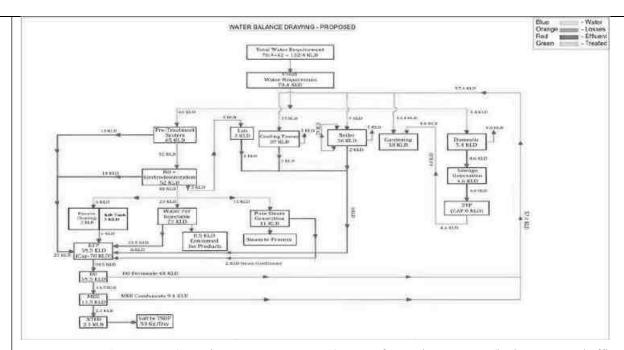
- ightharpoonup Total runoff Load = 638.36 m³/day
- \triangleright Total runoff load per hour =638.36/24 = 26.60 m3/hr.
- > RWH pits of 1.5m dia and 4.0 m depth, capacity of each pits= 3.53 m3 and we considered 50% percolation so the capacity of RWH pit is 1.77 m3.
- No. of RWH pits proposed = 26.60/3.53 = 15.02 Say 15 Nos.

15 no. of rainwater harvesting pits are proposed Storm water will be collected in RWH pitsthrough storm water drains and only ecess storm water will be let into TANSIDCO Drain. Layoutwith storm water drain is attached as an

Annexure -8.

Water balance(Non – Monsoon):

submitted.



Water balance (in Monsoon): During monsoon season, 18 KLD of treated wastewater (both sewage and effluent) will be send to common Sewage treatment plant (CSTP) of TANSIDCO.

66. Proximity to Areas declared as 'Critically Polluted' (or) the Project areas which attracts the court restrictions for proposed operations, should also be indicated and where so required, clearance certifications from the prescribed

Not applicable,

There is no Areas declared as 'Critically Polluted' (or) the Project areas which attract the court restrictions for proposed operations within 15 km radius.

Authorities	s, such as	the TNPC	B should	l be				
secured and furnished to the effect that the								
proposed	project	activities	could	be				
considered								

67. Description of water conservation measures proposed to be adopted in the Project should be given. Details of rainwater harvesting proposed in the Project, if any, should be provided.

The manufacturing process is designed on such a technology platform that, minimal water is used for cleaning purpose. The water consumption for process equipment is less than 30 % compared to standard process. The facility is designed as ZLD plant and all the treated effluent is recycled for gardening, toilet flush and colling tower applications. All the taps are provided with aerators to reduce the water consumption. Urinals are designed as either dry ones or with minimal water flush of recycled water. The Steam condensate which is generated after process heating application is also recirculated back to boiler for reuse. The building roofs are designed in a way to recover the rainwater and are channelized to the rainwater harvesting pit and ground water recharge.

Traffic study is carried out including type and frequency of vehicles, transportation of materials and additional traffic due to the proposed project based on IRC:106-1990- Guideline for capacity of urban road in plain area. Details are given in **Chapter 4**, **Section 4.1.3.2** of **EIA report**.

Existing and Proposed Vehicular movement in NH-77 per hour

68. Impact on local transport infrastructure due to the Project should be indicated.

S. No	Type of Vehicles	Existing vehicles	Existing PCU	Proposed vehicles	Proposed PCU	Total vehicles after project implementat ion	PCU Factors IRC (SP41)	Total PCU after project implementa tion
1	2wheelers	350	263	20	15	370	0.75	278
2	3Wheeler	42	84	0	0	42	2	84
3	Cars	442	442	4	4	446	1	446
4	Truck / Lorry/ Bus	90	333	3	11.1	93	3.7	344

5	Agri tractor	8	32	0	0	8	4	32
6	Light commercial	45	90	0	0	45	2	90
	Total	977	1244	27	30.1	1004	-	1274

Traffic Volume after Implementation of the Project

For the Road	Volume of Traffic	Volume (V)	Road Capacity (C)	V/C Ratio	LOS Category*	Traffic Classification
Existing	977	1244	15000	0.08	"A"	Free Flow Traffic
After implementation	1004	1274	15000	0.085	"A"	Free Flow Traffic

^{*}LOS (Level of Service) categories are A-Free Flow, B- Stable Traffic Flow, C- Restricted Flow, D- High Density Flow, E- Unstable flow, F- Forced or breakdown flow

Categorisation of traffic

V/C	LOS	Classification
< 0.35	A	Free flow Traffic
0.35-0.55	В	Stable flow Traffic
0.55-0.77	С	Restricted flow
0.77-0.92	D	High Density flow
0.92-1.0	Е	Unstable Flow
>1.0	F	Forced Traffic flow

Due to propose project there will be slight increment in the vehicle movement but the level of service (LOS) anticipated will be **Free Flow**.

69. A tree survey study shall be carried out

Currently there is No Tree available within the project Site. However, as per SEAC instruction we already planted



(nos., name of the species, age, diameter	50 tree saplings on 03.06.2024. Photos of greenbelt planting are given in	Figure 4-17 of Chapter-4.			
etc.,) at the project site.	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	angula i i or campter i			
70. Public Hearing points raised and					
commitments of the Project Proponent on					
the same along with time bound Action					
Plan with budgetary provisions to	Noted, draft EIA report is being submitting for public hearing. PH points raised and commitments will be provided in final EIA report along with budgetary provision.				
implement the same should be provided and					
also incorporated in the final EIA/EMP	1 8 8 1				
Report of the Project and to be submitted to					
SEIAA/SEAC with regard to the Office					
Memorandum of MoEF& CC accordingly					
71. The Public hearing advertisement shall	Noted, Same will be followed and PH advertisement will be published in	n one major National daily (English) and one			
be published in one major National daily	most circulated vernacular daily(tamil).				
and one most circulated vernacular daily.	most circulated vernacular dany(tanin).				
72. The Proponent shall produce/display the					
EIA report, Executive summery and other	Noted and will be submitted for an destine the Dublic bearing				
related information with respect to public	Noted, same will be submitted for conducting the Public hearing.				
hearing in Tamil Language also					
73. As a part of the study of flora and fauna	Suitable flore and found study will be conducted and details of some	will be advected to students in nearby Court			
around the vicinity of the proposed site, the	Suitable flora and fauna study will be conducted and details of same will be educated to students in nearby Govt. School as Part of CER activities. Budget of INR 5.0 lakhs will be allotted for Awarness Campus and distribution of				
EIA coordinator shall strive to educate the					
local students on the importance of	Tree sapling and seed ball to students				
preserving local flora and fauna by	Schools	Budget (INR. Lakhs)			
= •					

involving	them	in	the	study,	wherever
possible.					

74. The purpose of Greenbelt around the project is to capture the fugitive emissions, carbon sequestration and to attenuate the noise generated, in addition to improving the aesthetics. A wide range of indigenous plant species should be planted as given in the Appendix-I in consultation with the DFO, & Tamil Nadu Agriculture University. The plant species with dense/moderate canopy of native origin should chosen. Species small/medium/tall trees alternating with shrubs should be planted in a mixed manner

The purpose of developing the greenbelt in and around the project site is for:

- Preventing land degradation and erosion of topsoil due to activities during construction phase.
- Containment and abatement of pollution in the industrial environment, capturing of fugitive emissions if any and thereby improving the quality of the surrounding environment.
- Substantially reducing the adverse environmental impacts due to the proposed industrial activity.
- Serving as a barrier for attenuating the intensity of noise generated.
- Enhancing the biodiversity index of the region.
- Adding aesthetic value to the project area.
- Maintaining the ecological equilibrium of the area.

The following general guidelines and measures will be adopted:

• The plantation of trees will be initiated during construction stage so that substantial growth may be achieved when the project is completed. The greenbelt development programme will be

drawn to conform to natural climatic conditions and adaptability of the species.

- Species involved in green belt development will be indigenous, fast growing and eco-friendly.
- Proper drainage system and proper plantation techniques will be adopted.
- Plantation will be properly maintained and protected by fencing from grazing and felling.

The plantations would consist of a mixture of carefully chosen locally available species of trees, shrubs and herbs, preferably evergreen and resistant to pollution.

Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted (by considering 80% survival rate) in that around 50 trees was already planted as recommendation of TNPCB and forest department.

Tentative Proposed green belt Species

S.No	Scientific Name	Common Name	No of Trees	Yearwise	
1	Pongamia pinnata	Pungai	300	1 st Year	
2	Thespesia populnea	Poovarasu	300	2 nd Year	
3	Albizis lebback	Vaagai	150	2 Year	
4	Cassia fistula	Sarakondai	150	3 rd Year	
5	Lagestroemia Speciosa	Poo marudhu	150		
6	Pterocarpus Marsupium	Vengai	150		
7	Aegle Marmelos	Vilvam	150	4 th Year	
8	Madhuca longifolia	Iluppai	153		
	Total		1503		

(Note: The plant species proposed are based on the guidelines for developing green belt by CPCB- March 2000)

75. Taller/one year old Saplings raised in appropriate size of bags, preferably ecofriendly bags should be planted as per the advice of local forest authorities/botanist/Horticulturist with regard to site specific choices. The

Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted (by considering 80% survival rate) in that around 50 trees was already planted as recommendation of TNPCB and forest department.

Tentative Proposed green belt Species

S.No	Scientific Name	Common Name	No of Trees	Yearwise
1	Pongamia pinnata	Pungai	300	1 st Year
2	Thespesia populnea	Poovarasu	300	2 nd Year



propo	proponent shall earmark the greenbelt area				
with	GPS	coordinates	all	along	the
boundary of the project site with at least 3					
meters wide and in between blocks in an					
organized manner.					

3	Albizis lebback	Vaagai	150	
4	Cassia fistula	Sarakondai	150	3 rd Year
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year
6	Pterocarpus Marsupium	Vengai	150	
7	Aegle Marmelos	Vilvam	150	4 th Year
8	Madhuca longifolia	Iluppai	153	
	Total		1503	

(Note: The plant species proposed are based on the guidelines for developing green belt by CPCB- March 2000)

Layout plan showing green belt area along with GPS coordinates is given in Annexure-6

76. A Disaster management Plan and Risk Assessment and management Plan shall be prepared and included in the EIA/EMP Report.

Risk Assessment report including disaster management plan and Emergency evacuation plan is attached as an **Annexure-7.**

77. Occupational Health impacts of the Project should be anticipated and the proposed preventive measures spelt out in detail. Details of pre-placement medical examination and periodical medical schedules examination should he incorporated in the EMP. The project specific occupational health mitigation measures with required facilities proposed in the project site area may be detailed.

Occupational Health Monitoring

Medical Surveillance Program: Medical surveillance program is essential to assess and monitor employees' health and fitness both prior to employment and during the course of work; to determine fitness for duty and to provide emergency and other treatment as needed. Effectiveness of a medical program depends on active involvement of employees. Medical surveillance program will include the following major elements;

- Developing an OH-IH Medical Surveillance Program.
- Pre-Employment Examination and Periodic Medical Examinations
- Determination of Fitness for Duty.
- Communications.
- Emergency Medical Treatment.
- Medical Records.



Pre-Employment Screening/Examinations – All employees will be subjected to pre-placement medical examinations to determine their fitness for the jobs on site. Potential exposures to the work environment will be considered before placing an employee on the job.

Periodic Medical Examinations - Periodic medical examination is the same as the pre-employment screening and may be modified according to current conditions, such as changes in the employee's symptoms, site hazards or exposures.

Periodic medical examination is the same as the pre-employment screening. The frequency and content of examinations will be normally once in a year.

Occupational Health Centre (OHC):

Omexa will have agreement signed with nearby hospital for their valuable service during emergency along with 24/7 ambulance facility. Unit will provided Occupational Health Centre within their premises with facilities like bed and O₂ Generator. Cost estimation for OHC is given in below:

Cost Estimation for OHC

S. No.	Description	Capital cost (in lakhs)	Recurring cost / Month (in lakhs)
1	OHC Expenses	1.5	0.2
	Total	1.5	0.2

78. Public health implications of the Project and related activities for the population in the impact zone should be systematically evaluated and the proposed remedial measures should be detailed along with budgetary allocations

Health impact:

1. For Local Public:

Proposed project is manufacturing of monoclonal antibodies which will be used to treat disease such as cancer etc.

All statutory compliance will be followed and monoclonal antibodies will be manufactured as per the FDA/USA norms under closed environment. Hence no impacts on local public.

2. For Workers:

There is no impact on the workers due to the proposed project since all Personal Protective Equipments will be



provided to workers. Health status of workers will be monitored for every six months as per rules.

Occupational Health Centre (OHC):

Omexa will have agreement signed with nearby hospital for their valuable service during emergency along with 24/7 ambulance facility. Unit will provided Occupational Health Centre within their premises with facilities like bed and O₂ Generator. Cost estimation for OHC is given in below:

Cost Estimation for OHC

S. No.	Description	Capital cost (in lakhs)	Recurring cost / Month (in lakhs)
1	OHC Expenses	1.5	0.2
	Total	1.5	0.2

Environmental management plan is provided in **Chapter 10** and tentative budget for Environment Management Plan is provided in **Table 10-7**.

79. The Socio-economic studies should be carried out within a 5 km buffer zone from the project site. Measures of socio-economic significance and influence to the local community proposed to be provided by the Project Proponent should be indicated. As far as possible, quantitative dimensions may be given with time frames for implementation

Socio-economic studies was carried out within a 5 km buffer zone from the project site. Based on the observation, there is a need for development of educational and medical infrastructure within 5 km buffer Zone.

Quantitative dimensions with time frames for implementation will be done based on the requirement observed in the Public hearing.

80. Details of litigation pending against the project, if any, with direction /order passed

The company assures that there is no pending case and the affidavit for No Litigation has been attached as **Annexure-14.**



by any Court of Law against the Project	
should be given.	
	Project Benefits:
	Establishment of bulk drugs manufacturing facility not only increases the market availability of bio based drugs but
	also reduces the imports in the country and also support the government by paying the taxes.
	In addition to this, certain social contributions will help in economic growth of the area. Further the proposed project
	will result in improvement of infrastructure as well as up-liftment of social structure in the area. The people residing
	in the nearby areas will be benefited indirectly.
	It is anticipated that the proposed project will provide benefits to the locals in two phases i.e. during construction
	and operation phases.
81. Benefits of the Project if the Project is	1. Construction Phase Benefits
implemented should be spelt out. The	a)Employment Opportunities
benefits of the Project shall clearly indicate	The major benefit due to the proposed project will be in the sphere of generating temporary employment for
environmental, social, economic,	substantial number of personnel. Around 30 no. of persons would be required during the construction phase. Both
employment potential, etc.	skilled & un-skilled personnel's will be required during this phase of the activity.
	b) Community Services
	The industry shall suitably employ local people to the extent where ever possible. In addition, the project will
	develop necessary infrastructure like transportation, canteen, water supply, sewerage, medical facility, etc. for
	catering to the needs of the project personnel. The local people will be indirectly benefited by these developments.
	2 Operational Phase Benefits
	a) Infrastructural Facilities
	The proposed site is equipped with sufficient infrastructural facilities including drinking water, toilets, sanitation
	facilities, power, easily accessible approach roads, public transport, communication, etc. Hence some indirect

benefits to the public infrastructure is anticipated due to the proposed project. However, benefits due to CSR activities may be realized if any CSR activities would be related with such facilities.

b) Direct or Indirect Employment Opportunities

During the operational phase, about 120 people shall be employed. Proposed project would add livelihood opportunities in the study area which results in better scope for direct employment etc.

In addition to the direct employment mentioned above, there will be indirect employment of local people in terms of Logistics, Housekeeping, Horticulture, Water and Fuel supply, etc.

c) Community Welfare Measures

Various CSR activity as per company policy will be initiated in the surrounding villages as per below categories

- Education
- Health
- Infrastructure development
- Sports and Cultural activity

82. The Proponent shall prepare the EMP for the entire life of project and also furnish the sworn affidavit stating to abide the EMP for the entire life of project.

Environmental Management Plan Budget (tentative):

S. No	Particulars	Capital Investment (Rs in lakhs) Proposed	Recurring Cost per Annum (Rs in Lakhs)			
Environ	Environment Management Plan					
Water Po	ollution Control					
1	ETP	350	20			
2	MEE/ATFD and RO	330	20			
3	STP	8.5	2			
Air Poll	Air Pollution Control					



4	DG & Boiler Stack/ Wet scrubber	60	3			
Enviro	Environmental Monitoring					
5	Environmental Monitoring by third party	0	4.4			
Solid V	Vaste Management		•			
6	Solid Waste Management	2	3			
Greent	pelt					
7	Greenbelt Development	7	2			
Hazaro	lous Waste Management					
8	Hazardous Waste Management	2	5			
Storm '	Water and Rain water harvesting managemen	t				
9	Storm Water and Rain water harvesting management	26	2.6			
10	OHC Expenses	1.5	0.2			

Sworn affidavit stating to abide the EMP for the entire life of project will be submitted in final EIA report.

83. Concealing any factual information or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this Terms of Conditions besides attracting penal provisions in the Environment (Protection) Act, 1986.

Noted and accepted

SEIAA Specific Conditions:



		Life Cycle Impact assessment (LCIA)
		LCIA is one of the most important stages in Life Cycle Assessment to assess environmental impacts from its cradle
		to grave. This contributes to the environmental impacts for proposed products with respect to extraction of raw
1	The PP shall carryout detailed LCA study	material, impact. The LCIA presents the environmental performance of proposed products with a whole picture.
1	for the drugs to be manufactured	Methodology: Emission factors and calculation methodologies are used to calculate the environmental impacts
		(Acidification Potential, Eutrophication Potential, global warning potential & Ecotoxocity potential) for production,
		distribution up through end-of-life Take stage into consideration in evaluating.
		Detailed LCA Study for the proposed products will be provided in final EIA report.
		Global Warming Potential (GWP)
		Global Warming Potential (GWP) quantifies the potential of greenhouse gases (GHGs) to trap heat in the
		atmosphere, contributing to global warming. It is measured relative to carbon dioxide (CO ₂) over a specific time
		horizon, typically 100 years.
		Sources : The manufacturing process, energy consumption, and transportation of proposed products can contribute to
		GHG emissions, such as CO ₂ etc.
	Global warming potential /safety norms and	Impacts: Increased GWP leads to climate change, impacting weather patterns, sea levels, and ecosystems.
2	practices to be adopted	Implementing energy-efficient processes and reducing fossil fuel dependency can help mitigate GWP.
		Measures:
		> Building is designed in a way to reduce the heat gain and then by reducing the air conditioning requirements.
		> Chillers used for Air conditioning will be chosen with lowest GWP to and any potent greenhouse gas
		emission refrigerant wont be used in any of the application in the facility.
		> All other sources of natural source of energy like Solar power are utilized to reduce the consumption of
		power.

		➤ The facility operates with minimal emission of CO ₂ to atmosphere considering low consumption of fuel.
3	Safety Standards and impacts of single use and multiuse machinery to be used for drug production.	 All the components which are used as Single use & non metallic consumables are USP complied materials which are safe for drug production and also are having low impact on environment which treated through recommended methods. The multi use machineries undergo preventive maintenance backed with AMC for critical systems to ensure that, machineries operate in efficient, safe and clean manner. All the operators are trained with HSE policies and operation of systems by the engineering experts. Any movement of machineries, changes in building structures or works would require HSE approval before proceeding with implementation. The facility design & operation is planned for both Product & People safety with required planning, training & procedures
4	Biosafety standard and protocols of the raw materials used, process and manufactured products	Biosafety Recommendations and Containment Measures The implementation of an appropriate containment level includes the followinggeneral and more specific work practices and containment measures. Respect good microbiological practices, especially those that are aimed at avoiding accidental contamination. Avoid opening of culture vessels or contact with culture fluid through a defective culture vessel, stopper or poor technique because of the ever present likelihood of contamination with airborne pathogens. Treat each new culture that is manipulated for the first time in the laboratory facility as potentially infectious. Clean up any culture fluid spills immediately with a validated disinfectant. Work with one cell line at a time and disinfect the work surfaces between two handlings involving cell lines. Aliquot growth medium so that the same vessel is not used for more than one cell line.

		 Avoid pouring actions, which are a potential source of cross-contamination.
		• Proceed to an adequate use of the biosafety cabinet, this is turn on for a period before and after use,
		thoroughly disinfect biosafety cabinet surfaces after each work session and do not clutter the biosafety cabinet with materials.
		Restrict the use of antibiotics in growth media.
		• Quarantine new cell cultures to a dedicated biosafety cabinet or separate laboratory until the culture has
		been shown negative in appropriate tests.
		 Carry out a quality control of cells demonstrating the absence of likely contaminating pathogens on a regular basis or whenever necessary.
		• Handle cell cultures from undefined sources as risk group agents. If there is a reasonable likelihood of
		adventitious agents of higher risk class, the cell line should be handled under appropriate containment level
		until tests have proven safety.
		Personal Protective Equipment
		Coveralls and gowns
		Head covering
		• Gloves
		Protective eyewear
		Respiratory protective equipment
		Shoe covers
	Details of the energy conservation measures	The major power consumption for the facility is from Air conditioning and fans in Air handling units. These units
5	proposed	are equipped with VFDs to ensure the power consumption is low and is proportional to actual use. The lighting for
pr		the facility will be on LED and part load will be from Solar panel & capacitors. The boiler selection ensures that the

		Diesel flow is regulated as per the required steam generation and no fuel is consumed in excess than required. All							
		the pumps handling the chilled water, Hot water, Colling water are equipped with VFD for lowered pow							
		consumpti	consumption. As part of the design, Solar panels will be installed to generate the power and is diverted for ligh						
		and other	and other applications.						
		Carbon Sequestration:							
		Omexa, ii	n its commitment to	environmental sustainability, h	as committed to develop	of a greenbelt spanning			
		5011.40 so	quare meters. This gree	enbelt is composed of a variety	of native tree species that c	ontribute significantly to			
				ating the impact of CO ₂ emission	•				
				pelt and the environmental benef		опрососы томичист п			
			_		_	writed note of 200/ view			
	Carbon dioxide reduction and sequestration			lt of 5011.40 sq.m with the spec	ined tree species, with a sui	rvivai rate of 80% viz:			
						1			
		S.No	Scientific Name	Common Name	No of Trees	Yearwise			
6	technologies including GHG emissions and	S.No	Scientific Name Pongamia pinnata	Common Name Pungai	No of Trees 300	Yearwise 1 st Year			
6		1 2	.			1 st Year			
6	technologies including GHG emissions and	1	Pongamia pinnata	Pungai	300				
6	technologies including GHG emissions and	1 2	Pongamia pinnata Thespesia populnea	Pungai Poovarasu	300 300	1 st Year 2 nd Year			
6	technologies including GHG emissions and	1 2 3	Pongamia pinnata Thespesia populnea Albizis lebback	Pungai Poovarasu Vaagai Sarakondai	300 300 150	1 st Year			
6	technologies including GHG emissions and	1 2 3 4	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula	Pungai Poovarasu Vaagai Sarakondai Poo marudhu	300 300 150 150	1 st Year 2 nd Year			
6	technologies including GHG emissions and	1 2 3 4 5	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specio	Pungai Poovarasu Vaagai Sarakondai Poo marudhu	300 300 150 150 150	1 st Year 2 nd Year			
6	technologies including GHG emissions and	1 2 3 4 5 6	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specia	Pungai Poovarasu Vaagai Sarakondai Poo marudhu ium Vengai	300 300 150 150 150 150	1 st Year 2 nd Year 3 rd Year			
6	technologies including GHG emissions and	1 2 3 4 5 6 7	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specio Pterocarpus Marsup Aegle Marmelos	Pungai Poovarasu Vaagai Sarakondai Poo marudhu ium Vengai Vilvam Iluppai	300 300 150 150 150 150	1 st Year 2 nd Year 3 rd Year			
6	technologies including GHG emissions and	1 2 3 4 5 6 7 8	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specia Pterocarpus Marsup Aegle Marmelos Madhuca longifolia	Pungai Poovarasu Vaagai Sarakondai Poo marudhu ium Vengai Vilvam Iluppai	300 300 150 150 150 150 150 153 1503	1 st Year 2 nd Year 3 rd Year 4 th Year			
6	technologies including GHG emissions and	1 2 3 4 5 6 7 8	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specia Pterocarpus Marsup Aegle Marmelos Madhuca longifolia	Pungai Poovarasu Vaagai Sarakondai Poo marudhu vium Vengai Vilvam Iluppai	300 300 150 150 150 150 150 153 1503	1 st Year 2 nd Year 3 rd Year 4 th Year			
7	technologies including GHG emissions and risk reduction to be adopted	1 2 3 4 5 6 7 8	Pongamia pinnata Thespesia populnea Albizis lebback Cassia fistula Lagestroemia Specia Pterocarpus Marsup Aegle Marmelos Madhuca longifolia	Pungai Poovarasu Vaagai Sarakondai Poo marudhu ium Vengai Vilvam Iluppai Iluppai on and sequestration technologie	300 300 150 150 150 150 150 153 1503	1 st Year 2 nd Year 3 rd Year 4 th Year			



		1	General Solid Waste		-	e sludge from the ETP and other solid waste shall be sent for Incineration to an approved	
			Chemical Liquid Waste	I Treated effluent will meet TNPCR norms and will be used for landscani			
			Biological Solid Waste	_	enerated in the fac d agency for incine	cility will be autoclaved and handed over to a ration.	
			Biological Liquid Waste	Biological liquid waste is routed to a bio-kill tank where it is heated to 121°C to ensure there are no live organisms. This inactivated waste is then sent to the ETP for further treatment. Treated effluent will meet TNPCB norms and will be used for landscaping/ greenbelt development / toilet flushing etc. Zero discharge facility.			
		5	Hazardous Waste	Used oil, grease et	c to be handed ove	e/generate any hazardous chemical or waste. r to TNPCB authorizedVendors TNPCB authorizedVendors for reprocessing	
			•		•	with facilities like bed and O ₂ Generator. There	
		will be a generation of biomedical waste and same will be disposed as mentioned below:					
8	Storage and disposal of biomedical waste to be studied.	Sl.No	Waste Schedule	Waste type	Quanity (kg/month)	Method of Disposal	
		1	Yellow	Solid waste	4.34	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for Incineration	
		2	Red	Contaminated wastes	3.1	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for Sterilization	



		3	White	waste sharps including metals	0.186	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for shredding & disposal	
		4	Blue	Glassware	1.24	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for disinfection & recycling	
		Usage of N	New Technology:	Omexa Formulary P	vt Ltd proposes to	manufacture monoclonal antibodies/therapeutic	
		proteins in	a cost effective, n	nore efficient path wh	nich will ultimately	reduce the generation of waste. Manufacturing	
	New technologies and innovative	process inv	volves various uni	t operations and prod	cesses. For the pro	posed products, currently we are implementing	
9	C	the Single	Use technology, w	which will reduce the	e 70% of water con	sumption compared to the other Stainless steel	
	approaches adopted for sustainable production.	technology	, unit will adopt tl	ne latest and best tec	hnology available	so far in the market. Moreover, the unit is very	
	production.	concerned and conscious about the product quality and equally about the environmental protection and resource					
		conservation. The company will upgrade the technology as per requirement from time to time with the best as per					
		the require	ment.				
		• Sta	ack height of 30 m	is proposed for boile	er.		
		• Stack height of 30 m is proposed for DG.					
	Air emission control technologies proposed.	There are no process emissions from the proposed manufacturing facility.					
10		Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.					
		Ambient air quality monitoring will be carried out regularly at selected locations in order to check an					
		compare the predicted concentrations with the measured concentrations. NAAQS exceedance if any may be					
		checked thoroughly and adequacy/Performance of Air Pollution Control measures shall be reviewed.					
		• Ac	lequate Greenbelt	width will be provide	ed.		
			•	•		rity is reduced largely (70%). The wastewater is	
11	Water use efficiency in the bioprocess. As we are using Single use bioreactors, the water for cleaning activity is reduced largely (70%). The wastewater treated in ETP and reused for Utility generation and green belt development.						

		Water usage will be minimized by the selected methodology. It is a 'Zero' discharge method and no waste water
		will be sent to outside the project premises
12	Stability of the drugs and impact on air, water and other adsorption surfaces.	The stability of the drugs (Stability studies) will be studied for 24- 36 months in a closed container at different temperatures. The Drugs (protein) are very sensitive to the outside environment and not exposed to the outside environment and there is no impact on air, water and other adsorption surfaces.
13	Study report on the economic impact assessment covering water, electricity, waste and labour.	Study report on the economic impact assessment covering water, electricity, waste and labour will be detailed in Final EIA report.
		Washing strategy and safety protocol:
14	Washing strategy for the machinery and safety protocols to be adopted. Plastic usage reduction strategy	The Single Use Bioreactors are used for Only One time. After the usage the Single use bioreactor bags are
14		sanitized, disposed (Solid Waste) and sent outside for incineration. (3 rd party approved by TNPCB).
		 Sanitized solution from the Single used bioreactor sent to ETP for Further treatment.
		According to the Tamil Nadu Government Order (Ms) No.84 Environment and Forests (EC.2) department dated
		25.06.2018 regarding ban on one time use and throw away plastics irrespective of thickness with effect from
		01.01.2019 under Environment (Protection) Act, 1986. Omexa will follow the mitigation/action plan given below:
		Action Plan:
		Omexa will comply the plastic waste with the following measures:
15		Not to use/manufacture 'Single Use Plastic' within the premises.
		To support and promote use of eco alternatives.
		Create plastic free industrial campuses & canteens.
		To support the District Administration with CSR funds to stop plastic pollution.
		Omexa will strict the use of plastic item except few plastics used for the following purpose:-
		a) The plastic bags which constitute of form an integral part of packaging in which goods are sealed



		prior to use at manufacturing/processing units.					
		Carry bags made from compostable plastics bearing a label "compostable" and conforming to the Indian Standard:					
		IS or ISO 17088:2008 titled as specifications for "compostable plastics"					
		Usage of New Technology: Omexa Formulary Pvt Ltd proposes to manufacture monoclonal antibodies/therapeutic					
		proteins in a cost effective, more efficient path which will ultimately reduce the generation of waste. Manufacturing					
		process involves various unit operations and processes. For the proposed products, currently we are implementing					
16	Over all new innovative technologies to be	the Single Use technology, which will reduce 70% of water consumption compared to the other Stainless steel					
	adopted for production process	technology, unit will adopt the latest and best technology available so far in the market. Moreover, the unit is very					
		concerned and conscious about the product quality and equally about the environmental protection and resource					
		conservation. The company will upgrade the technology as per requirement from time to time with the best as per					
		the requirement.					
		➤ There is no wetland within 15km radius.					
		➤ Nearest water bodies – Pelakuppam Lake ~0.99 km, ESE					
		Safe guards to sensitive place:					
17	Safe guards to sensitive wetland, lakes,	1. ZLD will be maintained and there will be no outfall from the project site. So it will not reach any water					
1 /	waterbodies and the project site	bodies					
		2. Online monitoring system will be provided to monitor the flow.					
		3. Storm water from common area will be send to TANSIDCO drain and before sending, it will be check for					
		any pollutant.					
	Shala an afeta mata la tamanata	Safety protocols to prevent pollution:					
10	Study on safety protocols to prevent	For Air:					
18	pollution threats to villages, habitations near	Stack height of 30 m is proposed for boiler.					
	project site	Stack height of 30 m is proposed for DG.					
		Stack height of 30 in is proposed for Do.					



- There are no process emissions from the proposed manufacturing facility.
- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.

Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. NAAQS exceedance if any may be checked thoroughly and adequacy/Performance of Air Pollution Control measures shall be reviewed

For waste water:

Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.



The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- Chemical dosing system
- ightharpoonup Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste.

As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.

> Online monitoring System: All pollution generating stream will be connected to server of OCMS, TNPCB. So it will be continuously monitored.

For Solid & Hazardous waste:

- Municipal Solid Wastes generated will be segregated to organic and inorganic wastes. The organic wastes (33 kg/day) will be disposed to TANSIDCO Bins and inorganic waste (21.6 kg/day) will sell to TNPCB authorized vendors
- Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant.
- ➤ Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental



		Clearance f	from SEIAA, Tamil Nadu.	
		Impact on Ene	rgy requirement:	
		The environmen	ntal problems directly related to energ	y production and consumption includes air pollution, water
		pollution, and	solid waste disposal. The emission of	f air pollutants from fossil fuel combustion and Vehicular
		Movement is the	e major cause of air pollution	
		Source of Energ	gy Requirements are:	
		> Power s	supply from TANGEDCO (either from	Thermal or hydro power).
		➤ Fuel (H	ISD) for DG sets & Boiler	
19	Impacts on Energy requirement.	Vehicu	lar operation.	
		Due to consump	otion of more energy from Fossil Fuel le	ead to increase in greenhouse gas emission and cause negative
		impact by dama	ging the environmental conditions.	
		Mitigation Mea	asures:	
		• 100% r	enewable energy by 2030 and avoid use	e of fossil fuel such as HSD in future.
		➤ We are	proposed to install Solar panel on roof	top and obtain 100 KVA through Solar energy.
		Remain	ning 775 kVA will be sourced from re	newable green energy vendors who are authorized by from
		TNEB	and Agreement will be made them after	all statutory Approvals.
20	Impacts on living System (air, water, soil &			
20	microorganism)	Parameters	Impact on Living System	Mitigation Measures
	·		1	



Air	Uncontrolled emission from the proposed project may lead to negative impact on the farm such as infertility of plant growth	 Stack height of 30 m is proposed for boiler. Stack height of 30 m is proposed for DG. There are no process emissions from the proposed manufacturing facility. Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent. Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. NAAQS exceedance if any may be checked thoroughly and adequacy/Performance of Air Pollution Control measures shall be reviewed. Adequate Greenbelt width will be provided.
Water	Untreated wastewater if discharged into nearby surface water may affect the surface water and/or if disposed off on land without treatment may pollute the ground and surface water	Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented Proposed Kill Tank Systems:

➤ Transfer pumps – 1 working + 1 standby The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron

Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility
Draft EIA report

H/01/2024/CON/065 RP003 - R2

unsanitary conditions including fly infestation and odors as well as unsightly conditions. Spillage of waste oil from the D.G sets may also have an impact on soil quality unsanitary conditions including fly infestation and odors as well as unsightly conditions. Spillage of waste oil from the D.G sets may also have an impact on soil quality approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated through dedicated STP (6 KLD) and followed by RO and MEE. RO
--

Micro organism Discharge of untreated sewage, effluent and solid waste will have adverse impact on the land. It will damage the Life cycle of Micro organism permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

➤ 1 No. Collection tank





generating stream will be connected to server of OCMS, TNPCB. So it will be continuously

• Municipal Solid Wastes generated will be

monitored.

Solid & Hazardous waste:

		Items	Impact on terrestrial& aquatic within and surrounding areas	segregated to organic and inorganic wastes. The organic wastes (33 kg/day) will be disposed to TANSIDCO Bins and inorganic waste (21.6 kg/day) will sell to TNPCB authorized vendors • Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant. Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental Clearance from SEIAA, Tamil Nadu. Mitigation Measures
21	Impacts on terrestrial & aquatic habitats within and surrounding areas.	Water	Untreated wastewater if discharged into nearby surface water may affect the surface water and/or if disposed off on land without treatment may pollute the ground and surface water	Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented Proposed Kill Tank Systems: Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a



safe manner through Chemical inactivation method

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The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- > Chemical dosing system
- ightharpoonup Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-

	Capital Investment
Environmental Management Plan Bu	ıdget (tentative):
	So it will be continuously monitored.
	 Online monitoring System: All pollution generating stream will be connected to server of OCMS, TNPCB.
	as a regular process liquid waste.
	secondary treatment to the centralized effluent treatment
	which is free from biological contamination leads to
	pump recirculation system. Post treatment, the liquid
	to the tank system to treat the liquid with agitation and
	waste. As per the design, required residence time is given
	tank for inactivating the biological load in the liquid
	concentration) from a dosing system is transferred to the
	from collection tank, chemical dosing(NaOH of specified
	0.2 micron filter. Once the required liquid waste is transferred to this tank
	agitator, pumping system and hydrophobic sterile grade
	steel tank fitted with required instrumentation, nozzles,

As per the MoEF& CC office memorandum
F.No.22-65/2017-IA.III dated: 30.09.2020
and 20.10.2020 the proponent shall furnish
the detailed EMP mentioning all the
mitigation strategy as committed in the
action plan.

S. No	Particulars	Capital Investment (Rs in lakhs) Proposed	Recurring Cost per Annum (Rs in Lakhs)						
Environ	Environment Management Plan								
Water P	Water Pollution Control								
1	ETP	350	20						
2	MEE/ATFD and RO	330	20						
3	STP	8.5	2						
Air Poll	Air Pollution Control								
4	DG & Boiler Stack/ Wet scrubber	60	3						

3				
3				
3				
2				
5				
2.6				
0.2				
42.2				
omply the IGBC Standard and				
%				
23.24				
It is sufficient to handle the parking space for both Visitor and Workers. Layout plan showing the parking and traffic				
wage generated of approx. 4.6				
KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment				
]				



effluent/sewage outside the premises.

followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

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- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- ➤ Chemical dosing system
- ightharpoonup Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.



			e monitoring System: All p be continuously monitored.	ollution generating stream	n will be connected to server	r of OCMS, TNPCB. So	
26	Details of disaster management and disaster mitigation standards and evacuation protocols to avoid calamities	Details of disaster management and disaster mitigation standards and evacuation protocols to avoid calamities is given in Annexure-7 .					
		Action tal	ken for reduction of greenh	ouse gas emissions:			
		Omexa, ir	its commitment to enviro	nmental sustainability, h	as committed to develop of	of a greenbelt spanning	
		•	quare meters. This greenbelt	•	•	0 1 0	
				•	•		
			questration, thus mitigating t	-		ie expected reduction in	
	The proponent shall provide the action	CO2 emiss	sions due to this greenbelt an	d the environmental benef	fits it provides.		
	taken for reduction of greenhouse gas	It proposed	d to develop a greenbelt of 50	11.40 sq.m with the spec	ified tree species, with a sur	vival rate of 80% viz:	
27	emissions to support the climatic action to make it safe and sustainable buildings/ and production unit.	S.No	Scientific Name	Common Name	No of Trees	Yearwise	
27		1	Pongamia pinnata	Pungai	300	1 st Year	
		2	Thespesia populnea	Poovarasu	300	2 nd Year	
		3	Albizis lebback	Vaagai	150	2 I cai	
		4	Cassia fistula	Sarakondai	150	3 rd Year	
		5	Lagestroemia Speciosa	Poo marudhu	150	3 Tear	
		6	Pterocarpus Marsupium	Vengai	150		
		7	Aegle Marmelos	Vilvam	150	4 th Year	
		8	Madhuca longifolia	Iluppai	153		
			Total		1503		
	The project proponent shall conduct					inalydina bath the same	
	detailed study of biodiversity flora & fauna	For a comprehensive understanding of the detailed biological study conducted in the area,including both the core					
28	including invasives /endemic vulnerable	and buffer zones, please refer to Section 3.10 of chapter-3 .					
	species.	No Rare and Endangered species were observed.					
29	The project proponent shall conduct	Microflor	a				



detailed soil investigation including microflora /fauna and likely impact on soil microorganisms

Microflora of soil is an integral part of soil Organic Matter. Soil bacteria and fungi are the start of the soil food web that supports other organisms. Bacteria constitute the most abundant groups of microorganisms in soil and the fungal population of soils constitutes a very heterogenous group of organisms. The bacterial genera Nocardia, Streptomyces and Micromonospora belong to order actinomycetes (aerobic and heterotrophic) are capable of degrading many complex organic substances and consequently play an important role in building soil fertility. The soil food web is interconnected matrix of invisible (fungi, bacteria, protozoa, nematodes) and visible (earthworms, beetles, arthopods) creatures that have a whole host of functions which creates a healthy ecosystem for plant growth. Various microorganisms were isolated from different soil samples collected. Thus the population of total bacteria in rhizosphere was reported to be highest as compared as to non-rhizosphere. The majority of the bacteria were reported to be Bacillus and Micrococcus Species. The total fungal population densities were also decreased in nonrhizosphere while the highest fungal population was observed in rhizosphere. The majority of fungi were reported to be Aspergillus niger, Aspergillus fumigatus, Penicillum species and Fusarium species. A number of diazotrophs bacteria have abilities to fix Nitrogen, some strains may relieve deficiencies where there is an inadequate application of N fertilizers. Many heterotrophic bacteria live in the soil and fix significant levels of Nitrogen including Azotobacter, Azospirillum and Rhizobium. N fixing microorganisms are globally noteworthy due to the fact as they provide only natural biological source of fixed N in the biosphere. The population count of Azotobacter was also more in rhizosphere than non-rhizosphere sites.

Methodology

Microbial analysis of soil:Earthworms

Microbial analysis of soil was done by Media preparation, Autoclaving, Serial Dilution, Inoculation of the media for Isolation of organisms, Colony counting and identification of the same.

Earthworms:

The soil core was dug out and the warms were hand sorted according to the method described by Lewis and Taylor



(1968). The worms were sorted according to their species and kept separately in polythene bags containing the mother soil taken from the collection site. Care was taken while digging so as to avoid damaging earthworms or killing them. The worms were preserved in 5-10% formalin solution following the method suggested by Julka (1993) in the laboratory.

Microscopic observation and Identification

The microscopic observations of diatom isolates were carried out at 40x and 100x magnification using compound microscope (Olympus). The diatom flora was identified based on the taxonomic criteria as described by Cramer, (1984), Jensen, (1985), Krammer and Lange-Bertalot, (1988) and Benson, (1998).

List of Earthworms

Order	Family	Genera	Species
	Octochaetidae	Dichogaster	Dichogasterbolaui
	Glossocolecida	Pontoscolex	Pontoscolexcorethrurus(Muler)
		Daviovans	Perionyx excavatus (Muler)
Haplotaxida	Megascolecide	Perionyx	Perionyx sansibaricus(Muler)
Паріотахіца		Lampito	Lampitomauritii (Knberg)
	Eudrilidae	Eudrilus	Eudriluseugenia(Kinbeg)
	Eudiffidae	Polypheretima	Polypheretimaelongata
	Octochaetidae	Octochaetonona	Octochaetona serrata (Gates)
Moniligastrida	Moniligastridae	Drawida	Drawidawillsi (Michaelsen)
wioiniigastiida	Womingasuldae	Drawiaa	Drawida lamella (Gates)

List of Diatoms



		No	Species	Family	Sub Family	
		1.	Calonies sp.			
		2.	Pinnularia sp.			
		3.	Gomphonema sp.	Naviculaceae		
		4.	Gyrosigma sp.	Naviculaceae		
		5.	Navicula sp.			
		6.	Stauroneis sp.		Naviculoideae	
		7.	Nitzchia sp.	Nitzschiaceae		
		8.	Cocconeis sp.	Acanthaceae		
		9.	Acanthes sp.	Acammaceae		
		10.	Fragillaria sp.			
		11.	Tabularia sp.	Fragillariaceae		
		12.	Synedra sp.	Tragiliariaceae		
		13.	Cyclotella sp.		Coscinodiscaceae	
		14.	Neidium sp.	Nediaceae	Cosemodiscaccae	
		Source:	Anand, N. 1998. Indian freshwater microalgae. Shiva offs	et Press, Dehradun,India.		
			on Livelihood due to the proposed project: action Phase Benefits			
	livelihoods of locals	a)Emplo	oyment Opportunities			
30		The major benefit due to the proposed project will be in the sphere of generating temporary employment for				
		substantial number of personnel. Around 20 no. of persons would be required during the construction ph				
		skilled & un-skilled personnel's will be required during this phase of the activity.				
		b) Com	munity Services			



		The industry shall suitably employ local people to the extent where ever possible. In addition, the project will					
		develop necessary infrastructure like transportation, canteen, water supply, sewerage, medical facility, etc. for					
		catering to the needs of the project personnel. The local people will be indirectly benefited by these developments.					
		2 Operational Phase Benefits					
		a) Infrastructural Facilities					
		The proposed site is equipped with sufficient infrastructural facilities including drinking water, toilets, sanitation					
		facilities, power, easily accessible approach roads, public transport, communication, etc. Hence some indirect					
		benefits to the public infrastructure is anticipated due to the proposed site. However, benefits due to CSR activities					
		may be realized if any CSR activities would be related with such facilities.					
		b) Direct or Indirect Employment Opportunities					
		During the operational phase, about 120 people shall be employed. Proposed project would add livelihood					
		oportunities in the study area which results in better scope for direct employment etc.					
		addition to the direct employment mentioned above, there will be indirect employment of local people in terms of					
		Logistics, Housekeeping, Horticulture, Water and Fuel supply, etc.					
		c) Community Welfare Measures					
		Various CSR activity as per company policy will be initiated in the surrounding villages as per below categories					
		Education					
		Health					
		Infrastructure development					
		Sports and Cultural activity					
31	The project proponent shall furnish List of trees available in the area	Nil within the site.					
32	The project proponent shall conduct studies	A comprehensive biological study was conducted, and the findings are presented in the Section 3.10of Chapter-					



	on invasive and alien species	3. This detailed study of invasive and alien species has been included in below					
		Invasive and alien species	Lantana came	ra			
		and the species	Prosopis juliflora.				
33	Examine possibilities of increasing open space and green belt area	As per the design stage, Adequate space was prov	rovided in layout plan for greenbelt .There is no open space.				
		Land use for the study Area (10 km radius):					
		Description	%	Sq.Km	Acres	Hec	
		Crop land	60.45	193.83	47896.36	19383	
land cover within 10km of proj lands, particularly to agriculture	Study to evaluate changes in land use and land cover within 10km of project area, wet	Fallow	18.03	57.80	14282.67	5780	
		Tanks / Lakes / Ponds	11.54	37.01	9145.36	3701	
		Plantation	3.86	12.39	3061.63	1239	
	lands, particularly to agriculture, plantation,	Rural	3.01	9.66	2387.03	966	
	streams, river, existing urban and rural infrastructure, nor geomorphology impact	Urban	1.46	4.68	1156.45	468	
	on the prevalent hydrogeology of the area	Salt affected land	0.99	3.18	785.79	318	
		Scrub land	0.33	1.06	261.93	106	
		River / Stream / Canals	0.23	0.74	182.86	74	
		Barren rocky	0.06	0.19	46.95	19	
		Mining	0.04	0.12	29.65	12	



Total	100.00	320.66	79236.69	32066	
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Geomorphology for the study Area (10 km radius):

The total Geographical area of the study area is 320.66 Sq.Km.

Geomorphology of the Study Area

S.No.	Description	%	sq.Km	Acr	Hec
1	Denudational Origin-Pediment-PediPlain Complex	88.23	282.91	69908.48	28291
2	Waterbodies	11.77	37.75	9328.21	3775
	Total	100.00	320.66	79236.69	32066

Hydrogeology of the PIA district:

Villupuram district is underlain by crystalline metamorphic complex in the western part of the district and sedimentary tract in eastern side (Plate-II). The thickness of sediments exceeds 600m near southern part of the district. Groundwater occurs under phreatic and semi-confined conditions in consolidated formations, which comprises weathered and fractured granites, gneisses and charnockites whereas in unconsolidated sedimentary rocks the groundwater occurs in phreatic, semi-confined conditions in Vanur sandstone, Kadapperi kuppam formation and Turuvai limestone. The district is having rocky outcrops in major part of Kallakurichi, Sankarapuram and Tirukoilur taluks. The weathering is highly erratic and the depth of abstraction structures is controlled by the intensity of weathering and fracturing. The depth of wells varies from 6.64 to 17m bgl and water levels in observation wells tapping shallow aquifers variedfrom 0.74 to 9.7 m bgl during pre monsoon (May 2006) and it varies from 0.7 to 4.45 mbgl during post monsoon (January 2007). During pre monsoon, the depth to water levels in the range of >2 to 5 m bgl in major part of the district, in the range of >5 -10 m bgl in western and southeastern parts of the district and



range of 0-2 m bgl were recorded in two isolated pockets (Plate –III). During post monsoon the depth to water levels range of >2 to 5 m bgl exists in major part of the district, range of 0 - 2 m bgl prevails in central and northeastern parts of the district and range of >5 - 10 m bgl were recorded in two isolated pockets in the southwestern and north western parts of the district (Plate –IV).

The depth to piezometric surface ranged from 2.8 to 11.25 m bgl during Pre monsoon and 0.5 to 6.35 m bgl during post monsoon. The ground water is being developed my means of dug wells, bore wells and tube wells. The diameter of the well is in the range of 7 to 10 m and depth of dug wells range from 15 to 18 m bgl depending on the weathered thickness and joints. The dug wells yield up to 11ps in summer months and few wells remains dry. The yield is adequate for irrigation for one or two crops in monsoon period. The yield of bore wells in favorable locations vary from <1 to 61ps. The valley fills, intersection of lineaments, particularly, in the western part along the foot hills of Kalrayan hills are reported to have potential pockets suitable for dug wells and bore wells. The area of contact between crystalline and sedimentary formations has variable yield prospects. The cretaceous formations are very compact and yield prospects are low. The dug wells of 6 m diameter and 10 m bgl depth in sandy tracts give about 3.51ps. The yield of tube wells in the sedimentary formation ranges from 2.4 to 371ps

Protocol there ensure are no environmental impact on educational institutions. the existing industries. hospitals, government buildings religious places and human habitations and other units within the TANSIDCO industrial park

Protocol to ensure No impact on Following:

- > Following are the important place near to the project Site
 - o Education Institutions: Sri Rajarajeswari Matric Hr Sec School !0.48 km (SE)
 - o Industries: Cheyyar SEZ Developers Private Limited ~0.41 km (SSE)
 - o Government building: Avaraipakkam Sub Registrar Office ~1.88 km (E)
 - $\circ\,$ Religious place: Shri Ragavendrar Temple $\sim 0.32~km$ (S)
 - o Human Habitation: Venmaniyattur ~1.16 km (N) (Population- 1350 Nos)

For Air emission: There are no process emissions from the proposed manufacturing facility. Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent. Ambient air quality monitoring will be carried out

35

regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. NAAQS exceedance if any may be checked thoroughly and adequacy/Performance of Air Pollution Control measures shall be reviewed.

For water emission: Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented

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The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby



		➤ Chemical dosing system
		➤ Transfer pumps – 1 working + 1 standby
		The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent
		mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.
		The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles,
		agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.
		Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified
		concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste.
		As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump
		recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary
		treatment to the centralized effluent treatment as a regular process liquid waste.
		All emission sources will be connected to OCMS, TNPCB to continuously monitor the emissions are within the
		limit or not.
	The cradle to gotz assessment on syrin	Detailed remort on another acceptance on a prince viels. I wonbilised viels including formulation and dusts and
36	vials, Lyophilised vials, includ	Detailed report on cradle to gotz assessment on syringes vials, Lyophilised vials, including formulation products and
	formulation products and drug subsystem	drug subsystem will be submitted in Final EIA report.
	ı	
S.	T. C.D.C.	1.
No	Term of References Comp	liance
	B. Standard ToR	

The executive summary of the proposed project is given as a separate chapter in this EIA report.



Executive Summary

Introduction

i. Details of the EIA Consultant includin NABET accreditation	M/s. Hubert Enviro Care Systems (P) Ltd., Chennai. (NABET Accredited vide Certificate No. NABET/ EIA/ 24-27/ RA0335 Valid up to 31/03/2027) M/s. Omexa Formulary Private Limited has proposed a new manufacturing unit for Monoclonal antibodies with capacity of							
	520 Kg TANSI propose	g/Annum & DCO Indu ed project fa	formulation pr astrial Park, Pel alls under schedu	oducts (Syringes & vials) with Capacity of lakuppam Village, Tindivanam Taluk, Villuule 5 (f) as per the EIA Notification, 2006 and be able to cater to the needs of customers from	1,64,000 Nos/Month at Plot N puram District and Tamil Nado Category 'B' With the implement various industry segments.	To. 27 & 28, u State. The		
				Monoclonal antibodies Product deta		7		
			Sl. No.	Description	Proposed			
ii. Information about the			1	No of Products	34			
project proponent			2	Quantity of product (kg/Annum)	520			
		1		Formulations product details		-		
		Sl. No.		Description	Proposed in Nos/Month			
		1	Prefilled Syri	nges	100000			
		2 Vials and Lyophilized vialis			64000			
				Total	164000			
	The pr	oject cost i	s expected to a	around Rs. 95.00 Crores (Annexure-16) and	l is a Green Field Project by firs	st generation		
	•	ū	•	er as a technocrat in the chemical & pharma In	, , , , , , , , , , , , , , , , , , ,	C		
	Import	ance of the	project:		_			
iii. Importance and benefits of	>	Omexa int	ends to manufac	cture the monoclonal antibodies to treat cancer	patients at an affordable cost and	d also export		
the project				ia. This will contribute to nation vision to be	-	•		
1 3		•		es local employment and skills set developmen		<i>6</i> 12		

> The products are developed in house generic bio pharmaceutical products through biotechnological processes.

Benefits of the Project:

- > The project is technically feasible and financially viable.
- > The overall financial liquidity and profitability parameters of the project appeared to be reasonable and satisfactory.
- ➤ We conclude the capital expenditure of the company as a viable option subject to the weakness and threats associated with a business venture.
- > The operation of plant has significant positive impact on the socio-economic environment of the area which helps for development of this area including further development of physical infrastructure facilities. In the interest of mineral development and improve the social conditions of the local habitants this project should be allowed after considering all the environment aspects.

3 **Project Description**

i. Cost of project and time of completion.

Cost of the project:

S.No	Description	Cost (Crores)
1	Land cost	4.00
2	Building	20.00
3	Plant & Machinery	42.00
4	ETP/STP/Utilities	20.00
5	Other Assets	9.00
Total	(Crores)	95

Timeline:

- Environmental Clearance from SEIAA, TN October 2024
- CTE from TNPCB November 2024



	Construction act	ivities – 01.12.2024	
	• Operation of the	unit - 01.11.2025	
	Production capacity of the	e company will be as follows:	
	1.Monoclonal products	(drug substances)	
	Sl.no	Product	Kg Per annum
	1	Pembrolizumab	100
	2	Denosumab	20
	3	Ustekinumab	20
	4	Bevacizumab	10
	5	Adalimumab	20
	6	Aflibercept	10
ii. Products with capacities for the	7	Apixaban	50
proposed project.	8	Trastuzumab	20
	9	Olaratumab	10
	10	Omalizumab	10
	11	Palivizumab	10
	12	Panitumumab	10
	13	Tocilizumab	10
	14	Trastuzumab emtansine	10
	15	Infliximab	10
	16	Eculizumab	10
	17	Etanercept	10

	Total	520
34	Tenecteplase	20
33	Somatropin	10
32	Pertuzumab	10
31	Cetuximab	10
30	Alirocumab	10
29	Alglucosidase alfa	10
28	Alemtuzumab	10
27	Agalsidase beta	10
26	Abciximab	10
25	Abatacept	10
24	Brodalumab	10
23	Inotuzumab ozogamicin	10
22	Sarilumab	10
21	Raxibacumab	10
20	Ramucirumab	10
19	Rituximab	10
18	Ziv-aflibercept	10

2.Formulation products (drug products)

Filling Format	Quantity (Numbers per Month)
Prefilled Syringes	1,00,000
Vials	40,000



		Lyophilise	d Vials			24,000			
iii. If expansion project, details of existing products with capacities and whether adequate land is available for expansion, reference of earlier EC if any.	Not ap	plicable, since it is a fr	esh project						
iv. Details of existing products and production, if any, along with present product/production details in tabular format, to verify the compliance of the EIA Notifications	Not ap	plicable, since it is a fr	esh project						
	Sl. No.	Raw Materials:	Approx Quantity per annum (In Kgs)	Type of Package	Source	Storage Temperat ure	State (Solid/Liqui d/Gas)	Chemic al properti es	Mode of transpo
v. List of raw materials required and	Mon	oclonal products (Drug	substances)- f	or EC produ	ucts				
their source along with mode of transportation.	1	Sodium chloride	1800	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	colourles s & Odourles s	Road
	2	Potassium Chloride	10	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourles s	Road
	3	Sodium phosphate	60	Bag /Drum	Domestic / Imported	20- 25 deg C	Power Solid	White & Odourles s	Road



	4	Potassium phosphate	10	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourles s	Road
	5	Citric acid	500	Bottle /Box	Domestic / Imported	20- 25 deg C	Small beads (crystal)	White & Odourles s	Road
	6	Sodium Citrate	1150	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourles s	Road
	7	Tris Buffer	2300	Bag /Drum	Domestic / Imported	20- 25 deg C	Liquid	Clear & Odourles s	Road
	8	Sodium Acetate	600	Bag /Drum	Domestic / Imported	20- 25 deg C	Crystallline (solid)	white	Road
	9	Sodium Hydroxide	1500	Bag /Drum	Domestic / Imported	20- 25 deg C	Pellets (solid)	White & Odourles s	Road
	10	Glucose	400	Bag /Drum	Domestic / Imported	20- 25 deg C	Solid	White & Odourles s	Road
	11	Sodium bicarbonate	200	Bag /Drum	Domestic / Imported	20- 25 deg C	Power Solid	White & Odourles s	Road
	12	Pluronic F68	100	Bag /Drum	Domestic / Imported	2- 8 deg C	Liquid	NA	Road
	13	Cell Culture Media	2200	Bag /Drum	Domestic / Imported	2- 8 deg C	Dry powder (solid)	NA	Road
	14	L-Glutamine	30	Bottle /Box	Domestic /	2- 8 deg C	NA	NA	Road



					Imported				
	15	Sorbitol	200	Bottle /Box	Domestic / Imported	20- 25 deg C	Solid	White & Odourles s	Road
	16	Ethanol	100	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Clear & Odourles s	Road
	17	Phosphoric Acid	60	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Clear	Road
	18	Acetic Acid	40	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Odourles s	Road
	19	Hydrochloric acid	150	Bottle /Box	Domestic / Imported	20- 25 deg C	Liquid	Light yellow & pungent	Road
		OF ()	44440						
		Total	11410	-	-	-	-	-	-
			11410 Ormulation p		g products) –		1	-	_
	1				1		1	Clear	Road
	1 2	F	ormulation p	Bottle	g products) – Domestic	- for Non EC 20- 25	products	Clear Odourles	
	2	Phosphoric Acid	Formulation p	Bottle /Box	g products) – Domestic / Imported Domestic /	20- 25 deg C	products Liquid	Clear	Road
vi. Other chemicals and materials	3	Phosphoric Acid Acetic Acid	60 2200	Bottle /Box Bottle /Box Bottle /Box	g products) – Domestic / Imported Domestic / Imported Domestic / Imported	20- 25 deg C 20- 25 deg C 20- 25 deg C	Liquid Liquid	Clear Odourles s Light yellow &	Road Road
vi. Other chemicals and materials required with quantities and	3 For U	Phosphoric Acid Acetic Acid Hydrochloric acid	60 2200 20L	Bottle /Box Bottle /Box Bottle /Box	g products) - Domestic / Imported Domestic / Imported Domestic / Imported	20- 25 deg C 20- 25 deg C 20- 25 deg C	Liquid Liquid	Clear Odourles s Light yellow &	Road Road
	3 For U 1. 2.	Phosphoric Acid Acetic Acid Hydrochloric acid	60 2200 20L ank (HSD) -1	Bottle /Box Bottle /Box Bottle /Box A 20 KL (Cap	g products) – Domestic / Imported Domestic / Imported Domestic / Imported	20- 25 deg C 20- 25 deg C 20- 25 deg C	Liquid Liquid	Clear Odourles s Light yellow &	Road Road



hazardous waste generation and	Stack	k Emission (pr	ocess &	utility) and	d Transp	ortation									
their management.				Eval	Stack Details					Emissions					
_	S. No	Source	Fuel Type	Fuel Quantit y (KL / Day)	No. of Stack	Heigh t (m)	Temp (°C)	Dia (m)	Exit Veloc ity (m/s)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)		
	1	DG-600 KVA	HSD	2.88	1	30	200	0.2	9.5	7.43E -03	6.93E -03	1.05E -01	2.26E -02		
	2	DG-600 KVA	HSD	2.00	1	30	200	0.2	9.5	7.43E -03	6.93E -03	1.05E -01	2.26E -02		
	3	Boiler 1.5 TPH	HSD	2.509	1	30	210	0.3	10	3.41E -03	4.70E -04	6.62E -02	1.66E -02		
		Transportations													
	S.										sions				
	No	Type	of Vehic	le	e No. of Vehicle					PM	SO ₂	NO _x	CO		
										(g/s) 3.13E	(g/s)	(g/s) 6.25E	(g/s) 3.47E		
	1			20					-05	_	-04	-03			
	_		4				4			5.00E		1.39E	8.22E		
	2		4w		4					-05	-	-03	-03		
	3		Bus		2					6.94E		3.19E	2.78E		
		3 Dus								-06	-	-04	-03		
	4	4 Truck			1				3.47E -06		1.60E	1.39E -03			
										1 116	_	-04	1 113		

Total

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Process emission: There are no process emissions from the proposed manufacturing facility since its is biological process (Mammalian Cell culture Process).

Control measures:

- > Stack height of 30 m is proposed for boiler.
- > Stack height of 30 m is proposed for DG.



-02

-02

-01

-02

- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.
- Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. NAAQS exceedance if any may be checked thoroughly and adequacy/Performance of Air Pollution Control measures shall be reviewed.
- > Adequate Greenbelt width will be provided.

2. Effluent & Sewage and their management:

S. No	Description Proposed Quantity (KLD)		Final Disposal Points				
Constr	uction Phase	1					
1	Sayyaga	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will				
1	Sewage	1.22	be reused for greenbelt development				
Operat	ion Phase		1				
1	Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.				
2	Sewage	4.6	Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt.				

Hazardous waste and their management:

S.N o	Description of Waste	Category as per HWM Rules 2016	QTY/Annu m	Storage method	Method of disposal
1	Used /Spent Oil	5.1	1 KL	All the	Will be collected and



				generated	disposed through
				Hazardous	TNPCB Authorised
				waste will be	recycler
				stored on	Will be collected and
2	Waste or residues containing	5.2	1 Ton	Concrete	disposed through
	oil	3.2	1 1011	platform in	TNPCB Authorized
				leak Proof	TSDF
				Barrels in	Will be collected and
3	Discorded Containers/Page	33.2	4 Ton	designated	disposed through
	Discarded Containers/Bags	33.2	4 1011	areas	TNPCB Authorised
					recycler
4	MEE salt	37.3	16.5 Ton		
	WILL Sait	37.3	(50 kg/day)		
5	ETP Sludge	35.3	3.3 Ton		Will be collected and
	L11 Studge	33.3	(10 kg/day)		disposed through
	Off Specification Products				TNPCB Authorized
6	(Doesn't Met by	28.3	2 Ton		TSDF
	Specifications or standards)				
7	Expiry Products/Chemicals	28.5	1.5 Ton		

Authorization for hazardous waste management from TNPCB will be obtained after obtaining EC.

Other Solid waste:

Item Name	Proposed (MT/year)	Mode of disposal
Cartons, Paper and stationary scrap	0.5	To scrap vendors

Biomedical waste:

Sl.No	Waste Schedule	Waste type	Quanity (kg/month)	Method of Disposal
-------	-------------------	------------	-----------------------	--------------------



1	Yellow	Solid waste	4.34	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for Incineration
2	Red	Contaminated wastes	3.1	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for Sterilization
3	White	waste sharps including metals	0.186	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for shredding & disposal
4	Blue	Glassware	1.24	Will be sent to TNPCB Authorized common Biomedical waste Management Facility for disinfection & recycling

Water requirement:

Construction phase: About 40 KLD of water (for labour 1.4 KLD & Construction activities 38.6 KLD) will be required during the peak construction phase and it will be sourced through Private tankers.

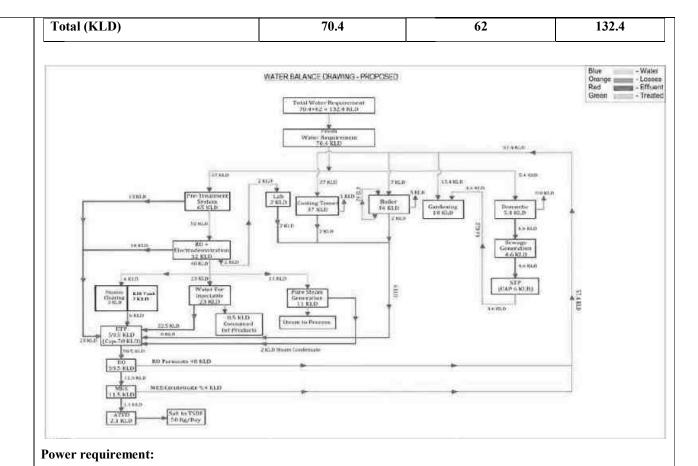
Operation phase: Total water requirement for the project is 132.4 KLD. Fresh water is 70.4 KLD and Recycled water is 62 KLD. Source of fresh water is TANSIDCO. Break up of water requirement for the proposed project is given in below table:

viii. Requirement of water, power, with source of supply, status of approval, water balance diagram, man-power requirement (regular and contract)

Water requirement for the proposed project

Description	Fresh water (KLD)	Recycle water(KLD)	Total Water(KLD)
Pre-Treatment System for process & Lab	65	0	65
Cooling tower	0	37	37
Boiler	0	7	7
Greenbelt	0	18	18
Domestic	5.4	0	5.4





Quantity

1745.64

Details

Power Requirement (kVA)



Source

TANGEDCO

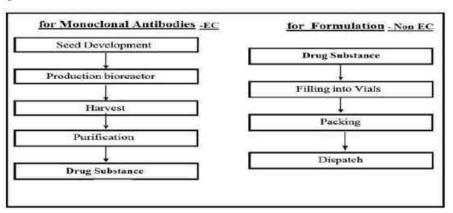
Back-up (kVA)	2x600*	DGSets
Boiler (kg/hr)	1x1500	For steam
Fuel Requirement:		
HSD (KLD) for Boiler	2.509	Local Supply such as HP, BHP &
HSD for DG set (KL/Hr)	0.12	IOC

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Manpower requirement

Type of Employee	No's of Employee
Construction Phase (Temporary Contract)	30
Employees Permanent (Operation Phase)	120

Process Flow Diagram



Process flow sheet for each products is detailed in Section 2.6.1 of Chapter – 2.



		Power requirement:		
		Details	Quantity	Source
		PowerRequirement (kVA)	1745.64	TANGEDCO
i	ix. Details of boiler/gensets (including	Back-up (kVA)	2x600*	DGSets
	stacks/ exhausts) and fuels to be	Boiler (kg/hr)	1x1500	For steam
	used	Fuel Requirement:		
		HSD (KLD) for Boiler	2.509	Local Supply such as HP, BHP &
		HSD for DG set (KL/Hr)	0.12	IOC
		Note: *In ToR application, DG sets capacity - 2x35	50 kVA.	
		Mammalian Cell culture Process		
		Mammalian Expression system is Chinese Hamst	er Ovary (CHO) cells	and theprocess time considered is 20
		days/batch. In the manufacturing of biopharmaceutic	als from mammalian cel	lls consists two stages those are upstream
		and downstream processes.		
2	x. Process description along with	a. Upstream Process		
	major equipments and	The inoculum generation is initiated with thawing of	of a vial from a cell bar	nk. The cells from the vial are expanded
	machineries. Process flow sheet	using shake flasks and seed bioreactors to obtain the	desired amount of inoc	ulum for starting a production bioreactor.
	(quantative) from raw material to	The mode of running the bioreactor is fed batch or	perfusion. The cells are	e allowed to grow for few days in batch
	products to be provided.	mode after which feeds of nutrients like glucose, am	ino acids, vitamins and	salts are fed in the bioreactor on different
		days. Thebioreactor is harvested at the end of the ferr	mentation and taken for o	downstream.
		b. Downstream Process		
		Cell clarification: Continuous centrifugation followers	ed by depth filtration is t	o separate the cells from the fermentation
		media, the supernatant of which will be clarified by d	lepth filtration.	



Capture by affinity chromatography: Target protein is among thousands of impurities will be specially retained over the affinity resin leaving impurities as unbound.

Virus inactivation: Inactivation of different viruses if any will be done in a sterilebag at a lower pH and probably at a controlled temperature between 2 and 25 degC.

Purification by ion exchange chromatography (IEC): The related impurities will be the next level of contaminants that needs to be separated from the target protein, ion exchange chromatography does the job be at an-ion or cat-ion exchange chromatography.

Virus removal by Nano-filtration: It is to remove the all forms of virus so there are no viral loads basically in the active pharmaceutical intermediate.

Concentration/ Buffer exchange by tangential flow filtration (TFF): It is critical to bring in the product to the required pre/formulation buffer which ensures the stability.

Final sterile filtration: This filtration is required to claim that the product is sterile and is qualified for fill finish requirement. Samples are collected at different stages during the batch and sent for analytical testing.

After final sterile filtration, the product will be sent to formulation unit.

a. List of proposed utilities within the facility

S.No	Description	Working	Standby	Total	Capacity
1	Compressor	2	0	2	2*200 CFM
2	Chillers	2	1	3	600 TR (3*200 TR)
3	Cooling Tower	1	0	1	750 TR
4	Gas bank(O ₂ , CO ₂ & N ₂)	15	15	30	15+15 cylinder
5	Boiler	1	0	1	1x1500 kg/hr
6	HSD yard (underground)	1	0	1	20 KL Capacity

List of Equipment in proposed manufacturing process is given in Table 2-15 & Table 2-16 of chapter-2.



xi. Hazard identification and details of

proposed safety systems.

A detailed Hazard Identification and Risk Assessment (HIRA) study has been conducted for the facility and contours for different scenarios have been prepared using PHAST software and the analysis along with HIRA matrix is given in the report, which is attached as **Annexure-7**.

The scope of the study mainly involves:

- ➤ Identifications of Hazards
- > Consequence modelling of:
 - o Dispersion of Vapour cloud
 - o Flash fire
 - Pool fire
 - Jet fire
- > Impact limits identifications
- > Contour mapping of the risk on the layouts.
- Mitigating measures for handling and storage to reduce impacts & prevent incidents.

The following data were collected to envisage scenarios:

- > Chemical storage conditions (Operating temperature, pressure)
- > Capacity of the storage containers.
- > Atmospheric conditions viz. Temperature, Humidity and Wind direction

In addition to this, a detailed HIRA study has also been conducted and major hazards & recommendations, especially for the construction phase, are given in the report.

A detailed Disaster Management Plan has also been prepared for the following emergencies:

- > Fire
- > Explosion
- > Toxic gas release

- Large Spills or release of toxic/corrosive/flammable chemicals
- Natural Calamities like Earthquake, Flood, cyclone etc.

The plan identifies the roles and responsibilities of key personnel along with details of procedures to be followed and communication system during emergencies.

The following pro-active steps have been taken to reduce the overall risk rating.

- > Risk Assessment: A detailed risk assessment has been conducted and the report is attached as **Annexure 7**.
- > Training: Proper periodical trainings are given to the employees and management for various topics, as per the nature of work, in which they are involved.
- Record Keeping: Proper Records will be kept, for any incidents, including near misses.
- Medical Check-up: Periodical health heck up is being conducted for the employees
- ➤ PPEs: Provision of proper PPEs to the employees and visitors.

The following recommendations are given in the report to improve the safety system.

- > The storage of the critical chemicals will be kept minimum and optimum to run the Plant smoothly.
- Even though most of the chemicals are stored in drums/barrels, the storage area will be kept effective to contain the material within and to clear the area immediately in case of any spillage in a safer way.
- > The firefighting equipment will be kept ready and tested periodically to confirm their efficiency.
- More employees will be trained to do the needful during emergencies.
- As the contours fall in surrounding area, the same information will be communicated to the communities nearby.
- Mock drills will be conducted with the cooperation of neighbourhood communities.
- Periodical training will be conducted by experts and the above group will also be included as the target audience
- > It is suggested that any person within the affected zone of (4 kW/m2) without proper PPE should

- immediately leave the area and firefighting shall be done with proper PPEs by fire and safety/authorized personnel only.
- > It is suggested to consider fire detectors (with alarm/beacon) in such areas for earliest detection and response by the operator in the control room and those in the field.
- ➤ Ensure active fire protection measures as per requirement mentioned under applicable standards/guidelines.
- All the project premises shall be monitored by surveillance cameras.
- > In order to prevent secondary incident arising from any failure scenario, it is recommended that sprinklers and other protective devices provided in the storage and processing area to be regularly checked to ensure that they are functional.
- > Emergency security / evacuation drills are organized at organization level to ensure preparation of the personnel's /workers working in facility for handling any extreme situation.
- Ensure active and passive fire protection measures (as applicable) are available for facility as per the design/safety study recommendations at all desired locations.
- > It is suggested to provide sign boards marking emergency/safe roads to be taken during any exigencies.
- > It is suggested to carry out preventive maintenance of critical equipment/vessels/tanks etc. time to time as per company practice to reduce the chances of their failure.
- ➤ The storage of raw materials shall strictly be in compliance with their respective MSDS.
- > Periodic training and refresher courses should be provided to employees addressing all the hazards prevailing in the process.
- ➤ Work Permit System should be strictly enforced.
- > MSDS shall be made easily available and the safety instructions to be communicated to all employees.
- > Safety Procedures and Do's and Don'ts should be prepared and displayed in handling and storage area.



- Mock Drills should be carried out regularly basis.
- > Occupational health surveillance programmes are to be done six monthly & their documentation should be maintained
- Periodic health check-up employees to be conducted and recorded.
- > Provision and use of proper PPEs to be confirmed.
- > The storage area will be kept effective to contain the material within and to clear the area immediately in case of any spillage in a safer way.
- > Periodic inspection of Pipelines and painting to be done to avoid corrosion and subsequent leak.
- > The firefighting equipment will be kept ready and tested periodically to confirm their efficiency.
- > Periodical training will be conducted by experts and the neighborhood employees will also be included as the target audience.
- > Operator training and retraining should be a continuous effort and Mock Drills should be carried out regularly on identified scenarios.
- > Smoking and carrying smoking accessories are to be strictly prohibited.
- Proper Ventilation with adequate air changes shall be provided in the storage area of all adhesives and especially those adhesives which release harmful fumes when first applied.
- > Static protection and integrity of explosion proof equipment should be ensured through regular inspection. Every electrical equipment and lighting features should meet explosion proof requirement, in classified area.
- > The EHS team shall be trained on industrial hygiene and sampling/ testing techniques.
- > Dispose of any hazardous waste in a closed metal container. Even the spilled flammable and combustible materials should be properly disposed of from the site in order to prevent fire hazards.
- > Ensure that workers are wearing proper PPE's.



- i. Expansion/modernization proposals:
- 1. Copy of all the Environmental Clearance(s) including Amendments thereto obtained for the project from MOEF/SEIAA shall be attached as an Annexure. A certified copy of the latest Monitoring Report of the Regional Office of the Ministry of Environment and Forests as per circular dated 30th May, 2012 on the status of compliance of conditions stipulated in all the existing environmental clearances including Amendments shall be provided. in addition. status of compliance of Consent to Operate for the ongoing Iexisting operation of the project from SPCB shall be attached with the EIA-EMP report.

2. In case the existing project has not obtained environmental clearance, reasons for not taking EC

Not applicable. Since it is a greenfield project

Not applicable. Since it is a greenfield project



under the provisions of the EIA Notification 1994 and/or EIA Notification 2006 shall be provided. Copies of Consent to Establish. No Objection Certificate and Consent to Operate (in case of units operating prior to EIA Notification 2006, CTE and CTO of Fy 2005-2006) obtained from the SPCB shall be submitted. Further, compliance report to the conditions of consents from the SPCB shall be submitted.

4 Site Details

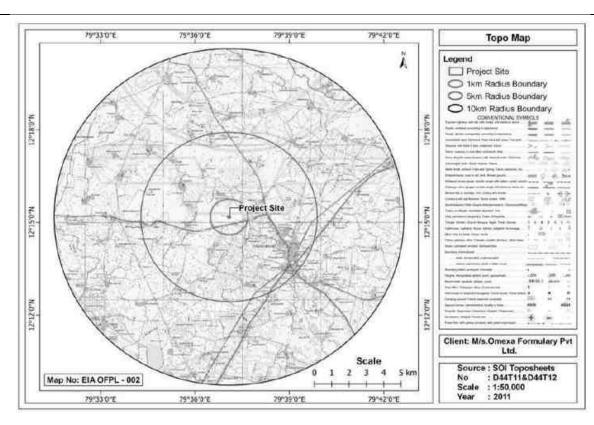
 Location of the project site covering village, taluks/tehsil, district and state, justification for selecting the site. Whether other sites were considered. M/s. Omexa selected the Industrial plot at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. No Alternative site was selected due to the following:

Specific Site Selection Crietria of the Unit have been given below:

- 1. It is allocated within Notified TANSIDCO industrial Park.
- 2. Site is well connected by road (~0.37km, S), railways (~4.31 Km, ESE) and Airway (~37.48 km, SSE)
- 3. Sufficient land is available within the TANSIDCO IP.
- $4.\,100\%$ assurance of water & power supply by TANSIDCO.



ii. A Topo sheet of study area of radius of 10km and site location on 1:50000/1:25000 scale on an A3/A2 sheet (including all ecosensitive areas and environmentally sensitive places)



Topomap of the study area (1:50000 scale)

No notified Eco-sensitive areas and environmentally sensitive places within 10 km radius from the project boundary. Topo sheet of study area of radius of 10 km and site location on 1:50000/1:25000 scales on an A3/A2 sheet including all eco-sensitive areas and environmentally sensitive places are given in **Chapter-3**, **Section 3.3**.

iii. Details w.r.t option analysis for

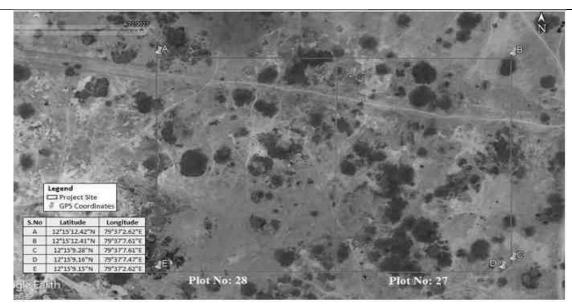
No Alternative site was selected since the Omexa selected the plot at Plot No. 27 & 28, TANSIDCO Industrial Park,



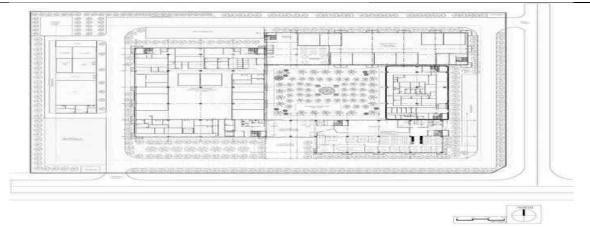
selection of site.	Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State					
	Specific Site Selection Crietria of the Unit have been given below:					
	1. It is allocated within Notified TANSIDCO industrial Park.					
	2. Site is well connected by road (~0.37km, S), railways (~4.31 Km, ESE) and Airway (~37.48 km,SSE).					
	3. Sufficient land is available within the TANSIDCO IP.					
	4. 100% assurance of water & power supply by TANSIDCO.					
	S.No	Latitude	Longitude			
	A	12°15'12.42"N	79°37'2.62"E			
iv. Co-ordinates (latitude-longitude) of	В	12°15'12.41"N	79°37'7.61"E			
all four corners of the site.	С	12°15'9.28"N	79°37'7.61"E			
	D	12°15'9.16"N	79°37'7.47"E			
	Е	12°15'9.15"N	79°37'2.62"E			



v. Google map earth downloaded of the project site

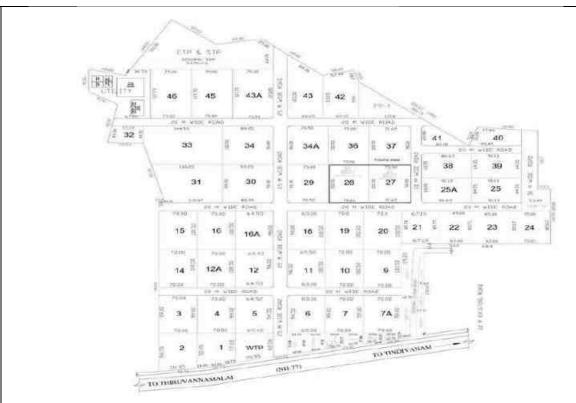


vi. Layout maps including exclusing unit as well as proposed unit indicating storage area, plant area, greenbelt area, utilities etc. If located within an industrial area/estate/complex, layout of industrial indicating location of the unit within the industrial area/estate



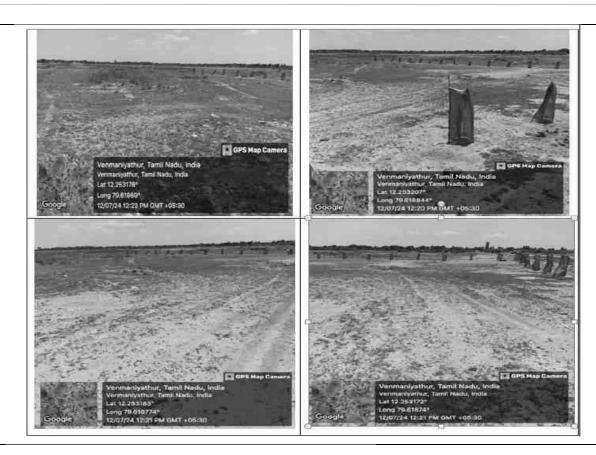
	Land Area Break	кир	
Items	Area in Sq.m	Area in Acres	%
Ground coverage (plinth)	6472.00	1.599	42.73
Greenbelt	5011.40	1.239	33.08
Open Space	144.00	0.036	0.95
Road & Parking	3520.00	0.869	23.24
Total	15147.40	3.743	100

Layout maps including proposed unit indicating storage area, plant area, greenbelt area, utilities etc is given in Annexure-9.



Industrial area, layout of industrial indicating location of the unit within the industrial area is enclosed as **Annexure-17.**

vii. Photographs of the proposed and existing (if applicable) plant site, existing show photographs of plantations/greenbelt in particular.



viii. Land use breakup of total land of project site (identified and acquired), government/ private-agriculture, forest, wasteland, water

Land use- industrial use as per DTCP and there will be no change in land use pattern.

included (not required for industric	1		
included (not required for industria			
area)			
	Nearby Existing Industries (10 km radius)		
	Industries	~Dist(km)	Dire
	Cheyyar SEZ Developers Private Limited	0.41	SSI
	Pioneer Cold Store & Cladding Pvt Ltd	0.62	NE
	Sri Ram Enterprises	0.68	NN.
	JRMB Auto Technologies Private Limited	0.76	N
	Dharshini Engineering Pvt Ltd	0.82	N
	Stellar Pipes	0.84	NN
	SAF Petroleum	1.25	NN
ix. A list of major industries with name	Kals rises India Pvt Ltd	1.31	NN
and type within study area (10 km	Shree Kubera Vinayagar Modern Rice Mill	5.52	Е
,	Kanishka Granites	6.09	Е
radius) shall be incorporated. land	Horizon Packs Pvt. Ltd	6.59	Е
use details of study area	Mini Star Engineering Pvt Ltd	6.7	Е
	Jayanthi Agro Industries	8.08	SE
	Senthaiyappa Modern Rice Mill	8.4	SE
	Prabakar Food Tech	8.89	SE
	KMC Rice Industry	9.11	SE
	KK Leathers	9.14	SE
	NCC Agro Industries	10.49	W
	Karuna Industries	10.5	SE
	Sulochana Engineering	10.64	ESI
	Suja shoe Industries Pvt ltd	14.79	ENI



 x. Geological features & Geohydrological status of study area shall be included. Geology: Villupuram district is underlain by crystalline metamorphic complex in the western part of the district and sedimentary tract in eastern side (Plate-II). The thickness of sediments exceeds 600m near southern part of the district. Groundwater occurs under phreatic and semi-confined conditions in consolidated formations, which comprises weathered and fractured granites, gneisses and charnockites whereas in unconsolidated sedimentary rocks the groundwater occurs in phreatic, semi-confined conditions in Vanur sandstone, Kadapperi kuppam formation and Turuvai limestone. The district is having rocky outcrops in major part of Kallakurichi, Sankarapuram and Tirukoilur taluks. The weathering is highly erratic and the depth of abstraction structures is controlled by the intensity of weathering and fracturing.

Hydrogeology: The depth of wells varies from 6.64 to 17m bgl and water levels in observation wells tapping shallow aquifers variedfrom 0.74 to 9.7 m bgl during pre monsoon (May 2006) and it varies from 0.7 to 4.45 mbgl during post monsoon (January 2007). During pre monsoon, the depth to water levels in the range of >2 to 5 m bgl in major part of the district, in the range of >5 -10 m bgl in western and southeastern parts of the district and range of 0-2 m bgl were recorded in two isolated pockets (Plate –III). During post monsoon the depth to water levels range of >2 to 5 m bgl exists in major part of the district, range of 0 - 2 m bgl prevails in central and northeastern parts of the district and range of >5 - 10 m bgl were recorded in two isolated pockets in the southwestern and north western parts of the district (Plate –IV).

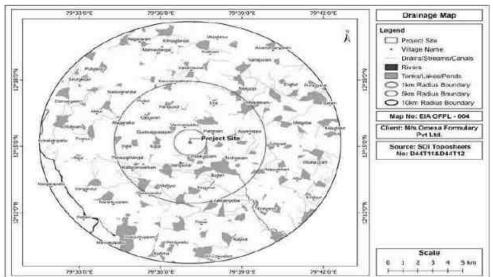
The depth to piezometric surface ranged from 2.8 to 11.25 m bgl during Pre monsoon and 0.5 to 6.35 m bgl during post monsoon. The ground water is being developed my means of dug wells, bore wells and tube wells. The diameter of the well is in the range of 7 to 10 m and depth of dug wells range from 15 to 18 m bgl depending on the weathered thickness and joints. The dug wells yield up to 1 lps in summer months and few wells remains dry. The yield is adequate for irrigation for one or two crops in monsoon period. The yield of bore wells in favorable locations vary from <1 to 6 lps. The valley fills, intersection of lineaments, particularly, in the western part along the foot hills of Kalrayan hills are reported to have potential pockets suitable for dug wells and bore wells. The area of

contact between crystalline and sedimentary formations has variable yield prospects. The cretaceous formations are very compact and yield prospects are low. The dug wells of 6 m diameter and 10 m bgl depth in sandy tracts give about 3.5lps. The yield of tube wells in the sedimentary formation ranges from 2.4 to 37lps.

39:03:0:€

Drainage map of the study area:

xi. Details of drainage of the project upto 5 km radius of the studyarea. If site is within 1km radius of any major river, peak and lean season river discharge as well as flood occurrence frequency based on peak rainfall data of the past 30 years. details of flood level of the project site and maximum of flood of river shall also be provided (mega Greenfield projects)



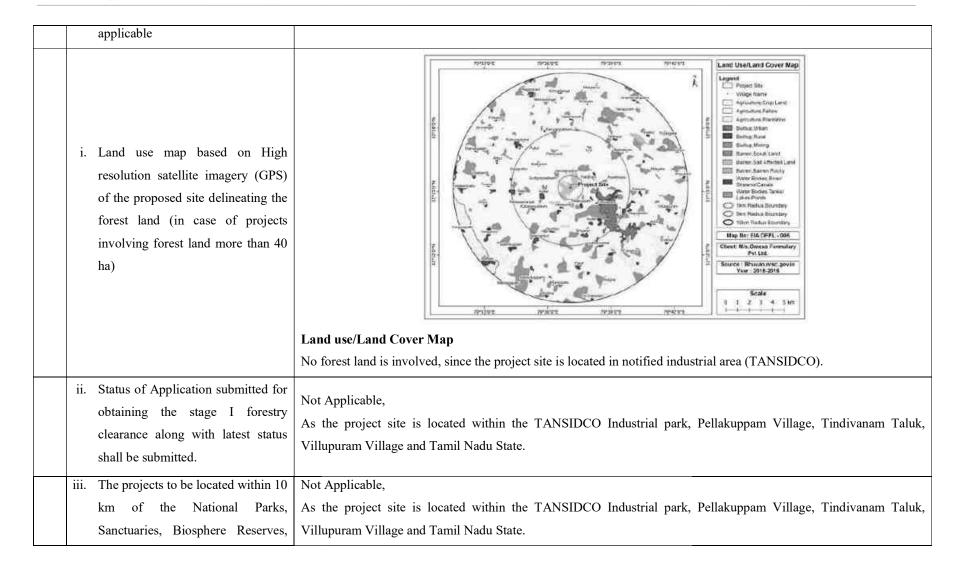
There is no river within 1 km radius of the project site. Hence flood map is not generated.

Sensitive places	~Dist (km)	Direc			
Waterbodies					
Pelakuppam Lake	0.99	ESE			
Pattanam Lake	1.59	NNE			
Buderi Lake	2.13	SSE			
Vempundi Lake	2.26	SW			
Melpakkam Lake	4.31	NE			



		Avaiyurkuppam Lake	7.36	SW	
		Kodiyam Lake	7.50	N	
		Saram Lake	7.97	ENE	
		Vilukkam Lake	8.21	W	
		Elamangalam Lake	8.60	WNW	
		Tondi Ar	8.75	SW	
		Saram R	8.91	ENE	
		Kondamur Ar	9.50	SE	
		Olakkur Lake	10.75	NE	
		Sankaraparani R/Varaha N	10.85	WSW	
		Etanemali Lake	10.98	NW	
		Ongur Channel	14.05	ENE	
	xii. Status of acquisition of land. If	Nallur Lake	14.68	N	
	acquisition is not complete, stage of the acquisition process & expected time of complete procession of the land.	The site is allotted to proponent by TANSIDCO. Land allotment of (1.883 Acres) & plot no: 28 (1.863 Acres) is attached as an Annexure	·) for the plot no: 27	
	xiii. R&R details in respect of land in line with state Government policy	R&R is not applicable; site is within TANSIDCO industrial Park.			
5	Forest & wildlife related issues (if appli	cable)			
	i. Permission and approval for the use				
	of forest land (forestry clearance),	Not Applicable since site is within TANSIDOO industrial Deal-			
	if any, and recommendations of the				
	State Forest Department. (if				







Migratory Corridors of Wild Animals, the project proponent shall submit the map duly authenticated by Chief Wildlife Warden showing these features visà-vis the project location and the recommendations or comments of the Chief Wildlife Warden there on

The Conservation Plan would focus on conservation of habitats of Schedule-I species identified during the study. We identified 1 IUCN red list bird species in the study area i.e. 10 km buffer area.

Fauna

 iv. Wildlife Conservation Plan duly authenticated by the Chief Wildlife Warden of the State Government for conservation of Schedule I fauna,if any exists in the study area

S.No Common Name		Species Name	IUCN	WPA 1972	
Birds					
1	Brahminy Kite	Haliastur indus	LC	Schedule I	

The budgetary provision has been made for implementation of wildlife conservation measures. Project proponent will allocate Rs.5,35,000 towards the conservation plan for implementing the following activities with the help of and in consultation with the Forest Department.

- Bird species Brahminy Kite
 - Capacity Building: Capacity building program on protection would be of high significance. Creation of awareness among local people as well as employees about the importance of protecting the habitat and foraging grounds.
 - o **Anti-Poaching Plan:** Poaching being one of the causes for depletion of wildlife in general and it being one of the main reasons for the poor faunal assemblage, it is necessary to increase protection

		for the RET species. The people living in the surrounding area should be rewarded for timely information about disturbing and/or poaching of the bird more specifically the threatened species. O Habitat Improvement: Sufficient food, water resources, vegetation cover, and breeding sites must be available at the release location. The proponent has proposed a sum of Rs. 5,35,000/-for the conservation plan under the following heads:							
		S.No	Work or Activity		Approximate Cost. Rs.				
				Year 1	Year 2	Year 3	Year 4	Year 5	
		1	Monitoring birds	105,000/-	105,000/-	52,500/-	-	-	
		2	Birds monitoring tools	1,00,000/-	-	-	-	-	
		3	Environmental awareness	24,000/-	24,000/-	24,000/-	24,000/-	24,000/-	
		3	programme	24,000/-	24,000/-	24,000/-	24,000/-	24,000/-	
		(Not inclu	ding water supply, grass seed coll	ection and plantat	ion)		•	,	
	v. Copy of Application submitted for								
	clearance under the wildlife								
	(protection) Act, 1972 to the	ne Not applicable.							
	standing committee of the National								
	Board for Wildlife.								
	vi. Recommendations and NOC from								
U7	the concerned State/UT Coastal								
0/	Zone Management Authority on	Not applicable.							
	CRZ angle								
6.En	nvironmental Status								



Determination of atmospheric inversion level at the project site site-specific microand meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall. AAQ data (except monsoon) at 8 locations for PM10, PM2.5, SO2, NOX, CO and other parameters relevant to the project shall be collected. The monitoring stations shall be based CPCB guidelines and take into account the pre- dominant wind direction, population zone and sensitive receptors including reserved forests

By considering Avg. temperature & wind speed, daily inversion level has been determined at the project site. From the graph plotted, the maximum inversion height is estimated using average temperature and wind speed. The daily inversion level at the project site varies from 50 to 3673 m during 6 AM to 4 PM, the maximum recorded at 3673 m during may 2024

S. No	Parameter	Observation
		Max. Temperature: 41°C
1	Temperature	Min. Temperature: 24°C
		Avg. Temperature: 31.15°C
2	Average Relative Humidity	73.36%
3	Average Wind Speed	3.61m/s
4	Predominant Wind Direction	South East

AAQ data at 8 locations for PM10, PM2.5, SO2, NOX, CO and other parameters relevant to the project are collected. The monitoring stations are identified based on CPCB guidelines & the pre-dominant wind direction, sensitive receptors & population zone including reserved forests are considered for monitoring.

Station Code	Location	Typeof Wind	Distance (~km) from Project boundary	Azimuth Directions
AAQ1	ProjectSite	-	0.23	ESE
AAQ2	Ural	c/w	3.08	NNE
AAQ3	Tindivanam	c/w	3.38	ESE
AAQ4	Pelakuppam	u/w	1.43	SE
AAQ5	Vempundi	c/w	2.31	SSW
AAQ6	Kollar	c/w	2.25	WSW
AAQ7	Kattusiviri	d/w	3.14	NW
AAQ8	pudur	d/w	4.52	NW

The ambient air quality has been monitored at 8 locations as per NAAQS, 2009 within the study area. The results obtained are summarised as below: The average baseline levels of PM₁₀ vary from 36.27 to 50.05 μ g/m³. The average baseline levels of PM_{2.5} vary from 21.42 μ g/m³ to 27.88 μ g/m³. The average baseline levels of SO_2 vary from $8.50 \mu g/m^3$ to $10.49 \mu g/m^3$. The average baseline levels of NO₂ vary from 19.42 μg/m³ to 21.81 μg/m³ Based on pre-dominant wind direction, population zone, sensitive receptors including reserved forests and CPCB guidelines, sampling locations were selected which is detailed in Chapter 3, Section 3.6.1. iii. Raw data of all AAO measurement for 12 weeks of all stations as per frequency given in the NAAQM Notification of Nov.2009 along Raw data of all AAQ measurement for 12 weeks of all stations as per frequency given in the NAAQM notification of November 2009 along with- min-max, average and 98% values for each of the AAQ parameters from data of all AAQ with-min.,max.,average&98% values for each of the AAO stations are provided as Annexure-12. parameters from data of all AAQ stations should be provided as an annexure to the EIA Report i. Surface water quality of nearby Surface water Sampling locations (100m upstream and S.No **Location Code** Distance in Km Location Direction downstream of discharge point) and PattanamLake SW1 1.60 N other surface drains at eight 2. Melapakkam Lake SW2 4.86 **ENE** locations as per CPCB/MoEF&CC 3 Lake near Pelakuppam SW3 1.21 Ε guidelines



4	BuderiLake	SW4	4.02	SE
5	Kondamur lake	SW5	9.60	S
6	VembudiLake	SW6	3.02	SSW
7	TondirAr	SW7	8.94	WSW
8	VenmaniyathurLake	SW8	1.41	WNW

Surface water quality results:

Parameter	Surface water sample	Surface water quality standards-IS 2296:1992				
	– IS 2296:1992	Class A	Class B	Class C	Class D	Class E
pН	7.34-7.74	8.5	8.5	8.5	8.5	8.5
Total Dissolved Solids (mg/l)	395-473	500	-	1500	-	2100
Hardness (mg/l)	175-265	300	-	-	-	-
BOD (mg/l)	2.0-5.0	2	3	3	-	-
COD (mg/l)	10-22	-	-	-	-	-

Class A- Drinking water without conventional treatment but after disinfection.

Class B-Water for outdoor bathing.

Class C-Drinking water with conventional treatment followed by disinfection

Class D-Water for fishculture and wildlife propagation.

Class E-Water for irrigation industrial cooling and controlled waste disposal

Surface water quality of nearby river and other surface drains at eight locations as per CPCB/ MoEF&CC guidelines are collected & analyzed and the details are provided in the Chapter 3, Section 3.8.2.

ii. Whether the site falls near to polluted stretch of river identified by the CPCB/MoEF&CC, if yes give details

No, the site is not located near to any polluted stretch of river which is identified by CPCB/MoEF&CC.



iii. Ground water monitoring at minimum at 8 locations shall be included

Ground water Sampling locations

S.No	Location	LocationCode	Distancein ~Km	Direction
1	ProjectSite	GW1	0.57	Е
2	Ural	GW2	3.05	NNE
3	Tindivanam	GW3	3.10	ESE
4	Pelakuppam	GW4	1.65	SSE
5	Kollar	GW5	2.35	WSW
6	Gudisaippalaiyam	GW6	2.25	WNW
7	Kattuvisiri	GW7	3.14	NW
8	Venmaniyathur	GW8	1.31	N

Ground water monitoring results at 8 locations

Parameter	Range of Results	ange of Results Drinking water stand		
1 at affected	IS 10500:2012	Acceptable Limit	Permissible Limit	
pH	6.91-7.60	6.5-8.5	No Relaxation	
Total Dissolved Solids (TDS) (mg/l)	650-750	500	2000	
Chloride (mg/l)	146-206	250	1000	
Hardness (mg/l)	226-243	200	600	

Ground water monitoring at minimum 8 locations are collected & analyzed. Further detailed Ground water monitoring results were provided in the **Chapter 3**, **Section 3.8.3**.

Noise Monitoring Locations & Noise levels monitoring results at 8 locations v

iv. Noise levels monitoring at 8 locations within the study area

v. Soil Characteristic as per CPCB

guidelines

S. N Location		Location Location		Azimu th	dB	Noiselevel in dB(A) Leq		PCB ndard	Environment
0	Location	Code	Project bound ary	Directi on	Da y	Nigh t	Lday (Ld)	LNigh t(Ln)	al Setting
1	ProjectSite	N1	Within	Within the site		49.3	75	70	Industrial
2	Pattanam	N2	1.67	ENE	47.6	42.5	55	45	Residential
3	Tindivanam	N3	3.09	ESE	52.8	43.6	55	45	Residential
4	Pelakuppam	N4	1.57	SSE	45.4	41.9	55	45	Residential
5	Kollar	N5	2.38	WSW	49.7	43.2	55	45	Residential
6	Gudisaippalaiyam	N6	2.35	WNW	50.2	43.5	55	45	Residential
7	Kattuvisiri	N7	3.14	NW	51.5	40.4	55	45	Residential
8	Venmaniyathur	N8	1.34	N	48.8	41.7	55	45	Residential

Noise levels monitoring at 8 locations within the study area are collected & analyzed. Further detailed Noise level monitoring results were provided in the **Chapter 3**, **Section 3.7**.

Soil Quality Monitoring Locations

S.No Location		Location Code	Distance in ~Km	Direction
1	ProjectSite	S1	With in th	e site
2	Pattanam	S2	1.67	ENE
3	Tindivanam	S3	3.09	ESE
4	Pelakuppam	S4	1.57	SSE
5	Kollar	S5	2.38	WSW
6	Gudisaippalaiyam	S6	2.35	WNW
7	Kattuvisiri	S7	3.14	NW
8	Venmaniyathur	S8	1.34	N

Soil characteristics:

• The pH of the soil samples ranged from 6.55 to 7.56.

•	Conductivity	of the soil	samples ranged	from 276 to	$346 \mu S/cm$.
---	--------------	-------------	----------------	-------------	------------------

- Nitrogen content ranged from 83.5 to 116.8 mg/kg.
- Phosphorous ranged from 3.6 to 5.3 mg/kg.
- Potassium content ranges from 37.5 to 50.3 mg/kg.

Futher detailed Soil characteristics are analyzed for 8 sampling locations as per ICAR guidelines are provided in the

Chapter3, Section 3.9.1.

Traffic study is carried out including type and frequency of vehicles, transportation of materials and additional traffic due to the proposed project based on IRC:106-1990- Guideline for capacity of urban road in plain area. Details are given in Chapter 4, Section 4.1.3.2 of EIA report.

Existing and Proposed Vehicular movement in NH-77 per hour

vi.	Traffic study of the area, type of
	vehicles, frequency of vehicles for
	transportation of materials,
	additional traffic due to proposed
	project, parking arrangement etc.

	zamong unu roposeu veneum movemene m var vv per nou							
S. No	Type of Vehicles	Existing vehicles	Existing PCU	Proposed vehicles	Proposed PCU	rotar vehicles after project implementa	Factors IRC (SP41)	after after project implementa
1	2wheelers	350	263	20	15	370	0.75	278
2	3Wheeler	42	84	0	0	42	2	84
3	Cars	442	442	4	4	446	1	446
4	Truck / Lorry/ Bus	90	333	3	11.1	93	3.7	344
5	Agri tractor	8	32	0	0	8	4	32
6	Light commercial	45	90	0	0	45	2	90
	Total	977	1244	27	30.1	1004	-	1274

Traffic Volume after Implementation of the Project

For the Road	Volume of	Volume	Road	V/C Ratio	LOS	Traffic
ror the Road	Traffic	(V)	Capacity	V/C Katio	Category*	Classification



			(C)			
Existing	977	1244	15000	0.08	"A"	Free Flow Traffic
After implementation	1004	1274	15000	0.085	"A"	Free Flow Traffic

^{*}LOS (Level of Service) categories are A-Free Flow, B- Stable Traffic Flow, C- Restricted Flow, D- High Density Flow, E- Unstable flow, F- Forced or breakdown flow

Categorisation of traffic

V/C	LOS	Classification
<0.35	A	Free flow Traffic
0.35-0.55	В	Stable flow Traffic
0.55-0.77	С	Restricted flow
0.77-0.92	D	High Density flow
0.92-1.0	Е	Unstable Flow
>1.0	F	Forced Traffic flow

Due to propose project there will be slight increment in the vehicle movement but the level of service (LOS) anticipated will be **Free Flow**.

Flora and Fauna study is carried out found within the 10km radius study area and the details are provided in Chapter

3. Section 3.10

A detailed biological survey of the core zone (Project site) and buffer zone (10 km radius from periphery of the proposed project) was carried out giving details of flora and fauna. There is one Schedule-I Species in study area i.e., named Brahminy Kite(*Haliastur indus*). The proponent has proposed a sum of Rs. 5,35,000/-for the conservation plan under the following heads:

S.No	Work or Activity	Approximate Cost. Rs.						
5.110	, violk of lictivity	Year 1	Year 2	Year 3	Year 4	Year 5		
1	Monitoring birds	105,000/-	105,000/-	52,500/-	-	-		
2	Birds monitoring tools	1,00,000/-	1	1	ı	-		

Detailed description of flora& fauna (terrestrial and aquatic) existing in the study area shall be given with special reference to rare, endemic & endangered species. If Schedule-I fauna are found within the study area,a Wildlife Conservation Plan shall be prepared and furnished.

		3	Environmental a	awareness programme	20,000/-	20,000/-	20,000/-	20,000/-	20,000/-
		(Not include	ding water supply,	grass seed collection and j	plantation)		<u>I</u>		
		Population	n profile within tl	ne study area:					
		_	S.No	Particula	rs	Study	area	Unit	
			1	Number of villages in th	e Study Area	59)	Nos.	
			2	Total Households		386	42	Nos.	
			3	Total Population		1625	540	Nos.	
			4	Children Population (<6	Years Old)	173	09	Nos.	
			5	SC Population		466	08	Nos.	
	vii. Socio economic status of the study		6	ST Population		197	71	Nos.	
	area		7	Total Working Population	on	704	70465 Nos.		
			8	Main Workers		569	66	Nos.	
			9	Marginal Workers		134	99	Nos.	
			10	Cultivators		102	05	Nos.	
			11	Agricultural labours		255	09	Nos.	
			12	Household Industries		147	79	Nos.	
			13	Other Workers		332	72	Nos.	
			14	Literates		1162	282	Nos.	
7	Impact and Environmental Managemen	nt plan							
	i. Assessment of ground level					<u> </u>			
	concentration of pollutants from the	AEDMOD	Coffman Varris	0.0.5 was used for -i- 1:-		ling and i	المادوناسس	a a wida	
	stack emission based on site-		ERMOD Software Version 8.0.5 was used for air dispersion modelling and is applicable neutrally buoyant emissions up to a range of 10 km. The air quality contours plotted o						•
	specific meteorological features. In	·		1			lotted on a	location ma	ap showing the
	case the project is located on a hilly			e shown in GLCs for prop	osed is given in	n below:			
		Total Max	ximum GLCs fro	n the Stack Emissions					
	terrain, AQIP modelling shall be								



done using inputs of the specific characteristics terrain determining the potential impacts of the project on the AAQ. Cumulative impact of all sources of (including emissions transportation) on the AAQ of the area shall be assessed. Details of the model used and the input data used for modelling shall also be provided. The air quality contours shall be plotted on a location map showing the location of the project site, habitation nearby, sensitive receptors, if any

Pollutant	Max. Base line Conc. (μg/m3)	Estimated Incremental Conc. (µg/m3)	Total Conc. (μg/m3)	NAAQ standard (μg/m3)
PM10	59.48	0.056	59.536	100
SO2	12.46	0.048	12.508	80
NOx	25.92	0.832	26.752	80
VOC	720	1.497	721.497	4000

Total Maximum GLCs from the Vehicular Emissions

Pollutant	Max. Base line Conc. (μg/m3)	Estimated Incremental Conc. (μg/m3)	Total Conc. (μg/m3)	NAAQ standard (μg/m3)
PM	59.48	0.03	59.51	100
NO _x	25.92	0.87	26.79	80
СО	720	22.16	742.16	4000

Total Maximum GLCs from the cumulative Emissions

Pollutant	Max. Base line Conc. (μg/m³)	Estimated Incremental Conc. (μg/m³)	Total Conc. (μg/m³)	NAAQ standard (μg/m³)
PM10	59.48	0.05	59.53	100
SO2	12.46	0.04	12.5	80
NO _x	25.92	0.87	26.79	80
СО	720	22.16	742.16	4000

Details of the model used and the input data used for modelling along with air quality contours plotted on a location map showing the location of the project site, habitation nearby, sensitive receptors is given in **Chapter 4**, **Section 4.1.2.1**.



	No Dis	charge outside as Zero	o Liquid Discharge c	oncepts are proposed for the plant.
	S. No	Description	Proposed Quantity (KLD)	Final Disposal Points
	Const	truction Phase		
	1	Sewage	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development
	Oper	ation Phase	•	
	1	Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.
	2	Sewage	4.6	Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt.

ii. Water quality modelling- in case of discharge in water body.

iii. Impact of the transport of raw material and end products on the surrounding environment shall be assessed and provided. In this regard, options for transport of raw materials and finished products and wastes (large quantities) by rail or railcum road transport or conveyor cum-rail transport shall be examined.

Impact of the transport of raw material, end products on the surrounding environment is mainly through Air and Noisedue to the vehicular movement.

Material Handling, Storage and Transportation:

- All transfers from drums will be done through pumps in closed pipelines.
- The loading of finished products to trucks and drums will be done through automated filling systems with over flow protections.
- All key raw materials will be charged to the reactors through closed pipeline systems.

Cumulative impact of all sources of emissions (including transportation) on the AAQ of the area is given in **Table 4-18**, **Section 4.1.3.1** of**chapter-4**.



Construction Phase: Total Sewage generation will be 1.22 KLD. It will be treated through mobile Sewage Treatment Plant of 3 KLD and treated sewage will be reused for Green belt development within the plant.

Operation Phase: Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented

Liquid waste Management

be reused for greenbelt development

will be used as a manure for greenbelt.

Final Disposal Points

Will be treated in mobile STP (3 KLD) and treated sewage will

Effluent generation from process, utilities & Pretreatment

followed by RO systems. Effluent will be treated in proposed

ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will

Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge

S. No	Description	Proposed Quantity (KLD)
Cons	truction Phase	
1	Sewage	1.22
Oper	ation Phase	
1	Effluent	59.5

Sewage

Technical Specification of STP (6 KLD) is attached as an **Annexure-5a** and Technical Specification of ETP (ZLD) is attached as an **Annexure-5b**.

4.6

be disposed to TSDF.

iv. A note on treatment of wastewater from different plant operations, extent recycled and reused for different purposes shall be included. Complete scheme of effluent treatment, characteristics of untreated and treated effluent to meet the prescribed standards of discharge under E(P)rules.

Proposed Kill Tank Systems:

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steelpiping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- Chemical dosing system
- \triangleright Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump



recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste

Characteristics of Sewage & Treated sewage

	Quantity			Parameter	•	
Description	Quantity (KLD)	pН	TSS(mg/l)	TN(mg/l)	BOD (mg/l)	COD (mg/l)
Domestic	4.6	6.0-8.0	200-300	40-60	250-300	400-500
STP treated sewage	4.6	6.5-8.5	20	20	<10	50

Characteristics of raw and treated Effluent water

	Quantity			Parameter		
Description	(KLD)	pН	TSS(mg/l)	TDS(mg/l)	BOD(mg/l)	COD(mg/l)
ETP feed	59.5	6.0-8.0	200-400	800-1000	1300-1500	4000-4500
ETP Outlet (Permeate)	59.5	6.0-8.0	<5	800-1000	<20	<200
RO Permeate	48	5.0-6.0	<5	<100	<20	<200
RO reject	11.5	7.0-8.0	<5	<5000	<20	<200

Proposed Stack emission details:

v.Details of stack emission and action plan for control of emissions to meet standards.

		T.	Fuel	Stack Details				Emissions				
S. N O.	Source	Fuel Type	Quantit y (KL / Day)	No. of Stack	Heigh t (m)	Temp (°C)	Dia (m)	Exit Veloc ity (m/s)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
1	DG-600 KVA	HSD	2 00	1	30	200	0.2	9.5	7.43E -03	6.93E -03	1.05E -01	2.26E -02
2	DG-600 KVA	HSD	2.88	1	30	200	0.2	9.5	7.43E -03	6.93E -03	1.05E -01	2.26E -02
3	Boiler 1.5 TPH	HSD	2.509	1	30	210	0.3	10	3.41E -03	4.70E -04	6.62E -02	1.66E -02



		Total		1.83E -02	1.43E -02	2.76E -01	6.17E -02
	Note: *In ToR application, I	OG sets capacity -	2x350 kVA.		l	·	ľ
	Control Measures • Stack height of 30 m	is proposed for boi	ler.				
	• 30m stack height will	be provided for De	G.				
	Adequate Green belt	area will be provid	ed.				
	Process Emission:						
	There are no process emissions from the proposed manufacturing facility.						
	Control Measures • Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.						
	• Ambient air quality	monitoring will be	e carried out regularly at selected	location	ns in ord	er to che	eck and
	compare the predict	ed concentrations	with the measured concentration	s. Adequ	acy/Perf	ormance	of Air
	Pollution Control me	asures shall be revi	ewed.				
	There will be chance of fugi The details of fugitive emission		to raw material handling, transport neasures	ation and	d Manufa	acturing a	activity.
	_		ve emission and its control measu	res			
vi.Measures for fugitive emission	Source	Probable pollutant parameter	Control I	Measure	s		
control	Loading/unloading and storage of raw materials and finished products	VOC & PM	 Loading/unloading of lique pipeline. It will be done in Local Exhaust ventilation 	a closed	system.	e done tl	hrough
	Raw material storage	VOC	Carry out work place concentration level in amb Closed transfer system will	ient air.		g to fin	d out



		Unit will carry out regular workplace monitoring.
Handling of raw Material in bags storage area	PM	 Provision of exhaust ventilation in plant area. Provision of PPE. Job rotation to reduce exposure.
Warehouse storing drums and bags	VOC&PM	 Spillages will be strictly prevented by proper handling of equipment. SOP will be followed.

Control Measures

- There are no process emissions from the proposed manufacturing facility.
- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.

The main source of hazardous waste generation from manufacturing process will be discarded in bags/drums/barrels, used oil, ETP sludge and evaporation residue.

vii. Details of hazardous waste generation and their storage, utilization and management, Copies of MOU regarding utilization of solid and hazardous waste in cement plant also be included. EMP shall include the concept of waste- minimization, recycle/ reuse/ recover techniques, Energy conservation, and natural resource conservation.

Hazardous waste details

S.N o	Description of Waste	Category as per HWM Rules 2016	QTY/Annu m	Storage method	Method of disposal
1	Used /Spent Oil	5.1	1 KL	All the generated Hazardous waste will be	Will be collected and disposed through TNPCB Authorised recycler
2	Waste or residues containing oil	5.2	1 Ton	stored on Concrete platform in leak Proof	Will be collected and disposed through TNPCB Authorized TSDF
3	Discarded Containers/Bags	33.2	4 Ton	Barrels in designated areas	Will be collected and disposed through TNPCB Authorised recycler



	5			37.3 35.3	16.5 Ton (50 kg/day) 3.3 Ton	Will be collected an	ıd
	6	(Doesi	Specification Products 1't Met by 1 ications or standards)	28.3	(10 kg/day) 2 Ton	disposed through TNPCB Authorized TSDF	d
	7	Expiry	Products/Chemicals	28.5	1.5 Ton		
	Haz	ardous was	te will be segregated and	stored under ro	ofshed on raised	platform. Proper leachate collection sy	ystem
	and	roof. Leach	hate, if any will be collect	eted and treated	in effluent treat	ment plant. Unit will take membership	with
	TSE	F and also	Authorization from TNPO	CB after getting	Environmental C	Clearance from SEIAA, Tamil Nadu.	
ii. Proper utilization of fly ash	shall be						
ensured as per Fly Ash not 2000. A detailed plan o shall be provided.	Not	applicable,	Since HSD is used as a fu	nel for DG and I	Boilers		
ix. Action plan for the g	reen belt Gre	enbelt Dev	elopment				
development plan in 33% area	i.e., land The	total land	area is 15147.40 Sq.m ar	d Greenbelt are	ea is 5011.40 Sq	.m (33.08%). Around 1503 numbers of	f tree
with not less than 1500 trees	s per Ha. (2m	x 2m spaci	ng for each trees) will be	planted as calcu	lated below:		
Giving details of Species,	width of	S.No	Description	Uı	nit Propo	sed Greenbelt within project site	
plantation, planning schedule		1	Total area of project site	Н	[a	1.5147	
be included.The green belt		2	Total Area of Green Bel	: H	[a	0.5011	
around the project boundar	·	3	Percentage of total proje	ct area %	6	33.08	
scheme for greening of the re		As per the MoEF&CC Requirement, No. of tree saplings to be planted as per guidelines(2500)					
for the project shall incorporated.	also be	tree/Ha) considering 80% survival rate					

4	As per MoEF&CC requirement	Nos	1503
5	Actual No. of plants present	Nos.	-
5	No of plants to be planted	Nos.	1503
6	Fund Allotted	Lakhs	6.00
7	Status of Implementation	-	Within 3 year

Recommended Species for Proposed Green Belt Development in project site (as per CPCB guideline for greenbelt development)

S.No	Scientific Name	Common Name	No of Trees	Yearwise	
1	Pongamia pinnata	Pungai	300	1 st Year	
2	Thespesia populnea	Poovarasu	300	2 nd Year	
3	Albizis lebback	Vaagai	150	2 nd Year	
4	Cassia fistula	Sarakondai	150	3 rd Year	
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year	
6	Pterocarpus Marsupium	Vengai	150		
7	Aegle Marmelos	Vilvam	150	4 th Year	
8	Madhuca longifolia	Iluppai	153		
	Total		1503		

Budget for greenbelt development is INR. 7.0 lakhs

Note: No fruit bearing trees was considered for the development of green belt.

x. Action plan for rainwater harvesting measures at plant site shall be submitted to harvest rainwaterfrom the roof tops and storm water drains to recharge the ground water and also to use for the various activities at the project site to

1. Rainwater harvesting calculation

Description	Area (m²)	Run off Coefficient	Intensity of rainfall-I (m/day)	Total Discharge-Q(m3/day)
Ground coverage (plinth)	6472	0.8	0.073	377.96
Greenbelt	5011.4	0.2	0.073	73.17
Open Space	144	0.7	0.073	7.36
Road & Parking	3520	0.7	0.073	179.87



conserve fresh water and reduce the	Total		15,147.40	0.00	0.00	638.36
water requirement fromother sources	Formula:					_
	Discharge,	$Q = CIA (m^3/day)$				
	Where,					
		Q= Discharge (in m³/day)				
		C=Coefficient of Runoff				
		I= Intensity of rainfall (in mm/day) (Max Flood in 12.11.2022- 73.79 mm as per IMD Villupuram) A= Area (in Sq.m)				
	Runoff ca					
	> To	otal runoff Load = 6	$38.36 \text{ m}^3/\text{day}$			
	> To	otal runoff load per	hour =638.36/	24 = 26.60 m	/hr.	
	➤ R	WH pits of 1.5m di	a and 4.0 m d	epth, capacity	of each pits= 3.53 m ³	and we considered 50% percolation
	so	the capacity of RW	/H pit is 1.77 ı	n3.		
	> N	o. of RWH pits prop	posed = 26.60	3.53 = 15.02 S	ay 15 Nos.	
	15 no. of r	ainwater harvesting	pits are propo	sed Storm wat	er will be collected in	RWH pitsthrough storm water drains
	and only	ecess storm water	will be let in	to TANSIDCO	Drain. Layoutwith	storm water drain is attached as an
	Annexure	-8.				
	Environm	ental Managemen	t Plan Budget	(tentative):		
					Capital Investmen	t
xi. Total capital cost and recurring	S. No	Pa	rticulars	L	(Rs in lakhs)	Recurring Cost per Annum (Rs in Lakhs)
cost/annum for environmental pollution					Proposed	Amain (RS in Earlis)
control measures shall be included	Environment Management Plan					
	Water P	Water Pollution Control				
	1	ETP			350	20
	2	MEE/ATFD and	RO		330	20



3	STP	8.5	2	
Air Po	llution Control			
4	DG & Boiler Stack/ Wet scrubber	60	3	
Enviro	nmental Monitoring			
5	Environmental Monitoring by third party	0	4.4	
Solid V	Vaste Management			
6	Solid Waste Management	2	3	
Greenl	pelt			
7	Greenbelt Development	7	2	
Hazaro	lous Waste Management			
8	Hazardous Waste Management	2	5	
Storm	Water and Rain water harvesting managemen	nt		
9	Storm Water and Rain water harvesting management	26	2.6	
10	OHC Expenses	1.5	0.2	
	Total	456.0	42.2	

CER activities:

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost (INR 1.9 crores) ie., will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing.

xii. Action plan for post-project environmental monitoring shall be submitted.

Environmental Monitoring Programme- Construction Phase

S.No	Item	Parameters	Frequency
1	Ambient air quality	All the parameters as per NAAQ Standards	Once in three months
2	Noise level	Equivalent Noise levels	Once in three months



3	Ground water	Physical, chemical and bacteriological	Once in three months	
4	Surface water	Physical, chemical and bacteriological	Once in three months	
5	Soil	General parameters	Once in three months	

Environmental Monitoring Program – Operation Phase

S. No	Area of Monitoring	Number of Sampling Stations	Frequency of Sampling	Parameters to be Analyzed
1.	Micro Meteorology	One	Hourly and Daily basis.	Wind speed and direction, Temperature, Relative Humidity, Atmospheric pressure, Rainfall.
2.	Ambient Air Quality	2 Stations (one in up wind and one in down wind)	Once in a year as per CTO condition through NABL labs	All the 12 parameters as per NAAQ Standards and Hydrocarbons
3.	Noise	2 (one within plant premises and one outside plant premises)	Once in 6 months through NABL labs	Ambient Equivalent continuous Sound Pressure Levels (Leq) at day and Night time.
4.	Water	One surface and ground water sample near the site	Once in 6 months through NABL labs	All the parameters as per IS 10500:2012
5.	Soil	2 (one within plant premises and one outside plant premises)	Once in 6 months through NABL labs	Physicochemical properties, Nutrients and Heavy metals
	Liquid Effluents	Effluent inlet and outlet	Once in 6 months through NABL labs	pH, Temp, Conductivity, Oil and Grease, TSS, TDS, BOD.
6.	1	STP inlet and outlet	Once in 6 months	pH, TSS, BOD & COD



		•			through NABL labs			
		7.	Boiler & DG set	Stack of Boiler & DG sets	Once in 6 months through NABL labs PM, SO ₂ , NO _x & CO			
	xiii. Onsite and Offsite Disaster (natural			1				
	and Man-made) Preparedness and							
	Emergency Management Plan including	Rick	assessment includ	ing Onsite and Offsite I	Disaster (natural and Man-made) Preparedness and Emergency			
	Risk Assessment and damage control.		Management Plan is attached as an Annexure-7 .					
	Disaster management plan should be	ivian	S					
	linked with District Disaster							
	Management Plan							
8	Occupational Health							
	i.Plan and fund allocation to ensure the	M/s	s Omexa will alloc	ate a fund 1.50 Lakhs fo	r Occupational health and safety of employees. Plan and fund			
	occupational health & safety of all	allo	ocation to ensure th	e occupational health & s	afety of all contract and casual workers is given in Chapter10,			
	contract and casual workers	Sec	ction10.1.7.					
	i. Details of exposure specific health	Me	dical Surveillance P	Program: Medical surveilla	nce program is essential to assess and monitor employees' health			
	status evaluation of worker. If the	and	l fitness both prior t	to employment and during	the course of work; to determine fitness for duty and to provide			
	worker's health is being evaluated	em	ergency and other to	reatment as needed. Effect	iveness of a medical program depends on active involvement of			
	by pre-designed format, chest x-	employees. Medical surveillance program will include the following major elements;						
	rays, Audiometry, Spirometry,		 Develop 	ing an OH-IH Medical Sur	veillance Program.			
	Vision testing (Far and near vision,	 Pre-Employment Examination and Periodic Medical Examinations 						
	colour vision and any other ocular	 Determination of Fitness for Duty. 						
	defect), ECG, during pre-	 Communications. 						
	placement and periodical		• Emerger	ncy Medical Treatment.				



	T	
	examinations give the details of the	Medical Records.
	same. Details regarding last month	Pre-Employment Screening/Examinations- All employees will be subjected to pre-placement medical
	analyzed data of above mentioned	examinations to determine their fitness for the jobs on site. Potential exposures to the work environment will be
	parameters as per age, sex, duration	considered before placing an employee on the job.
	of exposure and department wise.	Periodic Medical Examinations - Periodic medical examination is the same as the pre-employment screening and
		may be modified according to current conditions, such as changes in the employee's symptoms, site hazards or
		exposures. Periodic medical examination is the same as the pre-employment screening. The frequency and content
		of examinations will be normally once in a year.
	iii. Details of existing Occupational	
	& Safety Hazards. What are the	
	exposure levels of hazards and	
	whether they are Permissible	
	Exposure level (PEL) if these are	Not applicable since this is a new unit.
	not within PEL, what measures	
	the company has adopted to keep	
	them within PEL. So that health	
	of the workers can be preserved.	
	iv. Annual report of health status of	
	workers with special reference to	Not applicable since this is a new unit.
	Occupational Health and Safety.	
9	Corporate Environment Policy	
	i. Does the company have a Yes,	M/s.Omexa has prepared Environment, Health and Safety Policy and will be communicated and placed at appropriate
	well laid down place	es in the factory premises when the industry starts its operation. The proposed policy is attached below:



environmental Policy	Reference of the Control of the Cont
approved by its Board of	Others Formularly Pic Ltd.
Directors? If so,it may be	SAFETY, HEALTH & ENVIRONMENT POLICY
detailed in the EIA report	*** Provided and remarkshin and for all is invasionable, praid/kainle, plant, spanjument, austrams and surface constructions which are sufficient and surface and and decaying to groups and plant and and and decaying to groups and plant and and and decaying to groups and plant and and and and decaying to groups and plant and
	# Other Cores, 1700 to the Amous, Africa Inquir Standard and Standard Amous Stand
ii.Does the Environment	
Policy prescribe for standard operating process/ procedures to bring into focus any infringement/	EHS policy has been prepared and the complete SOPs along with proper EHS checklist will be developed and implemented
deviation /violation of the environment or forest norms/ conditions? If so, it	during operation of the project. Periodical Environmental Audit will be conducted and recorded.



may be detailed in the EIA	
iii.What is the hierarchical	
system or Administrative	
order of the company to	Any employee observing or coming to know of a non-compliance/ violation of environmental norm shall report the same to
deal with the environmental	the EHS in charge. The issue shall be resolved / escalated to the next level as appropriate till are solution occurs.
issues and for ensuring	Hierarchical system is to deal with the environmental issues and an Environmental Management Cell(EMC) will be in force.
compliance with the	Detailed in Chapter10, Section10.2, Figure 10-1 and Table 10-1.
environmental clearance	Detailed in Chapter 10, Section 10.2, Figure 10-1 and Table 10-1.
conditions? Details of this	
system may be given.	
iv.Does the company have	
system of reporting of non-	
compliances / violations of	
environmental norms to the	
Board of Directors of the	Company will have system of reporting of non-compliances/ violations of environmental norms to the Board of Directors of
company and / or	the company, as explained in Point No. iii. Detailed in Chapter10 , Figure10-1 and Table10-1 .
shareholders or	the company, as explained in Four No. in. Detailed in Chapter 10, Figure 10-1 and Fabre 10-1.
stakeholders at large? This	
reporting mechanism shall	
be detailed in the EIA	
report.	
v. Details regarding	Sanitation facility, restroom will be provided to labour force during construction phase.
infrastructure facilities	Sanitary facility, restroom, OHS, Canteen etc will be provided for employees and drivers during operation phase



such as sanitation, fuel, restroom etc. to be provided to the labour force during construction as well as to the casual workers including truck drivers during operation phase.

• Site layout indicating all the infrastructure facilities such as sanitation, fuel, etc. Site layout is enclosed as **Annexure** 9.

10 Enterprise Social Commitment (ESC)

Adequate funds (at least 2.5% of the project cost) shall be earmarked towards the Enterprise Social Commitment based on public Hearing issues and item-wise details along with the bound action plan shall be included. Socio-Economic development activities need to be elaborate

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost (INR 1.9 crores) i.e., will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing.

However, As per ToR Condition by SEAC, Suitable flora and fauna study will be conducted and details of same will be educated to students in nearby Govt. School as Part of CER activities. Budget of **INR 5.0 lakhs** will be allotted for Awarness Campus and distribution of Tree sapling and seed ball to students

Schools	Budget (INR. Lakhs)
Pattanam Panchayat Union Middle School:	
Awarness camp about local Flora and Fauna	1.0
 Distributing 50 Tree sapling and seed ball bags 	
Kollar Goverment Higher Secondary School:	
Awarness camp about local Flora and Fauna	2.0
 Distributing 100 Tree sapling and seed ball bags 	
Singanur Goverment ADW Higher Secondary School	2.0



Awarness camp about local Flora and Fauna	
 Distributing 100 Tree sapling and seed ball bags 	
Total	5.0

Add	itional studies/Measures to be considered- A	s per SEAC Observation					
		Usage of New Technology: Omexa Formulary Pvt Ltd proposes to manufacture monoclonal antibodies/therapeutic					
		proteins in a cost effective, more efficient path which will ultimately reduce the generation of waste. Manufacturing					
		process involves various unit operations and processes. For the proposed products, currently we are implementing					
1	Provide latest and ecofriendly technology	the Single Use technology, which will reduce the 70% of water consumption compared to the other Stainless steel					
1	for product manufacturing.	technology, unit will adopt the latest and best technology available so far in the market. Moreover, the unit is very					
		concerned and conscious about the product quality and equally about the environmental protection and resource					
		conservation. The company will upgrade the technology as per requirement from time to time with the best as per					
		the requirement.					
		The chemicals which are used in the process minimize or eliminate the use organization of substances hazardous to					
		humans, animals, plants, and the environment. There is no solvents usage in the process					
		The clean Manufacturing will be implemented by practicing the GMP requirements likePersonal Protective					
	Eurobasia Guara abanistra/Glass	Equipment:					
2	Emphasize on Green chemistry/Clean	Coveralls and gowns					
	Manufacturing	➤ Head covering					
		➢ Gloves					
		> Protective eyewear					
		> Personal /Material Movement					



- > Dedicated entry /exit for Man, material and waste
- ➤ HVAC System
- ➤ Clean room areas of Grade A/B/C and D environment
- ➤ Clean Utility
- > Use of Purified and WFI water for process.

		Sl.No	Product	CAS No.	Kg Per annum	Used to Treat
		1	Pembrolizumab	1374853-91-4	100	Lung cancer, head and neck cancer, melanoma and cervical cancer.
		2	Denosumab	615258-40-7	20	Treatment of osteoporosis. It is also used to treat bone loss in men with prostate cancer and in women with breast cancer
3	Provide CAS No. of products along with	3	Ustekinumab	815610-63-0	20	Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis,
	product list.	4	Bevacizumab	216974-75-3	10	Colon cancer, lung cancer, ovarian cancer, glioblastoma, and renal-cell carcinoma.
		5	Adalimumab	331731-18-1	20	Spondylitis, rheumatoid arthritis, psoriasis,
		6	Aflibercept	862111-32-8	10	Metastatic colorectal cancer.
		7	Apixaban	503612-47-3	50	Stroke prevention · Deep vein thrombosis · Pulmonary embolism
		8	Trastuzumab	180288-69-1	20	Breast and Stomach Cancer
		9	Olaratumab	1024603-93-7	10	Solid Tumors



10						
12 Panitumumab 339177-26-3 10 Colon and rectum Cancer Rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and other inflammatory disease 14 Trastuzumab entansine 1018448-65-1 10 Breast Cancer 15 Infliximab 170277-31-3 10 Rheumatoid arthritis Ankylosing spondylitis · Psoriasis 16 Eculizumab 219685-50-4 10 Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis · spondylitis · Psoriasis 18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		10	Omalizumab	242138-07-4	10	Moderate to severe asthma
Rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and other inflammatory disease 14 Trastuzumab emtansine 1018448-65-1 10 Breast Cancer 15 Infliximab 170277-31-3 10 Rheumatoid arthritis Ankylosing spondylitis · Psoriasis 16 Eculizumab 219685-50-4 10 Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis · spondylitis · Psoriasis 18 Ziv-affilbercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		11	Palivizumab	188039-54-5	10	Respiratory syncytial virus (RSV) infections
Trastuzumab arthritis and other inflammatory disease 14 Trastuzumab emtansine 1018448-65-1 10 Breast Cancer 15 Infliximab 170277-31-3 10 Rheumatoid arthritis: Ankylosing spondylitis Psoriasis 16 Eculizumab 219685-50-4 10 Paroxysnal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis: spondylitis: Psoriasis 18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 11notuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		12	Panitumumab	339177-26-3	10	Colon and rectum Cancer
14 emtansine 1018448-65-1 10 Breast Cancer 15 Infliximab 170277-31-3 10 Rheumatoid arthritis: Ankylosing spondylitis Psoriasis 16 Eculizumab 219685-50-4 10 Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis: spondylitis: Psoriasis 18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 10 Acute lymphoblastic leukemia 23 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		13	Tocilizumab	375823-41-9	10	psoriasis, psoriatic arthritis and other
15 Infliximab 170277-31-3 10 Psoriasis 16 Eculizumab 219685-50-4 10 Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis · spondylitis · Psoriasis 18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 1notuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		14		1018448-65-1	10	Breast Cancer
16 Eculizumab 219685-50-4 10 atypical hemolytic uremic syndrome (aHUS), 17 Etanercept 185243-69-0 10 Rheumatoid arthritis · spondylitis · Psoriasis 18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 10 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 1174395-19-7 10 Inflammatory diseases.		15	Infliximab	170277-31-3	10	
18 Ziv-aflibercept 862111-32-8 10 Colorectal Cancer 19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		16	Eculizumab	219685-50-4	10	
19 Rituximab 174722-31-7 10 Rheumatoid arthritis, blood cancer 20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		17	Etanercept	185243-69-0	10	Rheumatoid arthritis · spondylitis · Psoriasis
20 Ramucirumab 947687-13-0 10 Lung Cancer, Stomach Cancer and Rectum 21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		18	Ziv-aflibercept	862111-32-8	10	Colorectal Cancer
21 Raxibacumab 5655451-13-0 10 Prophylaxis and treatment of inhaled anthrax. 22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		19	Rituximab	174722-31-7	10	Rheumatoid arthritis, blood cancer
22 Sarilumab 1189541-98-7 10 Severely active rheumatoid arthritis 23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		20	Ramucirumab	947687-13-0	10	Lung Cancer, Stomach Cancer and Rectum
23 Inotuzumab ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		21	Raxibacumab	5655451-13-0	10	Prophylaxis and treatment of inhaled anthrax.
23 ozogamicin 635715-01-4 10 Acute lymphoblastic leukemia 24 Brodalumab 1174395-19-7 10 Inflammatory diseases.		22	Sarilumab	1189541-98-7	10	Severely active rheumatoid arthritis
		23		635715-01-4	10	Acute lymphoblastic leukemia
25 Abatacept 332348-12-6 10 Rheumatoid arthritis		24	Brodalumab	1174395-19-7	10	Inflammatory diseases.
		25	Abatacept	332348-12-6	10	Rheumatoid arthritis



		26	Abciximab	143653-53-6	10	Blood Clots
		27	Agalsidase beta	104138-64-9	10	Genetical Disorders
		28	Alemtuzumab	216503-57-0	10	Blood cancer (Chronic lymphocytic
		20	Alemtuzumao	210303-37-0	10	leukemia) · Multiple sclerosis (MS)
		29	Alglucosidase alfa	420784-05-0	10	Treatment of Pompe disease (Glycogen
		2)	7 Hgracosidase aria	420704 03 0	10	storage disease type II)
		30	Alirocumab	1245916-14-6	10	High cholesterol in Adults
		31	Cetuximab	205923-56-4	10	Meta static Colorectal Cancer, Head & Neck
			Cetuxinao	203723 30 4	10	Cancer
		32	Pertuzumab	380710-27-5	10	Metastatic HER2 positive Breast cancer
		33	Somatropin	12629-01-5	10	Growth Factors
		34	Tenecteplase	191588-94-0	20	Prevents Thrombosis
			Total		520	
	Provide details of amount of carbon					
4	sequestered in their unit through	Not applie	cable, since it is a Green	nfield project		
	greenbelt/other modes, in case of expansion	r tot uppir		miera project		
	project					
5	Life structure and sustainability for carbon	Life struc	ture and sustainability	for carbon and water	r foot print is	s under progress and same will be detailed in Final
	and water foot print.	EIA repoi	rt.			
6	Detailed pollution Load estimation	Detailed p	pollution load statement	t for the proposed pro	oject is giver	in Section 2.6.2 of Chapter-2.
7	Transportation of Hazardous substance,	Noted,				
	effluents etc shall be carriedout through					



	authorized and GPS enable vehicles/Trucks only.	>	There will be no effluent transpose.	port outside the	ractives since v	we are proposing	, zero nquia disenarge (zr			
		>	> Harzardous waste will be collected and disposed through TNPCB Authorized							
			(TNWML, gummidipoondi) th	rough GPS enal	ole vehicles/Tru	cks only.				
		Hazar	dous waste Generation and M	I anagement						
		S.N o	Description of Waste	Category as per HWM Rules 2016	QTY/Annu m	Storage method	Method of disposal			
		1	Used /Spent Oil	5.1	1 KL		Will be collected and disposed through TNPCB Authorised recycler Will be collected and disposed through TNPCB Authorized TSDF			
Ca 8	Category of Hazardous Wastes shall be	2	Waste or residues containing oil	5.2	1Ton	All the generated Hazardous				
	mentioned in the EIA/EMP report and in presentation.	3	Discarded Containers/Bags	33.2	4Ton	waste will be stored on Concrete platform in	Will be collected and disposed through TNPCB Authorised recycler			
		4	MEE salt	37.3	16.5Ton (50 kg/day)	leak Proof Barrels in				
		5	ETP Sludge	35.3	3.3Ton (10 kg/day)	designated areas	Will be collected and disposed through			
		6	Off Specification Products (Doesn't Met by Specifications or standards)	28.3	2Ton		TNPCB Authorized TSDF			
		7	Expiry Products/Chemicals	28.5	1.5Ton					

				Fue	Fuel		Sta	ack Deta	ails			Emissions		
		S. N O.	Source	l Typ e	Quant ity (KL / Day)	No. of Stac k	Heig ht (m)	Tem p (°C)	Dia (m)	Exit Velo city (m/s)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
	Details of greenhouse gases and	1	DG-600 KVA*	HS D	2.88	1	30	200	0.2	9.5	7.43 E-03	6.93 E-03	1.05 E-01	2.26 E-02
9	emissions shall be provided.	2	DG-600 KVA*	HS D	2.88	1	30	200	0.2	9.5	7.43 E-03	6.93 E-03	1.05 E-01	2.26 E-02
		3	Boiler 1.5 TPH	HS D	2.509	1	30	210	0.3	10	3.41 E-03	4.70 E-04	6.62 E-02	1.66 E-02
						otal					1.83 E-02	1.43 E-02	2.76 E-01	6.17 E-02
		Note: There are no process emissions from the proposed manufacturing facility. *In ToR application, DG sets capacity - 2x350 kVA.												
		Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted (by considering 80% survival rate) in that around 50 trees was already planted. List of green belt species proposed is given in Table 4-24 .												
		Tentative Proposed green belt Species												
		S.No Scientific		Name	Com		Common Name		No of Trees		ees	Yearwise		ise
		1 Pongamia pinna			а	Pungai			300				1 st Year	
	Greenbelt shall be developed in the first	2	Thespesia	populn	ea	Poovarasu			300				2 nd Year	
10	year of the project and wind breaks shall be	3	Albizis leb	back		Vaagai			150				2 I cai	
	erected.	4	Cassia fisi			Sarakondai			150				3 rd Year	
	crected.	5	Lagestroe			Poo m			150					
		6	Pterocarp		supium	Venga				150			4th x z	
		7	Aegle Mar		1:	Vilvam			150				4 th Ye	ar
		8 Madhuca longifolia Iluppai							153					
					otal					1503				
	Trees will be planted in such a way that it will act as a windbreak.													

11	Study area map shall be overlapped with all the associated features	Google Image Showing Environmental Benshive Areas Lingend Project Ste Horizon Fire Standard Environmental Benshive Areas Lingend Project Ste Non-Modelinable Benshive And The Standard Stendard Stendard Man Not Backer Boundary Source 3Ct Toposheetb G44778, VI.17, 18816							
12	Emphasize on green fuels.	We currently have the plan to use HSD as a source of fuel for the boiler and DG sets, though we may switch to local LNG or LPG in the future as its availability in that area.							
13	The project from NCR shall not use Coal as fuel. Further, PP shall avoid use of Coal in the CPAs and elsewhere also if alternatives are available.	Not applicable, Since we are not using Coal as a fuel for any of our process/utilities.							
14	Provide the Cost-Benefit analysis with respect to the environment due to the project.	Not applicable, Since the proposed site is located within TANSIDCO (part of SIPCOT which have a valid EC) and land was already under the procession of project proponent.							
15	Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation	Omexa, in its commitment to environmental sustainability, has committed to develop of a greenbelt spanning							



measures also needs to be analyzed and submitted for further appraisal of the SEAC carbon sequestration, thus mitigating the impact of CO2 emissions. This section outlines the expected reduction in CO2 emissions due to this greenbelt and the environmental benefits it provides.

It proposed to develop a greenbelt of 5011.40 sq.m with the specified tree species, with a survival rate of 80% viz:

S.No	Scientific Name	Common Name	No of Trees	Yearwise		
1	Pongamia pinnata	Pungai	300	1 st Year		
2	Thespesia populnea	Poovarasu	300	2 nd Year		
3	Albizis lebback	Vaagai	150	2 Year		
4 Cassia fistula		Sarakondai	150	3 rd Year		
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year		
6	Pterocarpus Marsupium	Vengai	150			
7	Aegle Marmelos	Vilvam	150	4 th Year		
8	Madhuca longifolia	Iluppai	153			
	Total		1503			

Detailed Carbon dioxide reduction and sequestration technologies will be given in final EIA report

Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof shall also be included. Has the unit received any notice under the Section 5 of Environment (Protection) Act, 1986 or relevant Sections of Air and Water Acts? If so, details thereof and compliance/ATR to the notice(s) and present status of the case.

The company assures that there are no pending cases and the affidavit for No Litigation has been attached as **Annexure-14.**

16

	A tabular chart with index for point wise	
	compliance of above TORs and its details	,
17	needs to be submitted in the EIA/EMP	1
	Report.	

Noted

Specific Condition

1

Solvents used and recovery:

There is no solvents usage in the process. The chemicals which are used in the process minimize or eliminate the use or generation of substances hazardous to humans, animals, plants, and the environment.

Solvent recovery: Nil

Boilers and DG sets are the two main sources that contribute to emissions from the plant. Industry is proposed 1.5 TPH HSD fired boiler. Particulate matter (PM), Sulfur dioxide (SO2), Carbon monoxide (CO) and Oxides of Nitrogen (NOx) will be the major pollutants. Stack height of 30 m is proposed to meet the CPCB guidelines. Diesel about 0.12 KL/hr will be used at full operation load in the DG sets. Proposed DG sets are of 2 x 600 kVA DG set will be used as stand by during power failure.

Details on solvents to be used, measures for solvent recovery and for emissions control.

Proposed Stack emission details

			FU FUEL Stack Details							Emissions					
	SL. NO	SOURC E	EL TY PE	QUAN TITY (KL / Day)	No. of Stac k	Hei ght (m)	Dia (m)	Exit Veloci ty (m/s)	Tem p (°C)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)		
	1	DG-600	HS				0.1	9	200	7.43E-	6.93E-	1.05E-	2.26E-		
	1	KVA*	D	2.88	1	30	0.1		200	03	03	01	02		
	2	DG-600	HS	2.00	1	30	0.1	9	200	7.43E-	6.93E-	1.05E-	2.26E-		
	2	KVA*	D				0.1	9	200	03	03	01	02		
ıĺ	3	Boiler 1.5	HS	2.500	1	20	0.2	10	210	3.41E-	4.70E-	6.62E-	1.66E-		
	3	TPH	D	2.509	1	30	0.3	10	210	03	04	02	02		

				1.83E- 02	1.43E- 02	2.76E- 01	6.17E- 02					
		*In ToR application, DG sets capacity - 2x350 kVA. Control Measures • Stack height of 30 m is proposed for boiler. • 30m stack height will be provided for DG sets.										
2	Details of process emissions from the proposed unit and its arrangement to control.	 There are no process emissions from the proposed manufacturing facility. Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent. 										
		*	Ambient air quality data has been done for NH ₃ (Not from process but as NAAQ parameter), other propollutants like Chlorine, HCl, HBr, H ₂ S, HF, etc will not be emitted from proposed process:									ss specific
	Ambient air quality data should include VOC, other process-specific pollutants* like NH3*, chlorine*, HCl*, HBr*, H2S*, HF*,etc.,(*-as applicable)			NAAQ				Loca	tions			
3		Parameters	Conc.	Standa rds	Near Proje ct Site	Ural	Tindiva nam	Pelaku ppam	Vemp undi	Kolla r	Kattus iviri	pudur
					A1	A2	A3	A4	A5	A6	A 7	A8
		Ammonia (NH ₃) (μg/m ³)	Avg.	400(24 hour)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(L O Q10)	BLQ(L O Q10)	BLQ(L O Q10)	BLQ(LO Q10)	BLQ(L O Q10)	BLQ(L O Q10)
		Note: BLQ (Below Limit of Quantification); LOQ (Limit of Quantification)										
		Following measur	es will b	e followed	l for safe	handling	of chemica	ls				
		☐ Containers shall be labelled and level indicators shall be installed.										
	Work zone monitoring arrangements for	☐ Appropriate Safety signs shall be posted.										
4	hazardous chemicals	☐ Material safety	Data she	ets shall b	e made av	vailable.						
		☐ Chemical safety training shall be provided and an inventory of hazardous chemicals is maintained.										
		☐ Proper preventi	_	•								



			☐ Regular inspection and checking to assure risk control (properearthling, functioning of safety interlocks, bonding								
		transfe	transferring inclosed system and no spillages).								
		☐ Peri	odical health check s	hall be made mand	latory for work forceinvolved in handling of these chemicals as per th						
		provis	ions of theFactory Ac	et.							
		1	•		e detoxified and certifiedby production in -charge before sending t						
				inici inicis shan o	e detoxified and certifiedby production in charge before sending t						
			al area.								
		Liquid	l waste Managemen	•							
		S. No	Description	Proposed Quantity (KLD)	Final Disposal Points						
		Construction Phase									
		1	Sewage	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development						
	Detailed officers to the second column	Operation Phase									
5	Detailed effluent treatment scheme including segregation of effluent streams for units adopting 'Zero' liquid discharge	1	Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.						
		2	Sewage	4.6	Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt.						
		Techn	ical Specification of	STP (6 KLD) is at	tached as an Annexure-5a and Technical Specification of ETP (ZLD						
		is attac	s attached as an Annexure-5b.								

		Odour Control	
		There is no odour from the process since it is done through closed environment only. Possible source of odour will	
		be from ETP and STP area only.	
6	Action plan for odour control to be	Mitigation Measures The entire QC lab vent will be routed through wet srubber connected with stack of 3.0m.	
	submitted	Aromatic Plants such as Ocimum americanum (Local Name: Nai thulasi), Ocimum basilicum (local name:	
		Karpura thulasi & Thiruneetrupatchai), Ocimum gratissimum (Local Name: Elumichanthulasi) & Ocimum	
		tenuiflorum (local Name: Thulasi) etc., will be planted to minimize Odour generated from STP and ETP	
		area.	
	A copy of the Memorandum of	Not applicable, since it is a greenfield project.	
	Understanding signed with cement	However, hazardous waste generated from the process will be stored in a separate hazardous waste storage area (90	
7	manufacturers indicating clearly that they	days) and will be disposed as per the Hazardous and Other Wastes (Management and Trans boundary Movement)	
	co-process organic solid/hazardous waste	Amendment Rules, 2016.	
	generated		
	Authorization/Membership for the disposal	Solid/Hazardous waste will be disposed through TSDF and Authorization will be obtained from TNPCB as per	
8	of liquid effluent in CETP and	Norms.	
	solid/hazardous waste in TSDF, if any.		
9	Action plan for utilization of MEE/dryers	Salt from ATFD will be collected periodically and Stored and disposed thorugh Authorized TSDF as per HW	
9	salts.	Norms.	
1.0	Material Safety Data Sheet for all the		
10	Chemicals are being used/will be used.	Material safety data sheet for all the chemicals being used/will be used is attached as Annexure 4a .	
11	Authorization/Membership for the disposal	Authorization/Membership for the disposal of solid/hazardous waste in TSDF will be done after obtaining necessary	



	of solid/hazardous waste in TSDF.	clearance.		
12	Details of incinerator if to be installed	Not applicable, since there is no incinerator proposed within the site		
13	Risk assessment for storage and handling of hazardous chemicals/ solvents. Action plan for handling & safety system to be incorporated	Risk Assessment Study Report is attached as Annexure-7 .		
14	Arrangements for ensuring health and safety of workers engaged in handling of toxic materials.	M/s.Omexa provides a safe and healthy work environment to its employees by conducting annual medical check-ups for all the employees. The main objectives are: Maintenance and promotion of worker's health and working capacity. Improvement of working environment by following well-being program for its employees. Monitor the workplace to maintain industrial hygiene practices. Development of work culture in a direction which will support health and safety at work and thereby promoting positive social climate for smooth operation that will enhance productivity. Employees undergo annual health check-up. All personnel are provided with personal protective equipments individually as required. Operational phase General functions of the safety committee will be; 1. Conduct routine workplace inspections. 2. Provide Personal Protective Equipment. 3. Develop and implement safe work procedures and rules. 4. Provide on-going safety training & Enforce safety rules and appropriate discipline. 5. Promote safety awareness and reduce the potential for injury/loss.		

Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation measures also need to be analysed and submitted for further appraisal of the SEAC.

- 6. Identify workplace hazards.
- 7. Enforce of safety rules, measure safety performance & reduce frequency/severity of injuries.

Carbon Sequestration:

Omexa, in its commitment to environmental sustainability, has committed to develop of a greenbelt spanning 5011.40 square meters. This greenbelt is composed of a variety of native tree species that contribute significantly to carbon sequestration, thus mitigating the impact of CO2 emissions. This section outlines the expected reduction in CO2 emissions due to this greenbelt and the environmental benefits it provides.

It proposed to develop a greenbelt of 5011.40 sq.m with the specified tree species, with a survival rate of 80% viz:

S.No	Scientific Name	Common Name	No of Trees	Yearwise
1	Pongamia pinnata	Pungai	300	1 st Year
2	Thespesia populnea	Poovarasu	300	2 nd Year
3	Albizis lebback	Vaagai	150	2 Year
4	Cassia fistula	Sarakondai	150	3 rd Year
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year
6	Pterocarpus Marsupium	Vengai	150	
7	Aegle Marmelos	Vilvam	150	4 th Year
8	Madhuca longifolia	Iluppai	153	
	Total		1503	

Detailed Carbon dioxide reduction and sequestration technologies will be given in final EIA report

CHAPTER – 2 PROJECT DESCRIPTION

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2 PROJECT DESCRIPTION

2.1 Condensed description of those aspects of the project (based on project feasibility study), likely to cause environmental effects. Details should be provided to give clear picture of the following:

2.1.1 Type of Project

M/s. Omexa Formulary Private Limited has proposed a new manufacturing unit of Monoclonal antibodies with Capacity of 520 Kg/Annum& formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. This is a Greenfield Project for a manufacturing facility by a new entrepreneur in a declared TANSIDCO Industrial Park which is not linked with any other Project and is not interdependent with any of the project

The project is termed under schedule 5 (f) Bulk drugs & intermediates - Category "B1" as per the EIA Notification, 2006.

2.2 Need for the project

Proposed project is needed to serve the increasing demand of Monoclonal antibodies from local & export market. The proposed project to Manufacture various Mab's are based on the market surveys. Omexa intends to manufacture the monoclonal antibodies to treat cancer patients at an affordable cost and also export to global market from India. This will contribute to nation vision to become India as a global supplier of biological products and also generates local employment and skills set development in the field of Biotechnology. The total production capacity of the company will be as follows:

Table 2-1Monoclonal antibodies Product details (EC category)

Sl. No.	Description	Proposed
1	No of Products	34
2	Quantity of product (kg/Annum)	520

Table 2-2Formulations product details (Non EC category)

Sl. No.	Description	Proposed in Nos/Month
1	Prefilled Syringes	100000
2	Vials and Lyophilized vialis	64000
	Total	164000

2.3 Location of the project site

The proposed project has planned to establish as a new unit for manufacture of Monoclonal antibodies with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos /Month at Plot No. 27 &28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam

Daga 221

Taluk, Villupuram District and Tamil Nadu State. National Highway NH-77 (Tindivanam-Krishnagiri)/ NH179B (Chennai-Tindivanam-Harur)~0.37 km (S). Venmaniyattur village is located 1.16 km, N. The nearest town is Tindivanam ~ 2.0 km,ESE. Salient features of the project site and its Environment are given in **Table 2-3**.

Table 2-3 Salient features of the project site and its environs within 10 km radius

S. No	Particulars		Details		
1	Geographical Location	Centroid(12°15'10.79"N,79°37'5.11"E)			
2	Present Land Use	Industrial use Zone as per site located in TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District			
3	Nearest Railway Station	Nearest Railway Station - Tindivanam ~4.31 km (ESE)			
4	Nearest Airport	Puducherry Airport ~37.48 k	cm (SSE)		
5	Nearest Highway	NH-77(Tindivanam-Krishna Harur)~0.37 km (S)	giri)/NH179B	(Chennai-Tin	divanam-
		Villages	~Dist	Dire	Population
	Nearest habitation	Hamlet(Periyar Ninaivu Samathuvapuram- Pattanam)	0.74km	NE	240
7		Venmaniyattur	1.16km	N	1,350
	/Village	Pelakuppam	1.39km	SSE	1,610
		Vempundi	1.47km	SSW	1,843
		Pattanam	1.53km	ENE	2,896
		Tindivanam	2km	ESE	72,796
8	Nearest Town/ City	Nearest Town: Tindivanam ~ 2 km (ESE) Nearest City: Puducherry ~ 38 km (SSE)			
9	Densely populated area	Tindivanam(Pop~72,796) ~2	km (ESE)		
10	Inland water bodies	Sensitive place	s	~Dist (km)	Direc
			Waterbodies		
		Pelakuppam Lake		0.99	ESE
		Pattanam Lake		1.59	NNE
	Reserved Forests/	Buderi Lake		2.13	SSE
11	Protected Forests	Vempundi Lake		2.26	SW
		Melpakkam Lake		4.31	NE
		Avaiyurkuppam Lake		7.36	SW
		Kodiyam Lake		7.50	N
		Saram Lake		7.97	ENE

		Vilukkam Lake	8.21	W
		Elamangalam Lake	8.60	WNW
		Tondi Ar	8.75	SW
		Saram R	8.91	ENE
		Kondamur Ar	9.50	SE
		Olakkur Lake	10.75	NE
		Sankaraparani R/Varaha N	10.85	WSW
		Etanemali Lake	10.98	NW
		Ongur Channel	14.05	ENE
		Nallur Lake	14.68	N
		Reserved F	orest	
		Sevur RF	12.39	Е
12	Defense Installations	Nil within 15 km radius		•
	Archeologically			
13	Important places/	Monument	~Dist	Direc
	sites	Pallava Rock-cut shrine	7.79km	N
14	Interstate/ National Boundaries	Nil within 15 km radius		
15	Notified Wildlife Sanctuary/ Notified national parks/	Nil within 15 km radius		
13	Ecologically sensitive areas	TVII WIGHII 15 KIII IAGIUS		

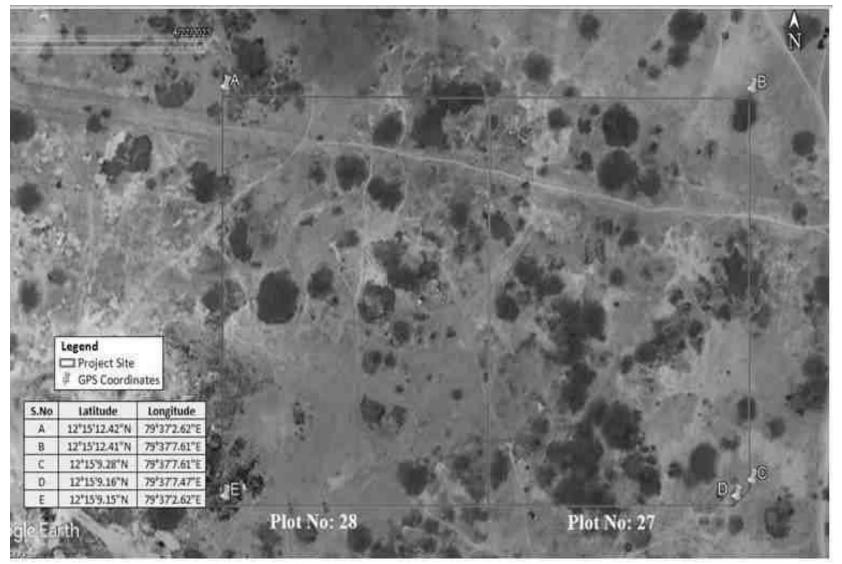


Figure 2-1 Satelite image of project site with GPS coordinates

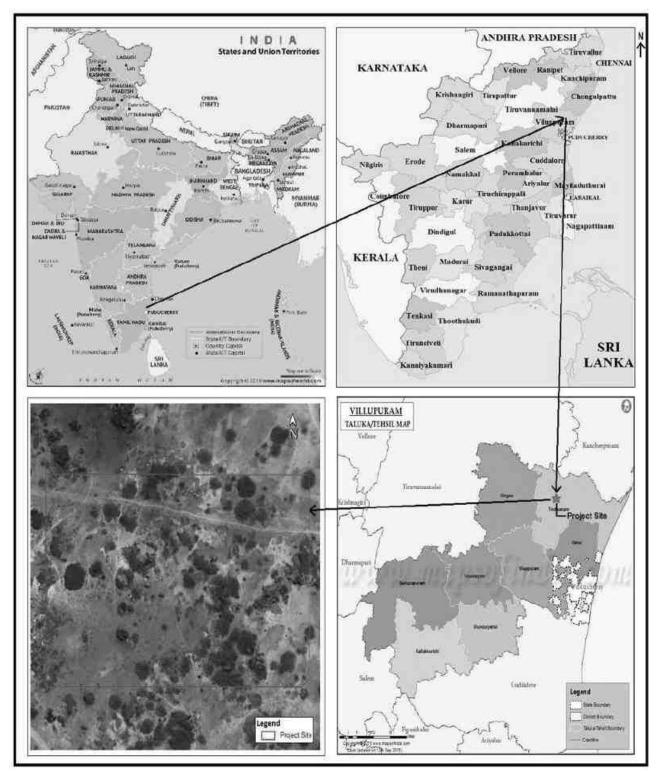


Figure 2-2Index map of the Project site

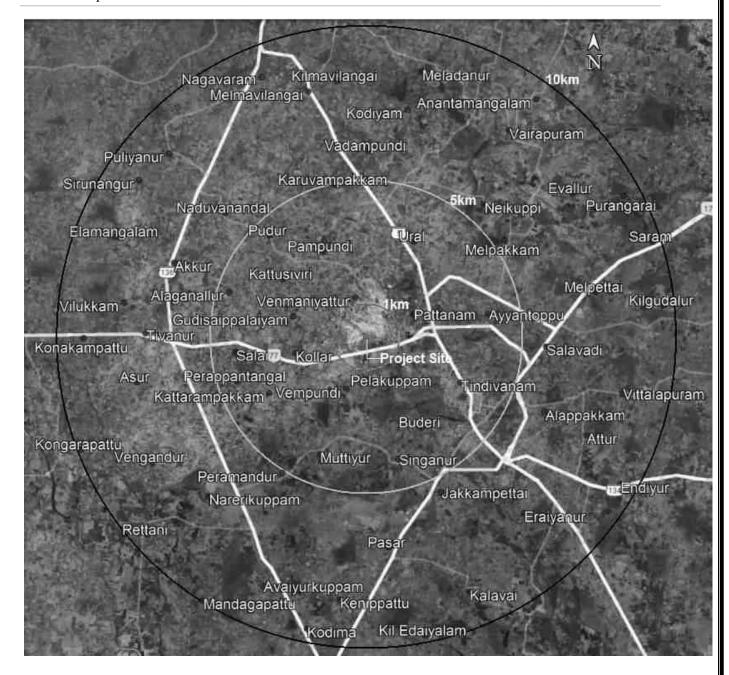


Figure 2-3Google image of project site (0-10 km radius)



Figure 2-4Google image of project site (0-5 km radius)



Figure 2-5Google image of project site (0-1 km radius)

2.3.1.1 Land Requirement

The total land area is 15147.40 Sq.m. The land area break-up details are provided in **Table 2-4** and builtup area is given in **Table 2-5**. The layout is attached as **Annexure-9**.

Table 2-4 Land Area Breakup

Items	Area in Sq.m	Area in Acres	%
Ground coverage (plinth)	6472.00	1.599	42.73
Greenbelt	5011.40	1.239	33.08
Open Space	144.00	0.036	0.95
Road & Parking	3520.00	0.869	23.24
Total	15147.40	3.743	100

Table 2-5 Tentative Builtup Area

Table 2.5 Tentauve Buntup Area		
Items	Area in Sq.m	
Manufacturing block	13370.00	
R&D Block	1950.00	
Admin/QC/QA block/reception	2400.00	
Pilot plant + Dining	3875.00	
Security Block	42.00	
Creche, OHC & Utilities	600.00	
Total	22237.00	



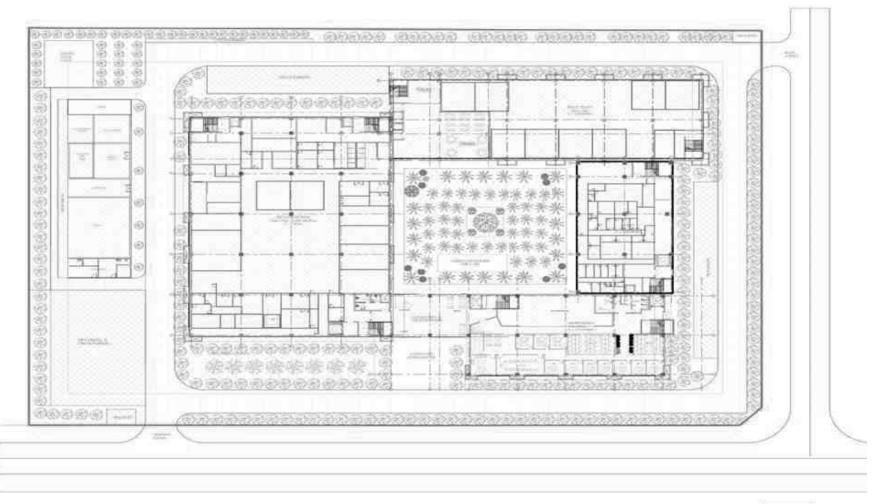




Figure 2-6 Proposed Plant-Master Layout

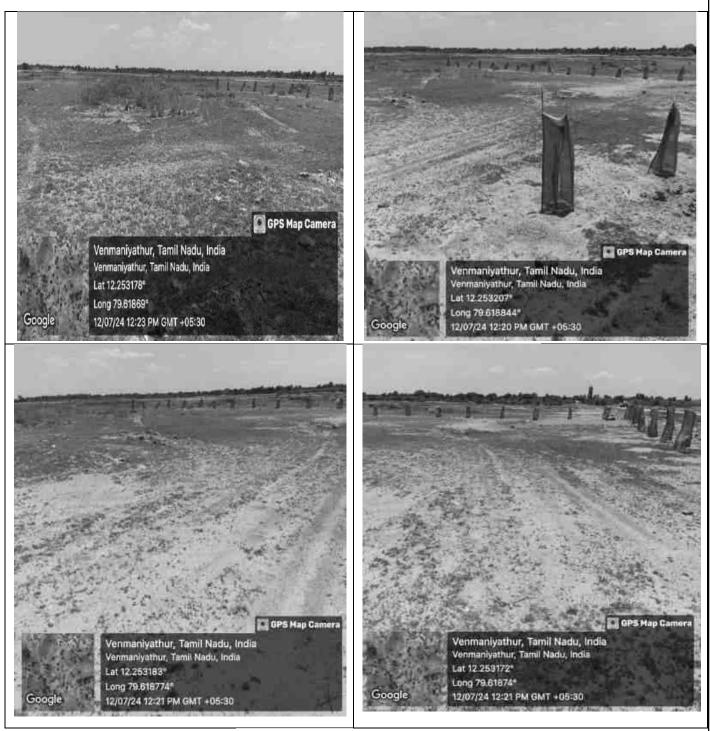


Figure 2-7 Site Photographs dated: 12.07.2024

2.3.1.2 Justification of Site Selection

No Alternative site was selected since the Omexa selected the plot at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State

Specific Site Selection Crietria of the Unit have been given below:

- 1. It is allocated within Notified TANSIDCO industrial Park.
- 2. Site is well connected by road (~0.37km, S), railways (~4.31 Km, ESE) and Airway (~37.48 km, SSE)
- 3. Sufficient land is available within the TANSIDCO IP.
- 4. 100% assurance of water & power supply by TANSIDCO.

2.4 Size or magnitude of operation

The proposed project will involve manufacturing of Monoclonal antibodies with Capacity of 520 kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/**Month**. The list of proposed products and their respective quantities are given in **Table 2-6**.

Table 2-6List of Proposed products with quantity

Monoclonal antibodies (drug substances)

Sl.No	Product	CAS No.	Kg Per annum	Used to Treat
1	Pembrolizumab	1374853-91-4	100	Lung cancer, head and neck cancer, melanoma and cervical cancer.
2	Denosumab	615258-40-7	20	Treatment of osteoporosis. It is also used to treat bone loss in men with prostate cancer and in women with breast cancer
3	Ustekinumab	815610-63-0	20	Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis,
4	Bevacizumab	216974-75-3	10	Colon cancer, lung cancer, ovarian cancer, glioblastoma, and renal-cell carcinoma.
5	Adalimumab	331731-18-1	20	Spondylitis, rheumatoid arthritis, psoriasis,
6	Aflibercept	862111-32-8	10	Metastatic colorectal cancer.
7	Apixaban	503612-47-3	50	Stroke prevention · Deep vein thrombosis · Pulmonary embolism
8	Trastuzumab	180288-69-1	20	Breast and Stomach Cancer
9	Olaratumab	1024603-93-7	10	Solid Tumors
10	Omalizumab	242138-07-4	10	Moderate to severe asthma
11	Palivizumab	188039-54-5	10	Respiratory syncytial virus (RSV) infections
12	Panitumumab	339177-26-3	10	Colon and rectum Cancer
13	Tocilizumab	375823-41-9	10	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and other inflammatory disease



14	Trastuzumab emtansine	1018448-65-1	10	Breast Cancer
15	Infliximab	170277-31-3	10	Rheumatoid arthritis Ankylosing spondylitis Psoriasis
16	Eculizumab	219685-50-4	10	Paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS),
17	Etanercept	185243-69-0	10	Rheumatoid arthritis · spondylitis · Psoriasis
18	Ziv-aflibercept	862111-32-8	10	Colorectal Cancer
19	Rituximab	174722-31-7	10	Rheumatoid arthritis, blood cancer
20	Ramucirumab	947687-13-0	10	Lung Cancer, Stomach Cancer and Rectum
21	Raxibacumab	5655451-13-0	10	Prophylaxis and treatment of inhaled anthrax.
22	Sarilumab	1189541-98-7	10	Severely active rheumatoid arthritis
23	Inotuzumab ozogamicin	635715-01-4	10	Acute lymphoblastic leukemia
24	Brodalumab	1174395-19-7	10	Inflammatory diseases.
25	Abatacept	332348-12-6	10	Rheumatoid arthritis
26	Abciximab	143653-53-6	10	Blood Clots
27	Agalsidase beta	104138-64-9	10	Genetical Disorders
28	Alemtuzumab	216503-57-0	10	Blood cancer (Chronic lymphocytic leukemia) · Multiple sclerosis (MS)
29	Alglucosidase alfa	420784-05-0	10	Treatment of Pompe disease (Glycogen storage disease type II)
30	Alirocumab	1245916-14-6	10	High cholesterol in Adults
31	Cetuximab	205923-56-4	10	Meta static Colorectal Cancer, Head & Neck Cancer
32	Pertuzumab	380710-27-5	10	Metastatic HER2 positive Breast cancer
33	Somatropin	12629-01-5	10	Growth Factors
34	Tenecteplase	191588-94-0	20	Prevents Thrombosis
	Total		520	

Formulation products (drug products)

Filling Format	Quantity (Numbers per Month)
Prefilled Syringes	1,00,000
Vials	40,000
Lyophilised Vials	24,000

MSDS for the proposed products are provided in Annexure-4b.

2.5 Proposed Schedule for approval and implementation

The estimation of cost break up for the proposed project was given in below



Table 2-7Proposed Project Cost breakup

S.No	Description	Cost (Crores)
1	Land cost	4.00
2	Building	20.00
3	Plant & Machinery	42.00
4	ETP/STP/Utilities	20.00
5	Other Assets	9.00
Total	(Crores)	95

GFA certificate for the proposed project is attached as an Annexure-16.

Tendative schedule for Project approval and Implementation

Construction work for the plant would start subsequent to receipt of Environmental Clearance (EC) and Consent to Establish (CTE) from State Pollution Control Board. Tentatively, work is expected to start and likely to be commissioned within 12 months after receipt of all the clearance from different statutory authorities.

Table 2-8Tentative schedule for approval and implementation

Activities	Timeline
Environmental Clearance from SEIAA, TN	October 2024
Consent to Establish from TNPCB	November 2024
Construction activities	December 2024
Operation of the unit	December 2025 (Commissioning)



2.6 Project description including drawings showing project layout, components of projected Schematic representations of the feasibility drawings which give information important for EIA purpose

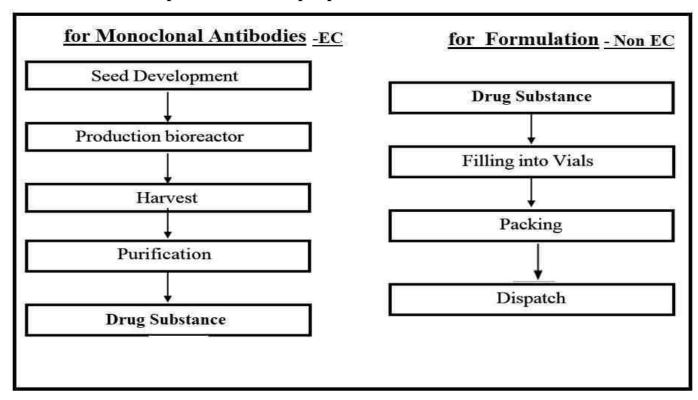


Figure 2-8General Manufacturing Process flowchart

2.6.1 Proposed Products-Detailed Manufacturing Process, Chemical Reaction & Material Balance

Mammalian Cell culture Process

Mammalian Expression system is Chinese Hamster Ovary (CHO) cells and theprocess time considered is 20 days/batch. In the manufacturing of biopharmaceuticals from mammalian cells consists two stages those are upstream and downstream processes.

a. Upstream Process

The inoculum generation is initiated with thawing of a vial from a cell bank. The cells from the vial are expanded using shake flasks and seed bioreactors to obtain the desired amount of inoculum for starting a production bioreactor. The mode of running the bioreactor is fed batch or perfusion. The cells are allowed to grow for few days in batch mode after which feeds of nutrients like glucose, amino acids, vitamins and salts are fed in the bioreactor on different days. Thebioreactor is harvested at the end of the fermentation and taken for downstream.



b. Downstream Process

Cell clarification: Continuous centrifugation followed by depth filtration is to separate the cells from the fermentation media, the supernatant of which will be clarified by depth filtration.

Capture by affinity chromatography: Target protein is among thousands of impurities will be specially retained over the affinity resin leaving impurities as unbound.

Virus inactivation: Inactivation of different viruses if any will be done in a sterilebag at a lower pH and probably at a controlled temperature between 2 and 25 degC.

Purification by ion exchange chromatography (IEC): The related impurities will be the next level of contaminants that needs to be separated from the target protein, ion exchange chromatography does the job be at an-ion or cat-ion exchange chromatography.

Virus removal by Nano-filtration: It is to remove the all forms of virus so there are no viral loads basically in the active pharmaceutical intermediate.

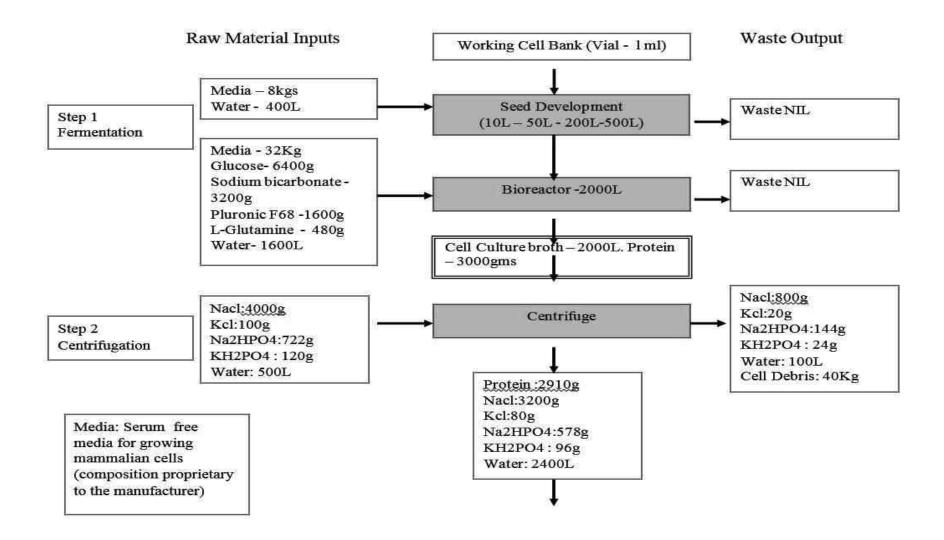
Concentration/ Buffer exchange by tangential flow filtration (TFF): It is critical to bring in the product to the required pre/formulation buffer which ensures the stability.

Final sterile filtration: This filtration is required to claim that the product is sterile and is qualified for fill finish requirement. Samples are collected at different stages during the batch and sent for analytical testing.

After final sterile filtration, the product will be sent to formulation unit.

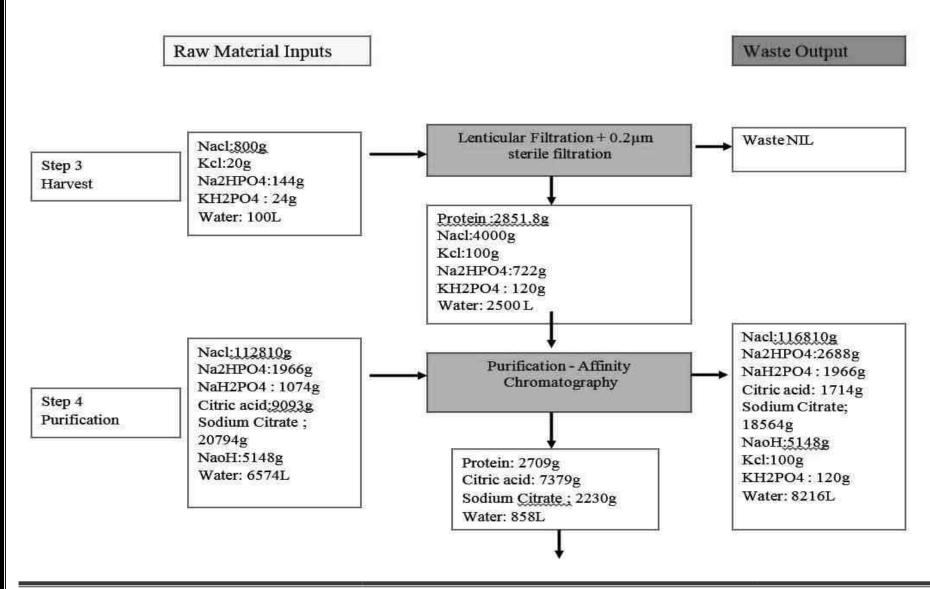


PROCESS MATERIAL BALANCE CHART

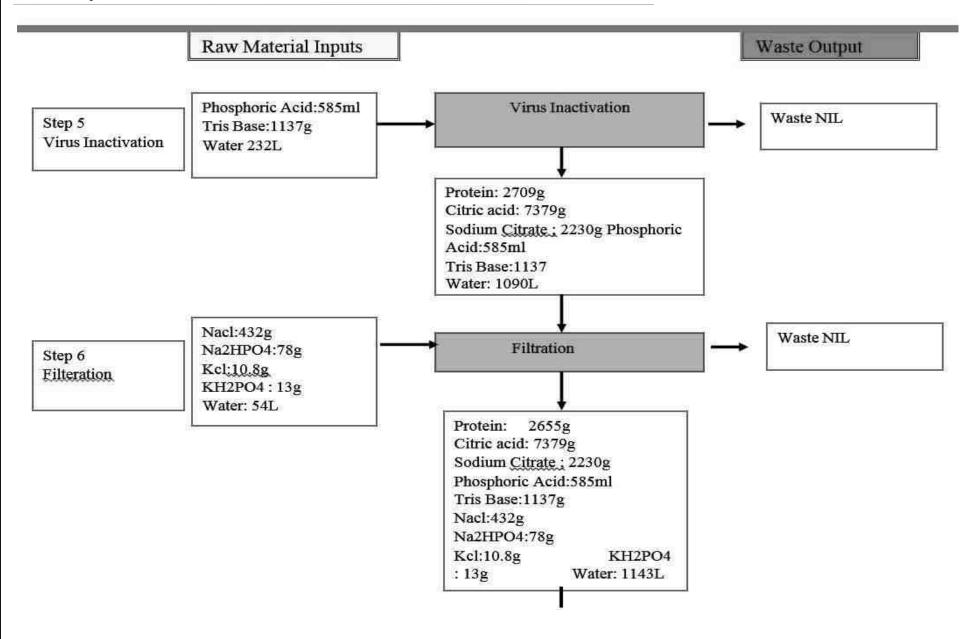




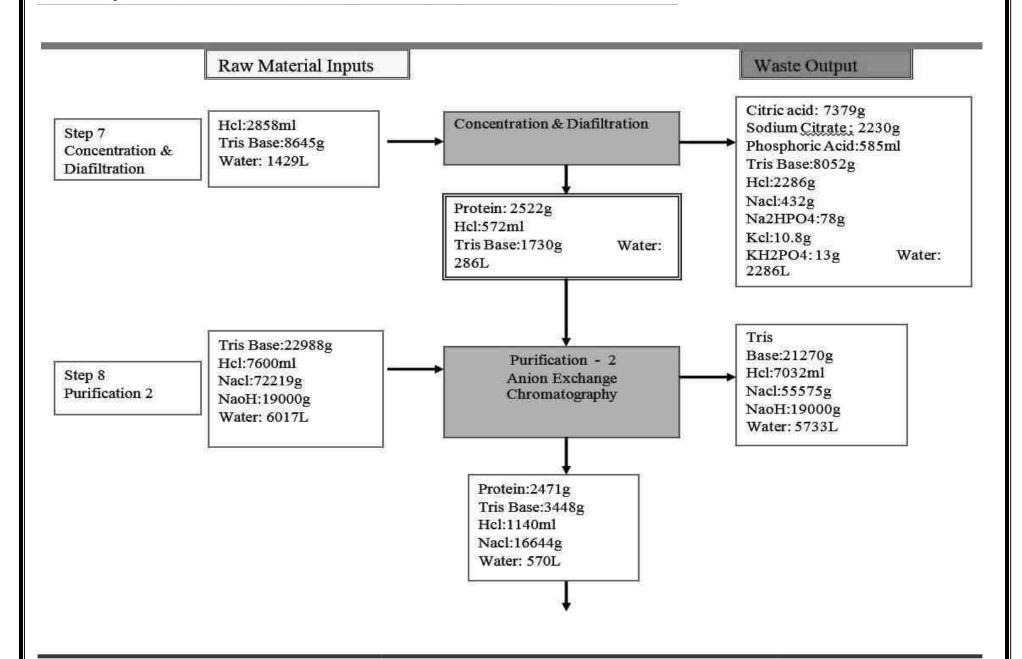
PROCESS MATERIAL BALANCE CHART

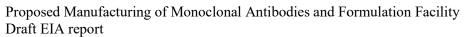




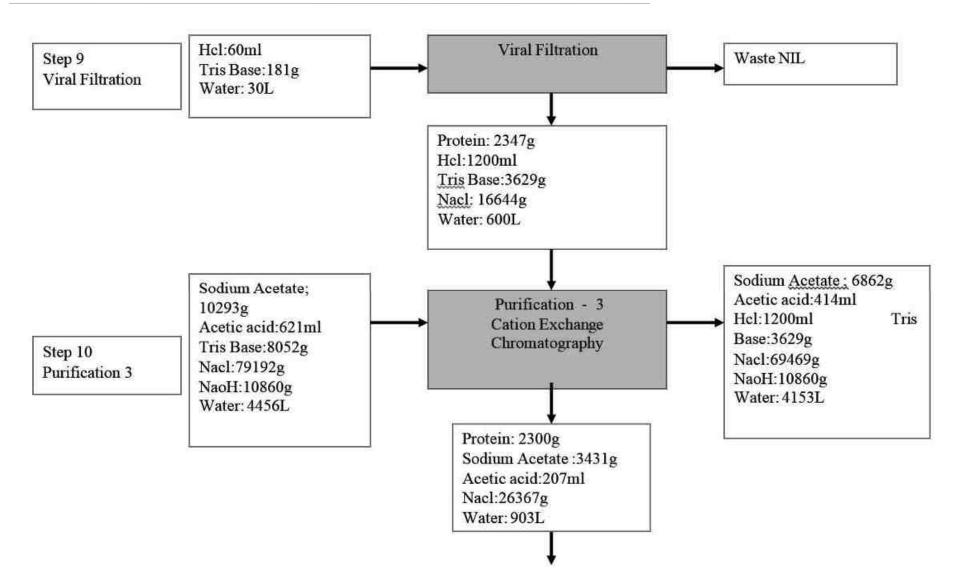




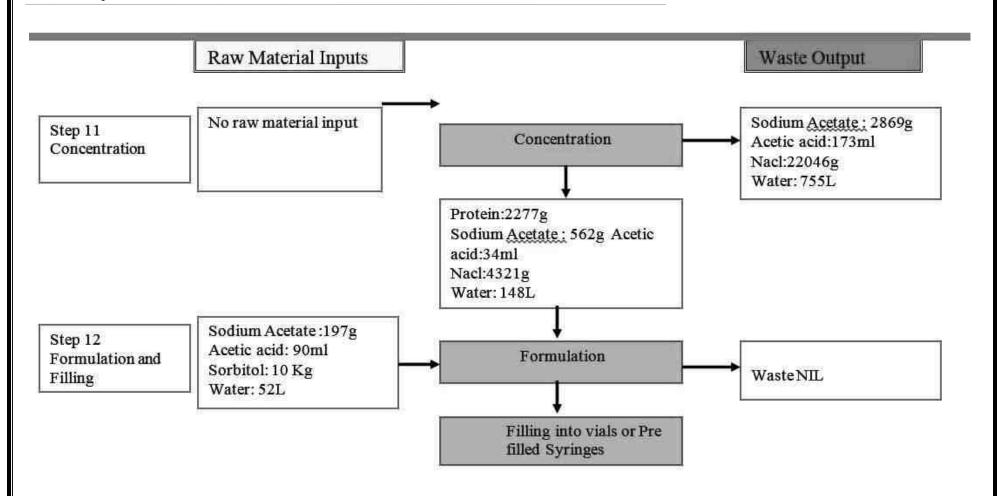




H/01/2024/CON/065 RP003 - R2









H/01/2024/CON/065 RP003 - R2

Table 2-9 Material Balance (for Pembrolizumab, Omalizumab, Palivizumab&Ramucirumab)

Raw Material	UOM	Total Input	Raw Material	UOM	Total Output	Output Destination		In Product
1ml Vial from WCB	ml	1	Protein (Product)	g	2400	Product	2400	-
Sodium chloride	g	31653	Sodium chloride	g	31221		432	As Buffer in the Product
Potassium Chloride	g	130.8	Potassium Chloride	g	130.8		0	-
Sodium phosphate	g	1074	Sodium phosphate	g	1074		0	-
Di Sodium phosphate	g	2910	Di Sodium phosphate	g	2910		0	-
Potassium phosphate	g	157	Potassium phosphate	g	157		0	-
Citric acid	g	9093	Citric acid	g	9093		0	-
Sodium Citrate	g	20794	Sodium Citrate	g	20794	- -	0	-
Tris Base	g	41003	Tris Base	g	41003		0	-
Sodium Acetate	g	10293	Sodium Acetate	g	9731	Solid Waste after Treatment and disposed as Salt	562	As Buffer in the Product
Sodium Hydroxide	g	25008	Sodium Hydroxide	g	25008	and disposed as Sait	0	-
Glucose	g	6400	Glucose	g	6400		0	-
Sodium bicarbonate	g	3200	Sodium bicarbonate	g	3200		0	-
Pluronic F68	g	1600	Pluronic F68	g	1600		0	-
Ethanol	ml	141	Ethanol	ml	141		0	-
Phosphoric Acid	ml	985	Phosphoric Acid	ml	985		0	-
Acetic Acid	ml	651	Acetic Acid	ml	651		0	-
Hydrochloric acid	ml	10696	Hydrochloric acid	ml	10696		0	-
Total		165788.8	Total		164794.8		994	



Table 2-10 Material Balance (for Trastuzumab, Trastuzumab emtansine, Denosumab, Eculizumab, Raxibacumab, Agalsidase beta, Alglucosidase alfa, Pertuzumab, Somatropin&Tenecteplase)

Product: Trastuz somatropin&Tenectep	,	Trastuzuma	ıb	emtansine, Denosum	ab,	Eculizumab,	Raxibacumab, Agalsidase beta,	Alglucosi	dase alfa, Pertuzumab,
Raw Material	UOM	Total Input		Raw Material	UOM	Total Output	Output Destination		In Product
1ml Vial from WCB	ml	1		Protein (Product)	g	2800	Product	2800	-
Sodium chloride	g	36540		Sodium chloride	g	36370		170	As Buffer in the Product
Potassium Chloride	g	171		Potassium Chloride	g	171		0	-
Nickel Sulphate	g	2300		Nickel Sulphate	g	2300			-
Sodium phosphate	g	2000		Sodium phosphate	g	2000		0	-
Di Sodium phosphate	g	3200		Di Sodium phosphate	g	3200		0	-
Potassium phosphate	g	140		Potassium phosphate	g	140		0	-
Citric acid	g	8830		Citric acid	g	8830		0	-
Sodium Citrate	g	19800		Sodium Citrate	g	19800		0	-
Tris Base	g	41003		Tris Base	g	41003	Solid Waste after Treatment and	0	-
Sodium Acetate	g	8500		Sodium Acetate	g	8430	disposed as Salt	70	As Buffer in the Product
Sodium Hydroxide	g	25008		Sodium Hydroxide	g	25008		0	-
Glucose	g	3400		Glucose	g	3400		0	-
Sodium bicarbonate	g	1600		Sodium bicarbonate	g	1600		0	-
Pluronic F68	g	990		Pluronic F68	g	990		0	-
Ethanol	ml	121		Ethanol	ml	121		0	-
Phosphoric Acid	ml	1400		Phosphoric Acid	ml	1400		0	-
Acetic Acid	ml	651		Acetic Acid	ml	651		0	-
Hydrochloric acid	ml	9600		Hydrochloric acid	ml	9600		0	-
Total		165254		Total		165014		240	



Table 2-11 Material Balance (for Bevacizumab, Ustekinumab, Panitumumab, Ziv-aflibercept, Aflibercept, Alirocumab & Cetuximab)

Product : Bevacizum	ab, Usto	ekinumab, P	anitumumab, Ziv-aflibe	rcept, A	Aflibercept, A	lirocumab & Cetuximab		
Raw Material	UOM	Total Input	Raw Material	UOM	Total Output	Output Destination		In Product
1ml Vial from WCB	ml	1	Protein (Product)	g	2600	Product	2600	-
Sodium chloride	g	38700	Sodium chloride	g	38250		450	As Buffer in the Product
Potassium Chloride	g	190	Potassium Chloride	g	179		11	As Buffer in the Product
Sodium phosphate	g	2100	Sodium phosphate	g	2100		0	-
Di Sodium phosphate	g	2500	Di Sodium phosphate	g	2500		0	-
Potassium phosphate	g	232	Potassium phosphate	g	232		0	-
Citric acid	g	7800	Citric acid	g	7800		0	-
Sodium Citrate	g	23100	Sodium Citrate	g	23100		0	-
Tris Base	g	36200	Tris Base	g	36200		0	-
Sodium Acetate	g	9800	Sodium Acetate	g	9238	Solid Waste after Treatment and disposed as Salt	562	As Buffer in the Product
Sodium Hydroxide	g	30000	Sodium Hydroxide	g	30000	disposed as Sait	0	-
Glucose	g	8900	Glucose	g	8900		0	-
Sodium bicarbonate	g	4300	Sodium bicarbonate	g	4300		0	-
Pluronic F68	g	800	Pluronic F68	g	800		0	-
Ethanol	ml	300	Ethanol	ml	300		0	-
Phosphoric Acid	ml	890	Phosphoric Acid	ml	890		0	-
Acetic Acid	ml	540	Acetic Acid	ml	540		0	-
Hydrochloric acid	ml	8000	Hydrochloric acid	ml	8000		0	-
Total		174352	Total		173329		1023	



Table 2-12 Material Balance (for Adalimumab, Tocilizumab, Infliximab, Etanercept, Rituximab, Sarilumab & Abatacept)

Raw Material	UOM	Total Input	Raw Material	UOM	Total Output	Output Destination		In Product
1ml Vial from WCB	ml	1	Protein (Product)	g	2200	Product	2200	-
Sodium chloride	g	25700	Sodium chloride	g	25640		60	As Buffer in the Product
Potassium Chloride	g	2100	Potassium Chloride	g	1949		151	As Buffer in the Product
Nickel Sulphate	g	3893	Nickel Sulphate	g	3893		0	-
Sodium phosphate	g	1074	Sodium phosphate	g	1074		0	-
Di Sodium phosphate	g	2910	Di Sodium phosphate	g	2910		0	-
Potassium phosphate	g	300	Potassium phosphate	g	300		0	-
Citric acid	g	8900	Citric acid	g	8900		0	-
Sodium Citrate	g	20000	Sodium Citrate	g	20000		0	-
Tris Base	g	34500	Tris Base	g	34500	Solid Waste after Treatment and	0	-
Sodium Acetate	g	10000	Sodium Acetate	g	9438	disposed as Salt	562	As Buffer in the Product
Sodium Hydroxide	g	34000	Sodium Hydroxide	g	34000		0	-
Glucose	g	9300	Glucose	g	9260		40	As Buffer in the Product
Sodium bicarbonate	g	3200	Sodium bicarbonate	g	3200		0	-
Pluronic F68	g	1600	Pluronic F68	g	1600		0	-
Ethanol	ml	230	Ethanol	ml	230		0	-
Phosphoric Acid	ml	1355	Phosphoric Acid	ml	1355		0	-
Acetic Acid	ml	300	Acetic Acid	ml	300		0	-
Hydrochloric acid	ml	5690	Hydrochloric acid	ml	5690		0	-
Total		165052	Total		164239		813	



Table 2-13 Material Balance (for Apixaban, Olaratumab, Inotuzumab ozogamicin, Brodalumab, Abcixima & Alemtuzumab)

Product : Apixaban,	Olaratı	ımab, Inotu	zumab ozogamicin, Bro	daluma	ıb, Abcixima	& Alemtuzumab		
Raw Material	UOM	Total Input	Raw Material	UOM	Total Output	Output Destination		In Product
1ml Vial from WCB	ml	1	Protein (Product)	g	2500	Product	-	-
Sodium chloride	g	31653	Sodium chloride	g	31221		432	As Buffer in the Product
EDTA	g	2700	EDTA	g	2700		0	-
Potassium Chloride	g	130.8	Potassium Chloride	g	130.8		0	-
Sodium phosphate	g	1074	Sodium phosphate	g	1074		0	-
Di Sodium phosphate	g	2910	Di Sodium phosphate	g	2910		0	-
Potassium phosphate	g	157	Potassium phosphate	g	157		0	-
Citric acid	g	9093	Citric acid	g	9093		0	-
Sodium Citrate	g	20794	Sodium Citrate	g	20794		0	-
Tris Base	g	41003	Tris Base	g	41003	Solid Waste after Treatment and	0	-
Sodium Acetate	g	10293	Sodium Acetate	g	9731	disposed as Salt	562	As Buffer in the Product
Sodium Hydroxide	g	25008	Sodium Hydroxide	g	25008		0	-
Glucose	g	6400	Glucose	g	6400		0	-
Sodium bicarbonate	g	3200	Sodium bicarbonate	g	3200		0	-
Pluronic F68	g	1600	Pluronic F68	g	1600		0	-
Ethanol	ml	141	Ethanol	ml	141		0	-
Phosphoric Acid	ml	985	Phosphoric Acid	ml	985		0	-
Acetic Acid	ml	651	Acetic Acid	ml	651		0	-
Hydrochloric acid	ml	10696	Hydrochloric acid	ml	10696		0	-
Total		168488.8	Total		167494.8		994	



2.6.2 Pollution Load Statement

a) Water and Wastewater Generation

Water Consumption, Waste Water Generation:

S. No	Heads	Fresh Water Consumption (KLD)	Water Recycled & Reused (KLD)	Water Consumption (KLD)	Water Loss (KLD)	Waste Water Generation (KLD)
1	Pre-Treatment System for process & Lab	65	0	65	0	55.5
2	Cooling tower	0	37	37	5	2
3	Boiler	0	7	7	5	2
4	Greenbelt	0	18	18	18	0
5	Domestic	5.4	0	5.4	0.8	4.6
	Total	70.4	62	132.4	28.5	64.1

Reference-Raw water analysis:

S.No	Description	KLD	pН	COD (mg/l)	BOD (mg/l)	TDS (mg/l)	TSS (mg/l)
1	Raw Water	6.5	6.0-8.0	15-20	3-5	300-500	100-200

Effluent (before and after treatment):

	Quantity (KLD)		Parameter						
Description	Quantity (IXLD)	рН	TSS(mg/l)	TDS(mg/l)	BOD(mg/l)	COD(mg/l)			
ETP feed	59.5	6.0-8.0	200-400	800-1000	1300-1500	4000-4500			
ETP Outlet (Permeate)	59.5	6.0-8.0	<5	800-1000	<20	<200			
RO Permeate	48	5.0-6.0	<5	<100	<20	<200			
RO reject	11.5	7.0-8.0	<5	<5000	<20	<200			

Sewage (before and after treatment):

	Quantity(VI D)	Parameter						
Description	Quantity(KLD)	pН	TSS(mg/l)	TN(mg/l)	BOD(mg/l)	COD(mg/l)		
Domestic	4.6	6.0-8.0	200-300	40-60	250-300	400-500		
STP treated sewage	4.6	6.5-8.5	20	20	<10	50		



b) Solid Waste Management Solid waste (municipal)

S.No	Waste	Proposed (kg/day)	Total (kg/day)	Method of disposal					
Operations Phase (120 Nos)									
1	Organic	32.4	32.4	To Local TANSIDCO bins					
2	Inorganic	21.6	21.6	To TNPCB Authorized Recyclers					
3	STP Sludge	0.6	0.6	Used as a manure for greenbelt.					
Total	•	54.6	54.6	-					
Constru	Construction Phase (30 Nos): 13.5 Kg/day (Disposal through local TANSIDCO bins)								

Note: As per CPHEEO norms - 0.45kg/capita/day

Other waste:

Item Name	Proposed (MT/year)	Mode of disposal
Cartons, Paper and stationary scrap	0.5	Toscrapvendors

Hazardous waste:

S.No	Description of Waste	Category as per HWM Rules 2016	QTY/Annum	Storage method	Method of disposal
1	Used /Spent Oil	5.1	1 KL	A11.1	Will be collected and disposed through TNPCB Authorised recycler
2	Waste or residues containing oil	5.2	1Ton	All the generated Hazardous waste	Will be collected and disposed through TNPCB Authorized TSDF
3	Discarded Containers/Bags	33.2	4Ton	will be stored on Concrete	Will be collected and disposed through TNPCB Authorised recycler
4	MEE salt	37.3	16.5Ton (50 kg/day)	Proof Barrels in designated areas	Will be collected and disposed
5	ETP Sludge	35.3	3.3Ton (10 kg/day)	designated areas	through TNPCB Authorized TSDF



6	Off Specification Products (Doesn't Met by Specifications or standards)	28.3	2Ton
7	Expiry Products/Chemicals	28.5	1.5Ton

c) Air pollution Source

Point source (utility and Process):

Point emission source	APC measures	Stack height from GL (in M)	Fuel Type	Consumption
DG Set 2 x 600 KVA*	Common Stack	30	HSD	0.12 KL/Hr
Boiler 1 x1.5 TPH	Stack	30	HSD	2.509 KLD

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Process emission: There are no process emissions from the proposed manufacturing facility.

Point emission source	APC measures	Stack height (in m)	Fuel type	Consumption
QC Lab Vent	Wet Scrubber with stack	3.0 (AGL)	N/A	N/A

Proposed Stack emission details

			FUEL	Stack Details					Emissions			
SL. NO	SOURCE	FUEL TYPE	QUANTIT Y (KL / Day)	No. of Stack	Height (m)	Dia (m)	Exit Velocity (m/s)	Temp (°C)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
1	DG-600 KVA*	HSD	2.00	1	20	0.1	9	200	4.34E-03	4.04E-03	6.11E-02	1.32E-02
2	DG-600 KVA*	HSD	2.88	1	30	0.1	9	200	4.34E-03	4.04E-03	6.11E-02	1.32E-02
3	Boiler 1.5 TPH	HSD	2.509	1	30	0.3	10	210	3.41E-03	4.70E-04	6.62E-02	1.66E-02
			To	tal					1.21E-02	8.55E-03	1.88E-01	4.29E-02

Note: *In ToR application, DG sets capacity - 2x350 kVA.



2.6.3 Infrastructure facilities

Total factory foot print is divided into various sections like Production Blocks, Engineering, Warehouses, Administration, and Toilets etc. The site layout is enclosed as **Annexure 9**respectively.

2.6.3.1 Plant and Machinery & utilities

The Plant Facilities have been designed and set up with the objective to carry out almost all chemical reactions and processes. The list of Plant and Machineries for proposed project are given in below

Table 2-14List of proposed utilities within the facility

S.No	Description	Working	Standby	Total	Capacity
1	Compressor	2	0	2	2*200 CFM
2	Chillers	2	1	3	600 TR (3*200 TR)
3	Cooling Tower	1	0	1	750 TR
4	Gas bank(O ₂ , CO ₂ & N ₂)	15	15	30	15+15 cylinder
5	Boiler	1	0	1	1x1500 kg/hr
6	HSD yard (underground)	1	0	1	20 KL Capacity

Table 2-15List of Equipment in proposed- (for Monoclonal & Formulation production and Quality Control Lab)

S.No	Room Name	Equipment	Capacity	Quantity
		Bulk Drugs (drug Substances)		
1	Cell Bank	Cell Bank Storage system (LN2)	~ 50L	1
1	Cell Balik	LN2 Supply system	~ 20L	1
		Bio Welder	-	1
		Bio Sealer	-	1
		Water bath or Dry bath	-	1
	Pre culture Room	Shaker flasks (SF125, SF500, SF1000)	-	As required
		Micro Pipette	-	2
		Pipet boy	-	2
		Biosafety Cabinet	6 feet	1
2		Table top batch centrifuge	-	1
		CO2 Shaker Incubator	~ 500L	2
		Analytical balance with antivibration table	-	1
		Weighing balance	-	1
		Dual Refrigerator (2-8 deg C)	~ 500L	1
		Peristaltic pump	-	1
		Wave Bioreactor 5 L	5L	1
		Wave Bioreactor 20 L	20 L	1
		SUB 200 L	200L	1
3	Cell culture Room	SUB 1000 L	1000L	1
		SUB 2000 L	2000L	1
4	Harvest	Depth Filtration skid	~ 30 m2	1



		Transfer Pump / Peristaltic pump	-	1
		Floor Scale		1
		Chromatography System -1	600 LPH	1
		Chrom column	450 mm	1
		Viral Inactivation system	~ 1000 L	1
		In-line dilution system (optional)	-	2
_	Purification 1 (Pre-	Chromatography System -2	2000 LPH	1
5	viral)	Chrom column	450 mm	1
	Chrom column	600 mm	1	
		Nano filtration (Virus filtration)	~ 1000 L	1
		Floor Scale	3000 Kg	1
		Transfer Pump / Peristaltic pump	-	1
		Ultrafiltration / Diafiltration (TFF)	20 m2	1
_	Purification 2	Ultrafiltration / Diafiltration (TFF)	10 m2	1
6 (Postviral)		Floor Scale	~ 1000 Kg	1
		Filter Integrity Testing		1
		Biosafety Cabinet	6 feet	1
		Sterile filter	-	1
7	7 Bulk Filtration	Weighing balance		1
		Bio Welder	-	1
		Bio Sealer	-	1
8	Freeze Thaw	Freeze Thaw	~ 100 L	1
		Floor Scale	~2000 kg	1
		Transfer Pump / Peristaltic pump	-	2
9	Media Preparation	Bag Integrity tester		1
		Weighing Balance	~ 5 kg	1
		pH / Conductivity meter	-	1
		Floor Scale	~2000 kg	1
		Weighing Balance	2000 Ng	1
10	Buffer Preparation	Transfer Pump / Peristaltic pump	_	2
		pH / Conductivity meter	-	1
		Slurry packing skid	-	1
11	Column Packing	Slurry tank	~300 L	1
		Sturry tank	600X600X60	1
12	Decontamination room	Decon Autoclave	0	1
		Water bath or Dry bath	-	2
		Inverted Microscope	-	1
		Cell Counter	-	1
		Table Top Centrifuge	-	1
13	IPQC	osmo meter	-	1
		Biochemical analyzer	-	1
		Spectrophotometer	_	1
		Vortex mixer		1



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		Micro Pipette	-	2
		Pippet boy	-	3
		Microscope with camera	-	2
		Biochemical analyser	-	1
		pH meter	-	2
		Conductivity meter	-	2
		flue / blood gas analyzer	-	1
		Labelling printer	-	1
		Refrigerator	~ 500 L	1
		Deep Freezer ('-20deg C)	~ 500 L	1
		Cold Room (Media Prep)	-	1
14	Cold Rooms	Cold room (buffer prep)	-	1
		Cold Room (Purification 1)	-	1
		SS racks to hold SU (holder bags)	-	As required
Day Store	Day Store	SS racks to hold SU (Mixer bags)	-	As required
Sterilization Autoclave room	Sterilization Autoclave	600X600X90 0	1	
	room	LAFU	-	1
17	Wash	Parts washing Machine	~ 200L	1
		Hold tanks 100 L	100 L	2
		Hold tanks 300 L	300 L	2
18	SUH	Hold tanks 500 L	500 L	4
		Hold tanks 1000 L	1000 L	2
		Hold tanks 1500 L	1500 L	2
		Mixing Tanks 200 L	200 L	2
		Mixing Tanks 500 L	500 L	2
19	SUM	Mixing Tanks 650 L	650 L	3
		Mixing tanks 1000L	1000 L	2
		Mixing tanks 1500L	1500 L	2
		Magnetic mixing drive	_	1
	Magnetic mixing	Magnetic mixing drive	-	1
20	drives	Magnetic mixing drive	-	2
		Magnetic mixing drive	-	2
21	Kill Tank System	Kill tank with collection system	-	1
	,	Aircurtains	-	2
		Hand Dryers	-	2
22	Miscellaneous and	Insect-o-cutterss	-	2
22	Change rooms	Firstaid Kit	-	2
		Change cabinets	_	As
		Change caomete		require



		Cross over bench	-	As required
		Garment Cabinet / LOCKERS	-	As required
		Dynamic Garment Cabinet		As required
		Used Garment Bins	-	As required
		Filter cleaning system	-	1
		Lift (Personnel)	-	1
	I	For Formulation (drug products)	L	
		SUM	200 L	1
		SUM	20 L	1
	Compounding /	pH/Conductivity meter	-	1
1	Blending	Floor scale	1 - 1000 Kg	1
	_		100 gm - 5	1
		Weighing Balance	Kg	1
		Single Use Mixer	200 L	1
		Single Use Mixer	20 L	1
	Filtration / holding		0.45+0.2	1
2		Sterile filter Assembly	micron	1
2		Peristaltic pump	6-18LPM	1
		Weighing Balance	10 kg	1
		Ceiling Suspended LAF	-	1
3	Loading area	Automatic loading system		1
	Louding area	Vial +PFS Combo Filling Machine with RABS	100	1
		(Automatic) & LAFU	Vials/Min	1
4	Filling room	Vial Sealing Machine with LAFU	100	1
			Vials/Min	1
5	Lyophilizer	Lyophilizer with Automatic loading & Unloading system operation under LAFU	10000 Vials/Batch	1
6	Sterilisation unloading	Ceiling Suspended LAF	-	1
		VHP Bio-Decontamination Unit	-	1
		Glove Leak Testing M/c	-	1
7	Others	Air Sampler	-	1
		Mobile LAF	-	1
		On line Particle Counter	-	1
-	D 0			As
8	Day Store	Racks & Table	-	required
	Disinfectant & storage	Disinfactant preparation and filtration skid	-	1
9	room	Fogger	-	1
1.0	D	Autoclave/Sterilizer loading	800L	1
10	Preparation area	Tyvek Bag Cutter / Sealer	_	1



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		Parts washing Machine	~ 200L	1
11	Wash	Dry heat oven	-	1
		LAFU with bench	-	1
11	Crimping room	Crimping machine	-	1
12	Inspection room	Vial/PFS inspection machine	-	1
	1	On - Line Labeling Machine	-	1
		Shipper packing machine	-	1
		On - Line Check Weigher	-	1
		BOPP taping machine	-	1
13	Packing room	Batch coding printers	-	1
		Barcode printers	-	1
		Manual inspection tables	-	1
		Packing belt	-	1
		Aircurtains	-	2
		Hand Dryers	-	2
		Insect-o-cutterss	-	2
		Firstaid Kit	-	2
				As
	Miscellaneous and Change rooms	Change cabinets	-	required
		Cuasa ayyan han ah		As
14		Cross over bench	-	required
17		Garment Cabinet / LOCKERS	_	As
		Garment Cabinet/ EOCKERS	_	required
		Dynamic Garment Cabinet		As
				required
		Used Garment Bins	-	As required
		Filter cleaning system		1
		Lift (Personnel)	-	1
			-	1
		Quality Control Lab Equipment List	<u> </u>	1
1	Sample receipt and	Cold cabinet (2-8 degree C & -20degree C)	-	
1	stores	Deep freezer Dual (-40degree C & -80 degree C) LAFU	-	1
			-	1
		Analytical balance Presision balance with antivibration table	-	1
	D 1:		-	1
2	Packing material	Bursting strength tester	-	1
	testing lab	Digital Vernier	-	1
		Digital Vernier	-	1
		Visual Inspection booth	-	1
2	D C	Deep freezer (-20°C)	-	1
3	Deep frezer	Deep freezer (-40°C)	-	1
		Deep freezer (-80°C)	-	1
4	Chemical store	Chemical storage cabinet	-	As



				required
		Storage racks	_	As
5	Retention sample			required
3	Retention sample	Refrigerator	-	2
		Deep Freezer (-20 deg C)	-	2
		Stability Chamber (2-8°C)	-	1
		Stability Chamber (-80°C)	-	1
		Stability Chamber (-40°C)	-	1
6	Stability room	Stability Chamber (-20°C)	-	1
		Stability Chamber (25°C)	-	1
		Stability Chamber (40°C)	-	1
		Photo stability Chamber	-	1
		Agarose Gel Electrophoresis Unit	-	1
		Power pack for electrophoresis assembly	-	1
		Power pack for electrophoresis assembly	-	1
		Gel Documentation System	-	1
		SDS PAGE running unit	-	1
		Western Blot running Unit	-	1
		Gel Dryer Unit	-	1
		Vacuum pump for Gel dryer	-	1
		pH meter	-	1
		Conductivity meter	-	1
		Vortex Mixer	-	1
		Centrifuge (table top)	-	1
		Viscometer	-	1
		Osmometer with auto sampler	-	1
7	Biochemistry lab	Density Meter	-	1
		RT-PCR	-	1
		Liquid Particle Counter	-	1
		Dynapro with computer	-	1
		Karl Fischer	-	1
		BET (LAL test)	-	1
		Automatic melting point apparatus	-	1
		Hot Plate	-	1
		Oven	-	1
		Deep Freezer (-20 Deg C)	-	2
		Multimode reader + Washer + Nanodrop	-	1
		UV Spectrophotometer with computer	-	1
		Inverted Microscope	-	1
		Microplate Shaker	-	2
		Refrigerator	-	2
8	Consumable stores	Storage cabinet	-	As



				required
9	Stability - Cold room	Walk-in Stability Chamber (2 to 8 deg C)	-	1
10	Lab Furniture			As
10	Lao Fulliture	-	-	required
		Dessicator	-	1
		Vortex Mixer	-	1
		LOD Oven	-	1
		Magnetic Stirrer	-	1
		Capillary Electrophoresis (UV, PDA & LIF) with computer	-	1
		Thin Layer Chromatography	_	1
		pH/ & Conductivity Meter	-	1
		Shaking Incubator	-	1
		Analytical Balance (small and wide range)	_	1
		Water Bath	_	1
	Instrumentation, Buffer	Vacuum Pump	_	1
11	Prep & Special	Refrigerator		1
	Instruments Room	Deep freezer (-20 Deg C)		1
		Centrifuge	-	1
			-	3
		HPLC System with Computer	-	3
		UPLC System with Computer FTIR Spectrophotometer	-	
		GC-MS	-	1
		LC-MSMS	-	1
			-	1
		ELISA Reader	-	1
		Spectrophotometer	-	1
		Ion Chromatography	-	1
		Gas chromatography	-	1
		Water bath	-	1
		Magnetic Stirrer	-	2
		Refractometer	-	1
		Polarimeter	-	1
		pH & Conductivity meter	-	2
		TOC analyzer	-	2
12	Chemical lab	Refrigerator	-	4
		Analytical balance	-	1
		Weighing Balance	-	5
		Vortex Mixer	-	4
		Oven	-	1
		Bottle Dispenser	-	1
		Acid and Base Storage Cabinets	-	1
		Sonicator	-	1



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		Drying Oven	-	1
		Vacuum Oven	-	1
13	Hot room	Muffle furnace	-	1
		Heating Mentle	-	1
		Fume Hood	-	2
14	Fumehood room	Exhaust system	-	1
		Analytical Balance	-	1
		Sterilization Autoclave	-	1
		Weighing balance	-	2
		Vortex Mixer	_	2
		pH meter	-	1
15	Media preparation	Water bath	-	1
		Oven	-	1
		Magnetic stirrer	-	1
		Bag Sealer	_	1
		Peristalitic pump	_	2
		Microbial Air Sampler	-	1
		pH and Conductivity meter	_	1
	Microbiology & Water Test lab	Water Bath	_	1
		Magnetic Stirrer		1
16		Vacuum pump		1
10		Vortex		1
		Biosafety Cabinet		1
		Analytical Balance		2
		Colony/Cell Counter		1
		Sterility Test Apparatus		1
17	Sterility lab	Biosafety Cabinet		1
18	Autoclave unloading	LAFU		1
10	Tutociave amouning	Incubator (25°C)	_	1
		Incubator (35°C)		1
19	Incubator room	Incubator (45°C)		1
. ,	incubator room	BOD incubator		1
		BOD incubator (Dual Chamber)		1
		Decontamination Autoclave		1
		Hot air Oven		1
		ICE Machine	_	1
20	Wash + decon	Washing sink with jet provision		1
		Glassware/Part Washer		1
		Water Purification System		1
21	Office	Office furniture	-	Lumpsu
∠ 1	Miscellaneous and	Aircurtains	-	Lampsu
22	Change rooms	Hand Dryers		_



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	Insect-o-cutterss	-	-
	Firstaid Kit	-	-
	Change cabinets	-	-
	Cross over bench	-	-
	Garment Cabinet / LOCKERS	-	-
	Dynamic Garment Cabinet	-	
	Used Garment Bins	-	-
	Filter cleaning system	-	-
	Lift (Personnel & Material)	-	-

Table 2-16List of Equipment in proposed- (for Warehouse)

	Table 2-16List of Equipment in proposed- (for Warehouse)					
S. NO	Room Name	Equipment	Quantity	Remarks		
		Sampling booth	1	4 feet X 3 feet		
1	Sampling	Weighing Scale/ Platform Scale	1	1-100 kg		
		Weighing Balance	1	1-1000 g		
		Weighing Balance	1	0.5 - 200 gm		
		Dispending booth	1	6 feet X 4 feet		
2	Dispensing DS	Weighing Scale/ Platform Scale	1	1-100 kg		
		Weighing Balance	1	1-1000 gm		
		Weighing Balance	1	0.5 - 200 gm		
		Dispending booth	1	6 feet X 4 feet		
3	Dispensing DP	Weighing Scale/ Platform Scale	1	1-100 kg		
		Weighing Balance	1	1-1000 g		
		Weighing Balance	1	0.5 - 200 gm		
4	Freeze thaw room		0	Equipment Considered in DS		
7	FICEZC tilaw 100111	-	U	equipment list		
		Freezer	1	-20 Deg C		
5	Freezer room	Freezer	1	-40 Deg C		
		Freezer	1	-80 Deg C		
6	RM & PM stores	Storage Racks (Pallet Space)	300	1500 kg, conollidated for warehouse area		
O	KIVI & I IVI STOTES	Pallets	300	1200 x 1200 mm, conollidated for warehouse area		
7	Pre dispensing staging	Storage racks	As required	-		
8	Post dispensing staging	Storage racks	As required	-		
9	Recall cold room	Storage racks	As required	-		
10	Cold store (DS)	cold room	-	-		
	1					



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11	RM cold store	cold room	-	-
12	cold store future	cold room	-	-
13	FG store - Cold room	Cold room	-	-
14	Pre-dispatch preparation / palletization	Storage racks	As required	-
15	Solvent Cabinet	Solvent Storage cabinet - Flameproof	1	-
16	Reject store	Cold room	-	-
17	Recall	Storage racks	As required	-
18	Quarantine & under test (RM)	Storage racks	As required	-
19	Quarantine & under test (PM)	Storage racks	As required	-
	(1111)	Dock Leveller	2	2000 Kg
20	Loading / Unloading bay	Floor Scale	2	500 - 3000 kg
		Floor Scale	1	Upto 500 kg
		De-dusting tunnel	1	-
		Air curtian	1	-
	Material receipt & dedusting bay	Insectocuters	6	_
		Rolling Shutters	2	_
21		Roll up doors	5	-
		Fork Lift - Electric	2	2000 kg
		Pallet Trucks - Manual	2	1500 kg
		Pallet Trucks - Electric	2	1500 kg
		Battery charging station	1	-
22	Clean pallet wash	Pallet washer	1	-
23	Clean pallet store	Storage rack	As required	-
24	Office	Office furniture	Lumpsu m	-
	Used garment staging &	Garment washing Machine	1	TBD
25	technical	Dryer & pressing	1	TBD
26	Garment preparation	SS Storage racks & Working table	As required	TBD
27	Clean garment store & distribution	SS Storage racks & Working table	As required	TBD
28	Engineering store & office	Storage racks	As required	-
		Aircurtains	-	2
		Hand Dryers	-	2
29	Miscellaneous and Change	Insect-o-cutterss	-	2
=-	rooms	Firstaid Kit	-	2
		Change cabinets	-	As required



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	Cross over bench	- !	As required
	Garment Cabinet/ LOCKERS	-	As required
	Dynamic Garment Cabinet		As required
	Used Garment Bins	-	As required
	Filter cleaning system	-	1
	Lift (Material)	-	2
	Lift (Service)	-	1

a) Kill Tank Systems

Kill system also referred to as Inactivation system is a Process equipment module with multiple vessels to treat the biologically loaded process liquid effluent waste in a safe manner through Chemical inactivation method

As a design basis, the Process waste is separated as 'biologically contaminated' or 'regular' waste at the source of equipment /drain point. Both types of liquid waste will be transported with separate piping network in closed condition to the targeted system for further treatment

The biologically contaminated process liquid waste herein referred as 'liquid waste' at the source point, from the process equipment drain point is led to a common drain network made from Stainless-steel piping network in closed operation. The drain traps and design of the piping is carried out as per clean room requirements and to ensure no flow back happens to the equipment. The liquid waste from process equipment is led by gravity flow through common drain network to the Kill system located on the Ground floor.

The Kill system consists of the following which act through a common automation system:

- ➤ 1 No. Collection tank
- ➤ 2 Nos of Treatment vessels 1 working +1 standby
- ➤ Chemical dosing system
- ightharpoonup Transfer pumps 1 working + 1 standby

The liquid waste is collected in the collection tank which is completely a closed tank system with an air vent mounted with a hydrophobic sterile grade 0.2 micron filter. This is only a storage tank with no treatment system.

The liquid from this tank is then pumped into a stainless-steel tank fitted with required instrumentation, nozzles, agitator, pumping system and hydrophobic sterile grade 0.2 micron filter.

Once the required liquid waste is transferred to this tank from collection tank, chemical dosing(NaOH of specified concentration) from a dosing system is transferred to the tank for inactivating the biological load in the liquid waste. As per the design, required residence time is given to the tank system to treat the liquid with agitation and pump recirculation system. Post treatment, the liquid which is free from biological contamination leads to secondary treatment to the centralized effluent treatment as a regular process liquid waste.



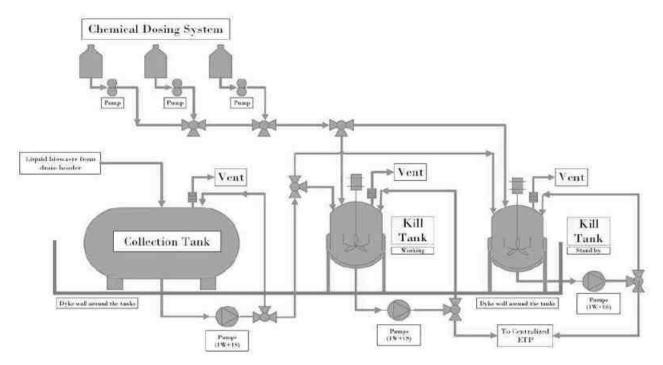


Figure 2-9 Typical flow diagram of batch chemical inactivation system for liquid biowaste Potential Risks & Mitigation Plan:

Sl.No	Potential Risk	Mitigation Plan:
1	Risk of biologically contaminated liquid waste from process equipment exposure to working environment	The Process systems are automated systems with minimal human intervention. Liquid waste discharge also happens through automated systems in closed piping network. The piping network which is pre-tested for any possible leakages is used for the transfer with no possibility of any leakage to environment or people working
2	Excess Process liquid waste flooding the collection tank	Pre-study and planning of actual waste generation is carried out as part of engineering design and equipment sizing. As an additional precaution, the collection tank is slightly sized bigger and there is a standby treatment vessel as well to accommodate
3	Biologically contaminated partially treated liquid waste being led through common drains to secondary treatment	The system is timer based and operates as per the residence time predefined as a validated process. Apart from this, the kill system is equipped with instrumentation like pH sensor transmitter which will restrict the liquid escaping to secondary

		treatment system without neutralization
4	Possible minor leakage also leading to impact on environment and personnel	The kill system is housed a separate room with hermetically sealed doors and system enclosures. The room is also equipped with a fan system with HEPA filter which will ensure negative pressure in the room and retain any perceived contamination from system escaping through air
5	Trespassing of unqualified personnel entering the Kill system room	The room is equipped with access control and allows only authorized personnel to enter the room.

2.6.3.2 Fire and Safety Equipments

Fire hydrant will be placed across the plant & required firefighting equipments like extinguishers, Fire safety alarms, fire buckets etc will be provided where ever required. Trained people will be allotted to mitigate the fire during emergency and regular mock drills will be conducted to enrich the knowledge of the people.

Table 2-17List of safety Equipments Proposed

S. No.	Safety And Fire Fighting Equipments Description	Qty	Capacity
1.	Underground static water tank	1 No	300 KL
	Fire water pumps (as per NBC guidelines and Tamil Nadu Fire and Rescue services guideline)	1 No	130Cum/Hr
3.	Jockey pumps	1No's	40Cum/Hr
4	Note: Delugevalves, Manual Call Points, Hand Siren, Gas Monitoring System, Foam trolley, Fire Hydrant Lines, MVW Sprinkler etc.,	Will be pr	ovided as per iiled design

Fire extinguishers:

S. No.	Type of Fire Extinguishers	Capacity	Unit	Quantity
1	CO_2	4.5	Kg	10
2	DCP	9.0	Kg	50
3	Foam	50.0	Litres	10

Fire Hydrant system

Pressurized (6.0 kg/cm²) automatically operated Fire Hydrant System will be installed with rings and wetrisers around all blocks to achieve maximum coverage. Water reservoir of 300 m³ (Hydrant Tank)capacities will be provided for approximately 2hr fire fighting.

	S. No.	Description	Capacity	Startsatpressure (Kg/Cm²)
Ī	1	Main Electrical Pump	Discharge capacity 130 m ³ /Hour@70mhead	6.0



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-				
	2	Jockey Pump	Discharge capacity 40 m ³ /Hour@60m	

Layout plan showing the location of fire hydrant and Hose and Fire tank Resource is attached as an **Annexure-13**.

2.6.4 Raw Materials requirement

All the raw materials required for manufacturing will be procured either from local markets or imported and FG will be transported through road. All chemicals used in the process will be stored in a designated area with proper labels in warehouse. The lists of raw materials are given in **Table2-18**.



Table 2-18Details of Raw materials, and their linkage

Sl. No.	Raw materials	Approx Quantity per annum (In Kgs)	Type of Package	Source	Storage Temperature	State (Solid/Liquid/Gas)	Chemical properties	Mode of transport
Monoc	clonal products (Drug substances	s)- for EC products						
1	Sodium chloride	1800	Bag /Drum	Domestic/ Imported	20- 25 deg C	Solid	colourless & Odourless	Road
2	Potassium Chloride	10	Bag /Drum	Domestic/ Imported	20- 25 deg C	Solid	White & Odourless	Road
3	Sodium phosphate	60	Bag /Drum	Domestic/ Imported	20- 25 deg C	Power Solid	White & Odourless	Road
4	Potassium phosphate	10	Bag /Drum	Domestic/ Imported	20- 25 deg C	Solid	White & Odourless	Road
5	Citric acid	500	Bottle /Box	Domestic/ Imported	20- 25 deg C	Small beads (crystal)	White & Odourless	Road
6	Sodium Citrate	1150	Bag /Drum	Domestic/ Imported	20- 25 deg C	Solid	White & Odourless	Road
7	Tris Buffer	2300	Bag /Drum	Domestic/ Imported	20- 25 deg C	Liquid	Clear & Odourless	Road
8	Sodium Acetate	600	Bag /Drum	Domestic/ Imported	20- 25 deg C	Crystallline (solid)	white	Road
9	Sodium Hydroxide	1500	Bag /Drum	Domestic/ Imported	20- 25 deg C	Pellets (solid)	White & Odourless	Road
10	Glucose	400	Bag /Drum	Domestic/ Imported	20- 25 deg C	Solid	White & Odourless	Road
11	Sodium bicarbonate	200	Bag /Drum	Domestic/ Imported	20- 25 deg C	Power Solid	White & Odourless	Road



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12	Pluronic F68	100	Bag /Drum	Domestic/ Imported	2- 8 deg C	Liquid	NA	Road
13	Cell Culture Media	2200	Bag /Drum	Domestic/ Imported	2- 8 deg C	Dry powder (solid)	NA	Road
14	L-Glutamine	30	Bottle /Box	Domestic/ Imported	2- 8 deg C	NA	NA	Road
15	Sorbitol	200	Bottle /Box	Domestic/ Imported	20- 25 deg C	Solid	White & Odourless	Road
16	Ethanol	100	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Clear & Odourless	Road
17	Phosphoric Acid	60	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Clear	Road
18	Acetic Acid	40	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Odourless	Road
19	Hydrochloric acid	150	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Light yellow & pungent	Road
	Total	11410	-	-	-	-	-	-
	Formulation products (drug products) – for Non EC products							
1	Phosphoric Acid	60	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Clear	Road
2	Acetic Acid	2200	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Odourless	Road
3	Hydrochloric acid	20L	Bottle /Box	Domestic/ Imported	20- 25 deg C	Liquid	Light yellow & pungent	Road

Note: All raw materials will be purchased through Open market

RM MSDS is attached as Annexure-4a.



Resource optimization/Recycling and reuse

- There is no solvent recover proposed since no solvent is used for the product manufacturing.
- Various technologies will be employed to treat and recycle wastewater in a manner similar to household
 water treatment. This will involve the use of specialized facilities: an exclusive plant for treating industrial
 wastewater, along with subsequent employment of MEE and ATFD processes. Additionally, sewage
 generated within industrial premises will undergo treatment in a dedicated sewage treatment plant.

2.6.5 Water Requirement

Construction phase:

About 40 KLD of water (for labour-1.4 KLD & Construction activities -38.6 KLD) will be required during the peak construction phase and it will be sourced through Private tankers.

Operation phase:

Total water requirement for the project is 132.4 KLD. Fresh water is 70.4 KLD and Recycled water is 62 KLD. Source of fresh water is TANSIDCO. Details of water requirement for the proposed project are given in **Table 2-19**.

Table 2-19Water Requirements-Proposed

Description	Fresh water (KLD)	Recycle water (KLD)	Total Water (KLD)
Pre-Treatment System for process & Lab	65	0	65
Cooling tower	0	37	37
Boiler	0	7	7
Greenbelt	0	18	18
Domestic	5.4	0	5.4
Total (KLD)	70.4	62	132.4

Proposed Water balance chart is given in Figure 2-10.



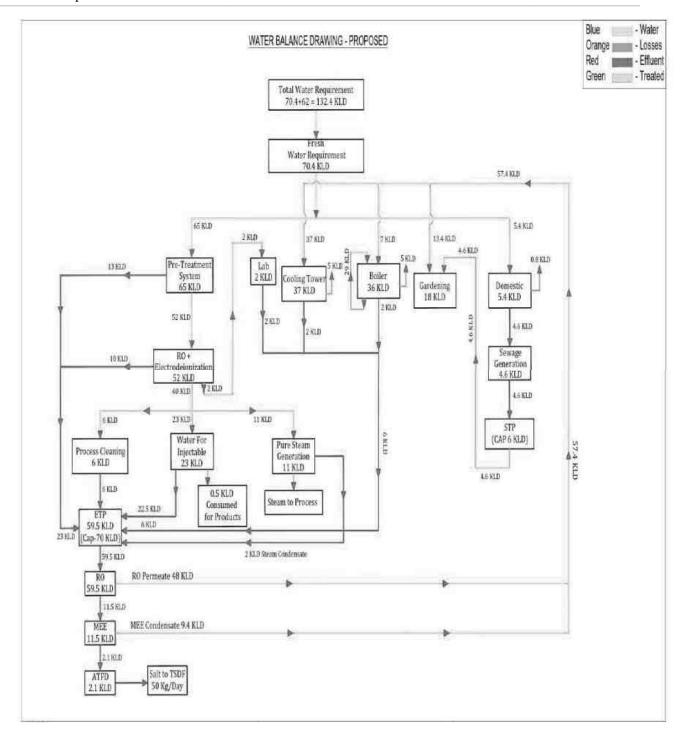


Figure 2-10Water Balance Chart (Proposed)

2.6.6 Power Requirement

Power requirement will be met from TANGEDCO. Two(2) DG set will be installed as back-up power requirement during power failure. The power and energy requirement details are provided below.



Table 2-20Power and Energy Requirement

Details	Quantity	Source
Details	Quantity	Source
Power Requirement (kVA)	1745.64	TANGEDCO
Back-up (kVA)	2x600*	DG Sets
Boiler (kg/hr)	1x1500	For steam
Fuel Requirement:	•	•
HSD (KLD) for Boiler	2.509	Local Supply such as HP, BHP & IOC
HSD for DG set (KL/Hr)	0.12	-Local Supply such as fir, Bffr & loc

Note: *In ToR application, DG sets capacity - 2x350 kVA.

2.6.7 Manpower Requirement

Total Manpower requirement Breakup is given below.

Table 2-21Manpower Requirements

S.No	Manpower	Construction Phase	Operation Phase
1	Contract	30	30
2	Permanent	0	90
	Total	30	120

Additional employment opportunity for product dealers and distributors, and transport sectors for product movement will increase the employment opportunity indirectly.

2.6.8 Schematic representations of the feasibility drawings which give information important for EIA purpose

The EIA Cycle based on the above stages has been illustrated as per the ToR issued in Figure2-11.



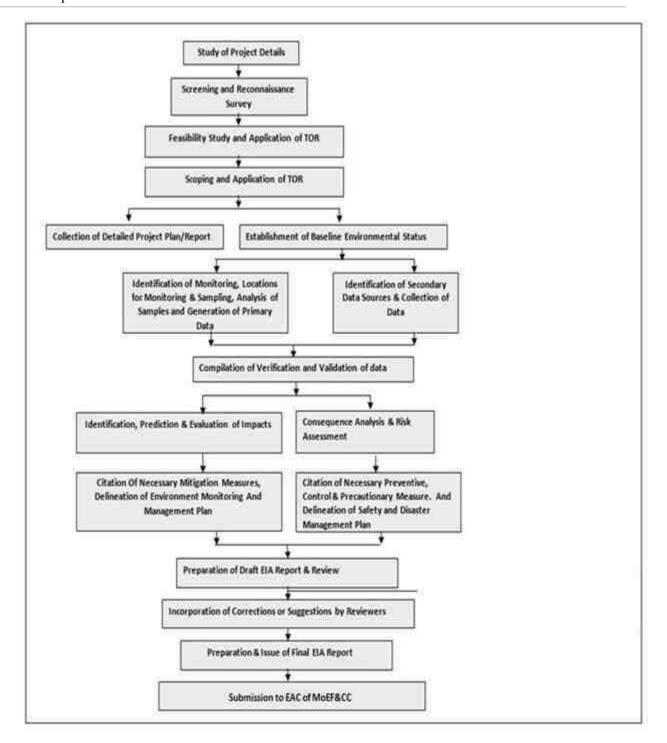


Figure 2-11EIA Cycle based

2.7 Description of mitigation measures incorporated into the project to meet environmental standards, environmental operating conditions, or other EIA requirements (as required by the scope)

2.7.1 Air Emission and Control Measures

Boilers and DG sets are the two main sources that contribute to emissions from the plant. Industry is proposed 1.5 TPH HSD fired boiler. Particulate matter (PM), Sulfur dioxide (SO2), Carbon monoxide (CO) and Oxides of Nitrogen (NOx) will be the major pollutants. Stack height of 30 m is proposed to meet the CPCB guidelines. Diesel about 0.12 KL/hr will be used at full operation load in the DG sets. Proposed DG sets are of 2 x 600 kVA DG set will be used as stand by during power failure.

Stack Details Emissions FUE FUEL No. QUANTI SL. L Heig Exit Tem SOURCE Dia PM of SO_2 NO_{x} CO NO **TYP** TY (KL / ht Velocit Stac (m) (g/s)(g/s)(g/s)(g/s) \mathbf{E} Day) (^{0}C) (m) y (m/s)k DG-600 7.43E-6.93E-1.05E-2.26E-**HSD** 9 200 1 0.1 kVA* 03 03 01 02 2.88 30 1 7.43E-6.93E-1.05E-2.26E-DG-600 9 2 **HSD** 0.1 200 kVA* 03 03 01 02 3.41E-4.70E-6.62E-1.66E-Boiler 1.5 3 **HSD** 1 210 2.509 30 0.3 10 TPH 03 04 02 02

1.83E-

02

1.43E-

02

2.76E-

01

6.17E-

02

Table 2-22Proposed Stack emission details

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Control Measures

- Stack height of 30 m is proposed for boiler.
- 30m stack height will be provided for DG
- There are no process emissions from the proposed manufacturing facility.

Total

- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.
- Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. Adequacy/Performance of Air Pollution Control measures shall be reviewed.
- Water sprinkling shall be carried out on road surfaces at the project site.
- Adequate Green belt area will be provided.

2.7.2 Fugitive Emission & Odour Control Measures

There will be chance of fugitive emission due to raw material handling, transportation and Manufacturing activity. The details of fugitive emissions and its control measures.



Table 2-23Details of Fugitive emission and its control measures

Source	Probable pollutant parameter	Control Measures
Loading/unloading and storage of raw materials and finished products	VOC & PM	 Loading/unloading of liquid material will be done through pipeline. It will be done in a closed system. Local Exhaust ventilation will be provided.
Raw material storage	VOC	 Carry out work place area monitoring to find out concentration level in ambient air. Closed transfer system will be provided. Unit will carry out regular workplace monitoring.
Handling of raw Material in bags storage area	PM	 Provision of exhaust ventilation in plant area. Provision of PPE. Job rotation to reduce exposure.
Warehouse storing drums and bags	VOC&PM	Spillages will be strictly prevented by proper handling of equipment. SOP will be followed.

Odour Control

There is no odour from the process since it is done through closed environment only. Possible source of odour will be from ETP and STP area only.

Mitigation Measures

- The entire QC lab vent will be routed through wet srubber connected with stack of 3.0m.
- Aromatic Plants such as Ocimum americanum (Local Name: Nai thulasi), Ocimum basilicum (local name:
 Karpura thulasi & Thiruneetrupatchai), Ocimum gratissimum (Local Name: Elumichanthulasi) & Ocimum
 tenuiflorum (local Name: Thulasi) etc., will be planted to minimize Odour generated from STP and ETP
 area.

2.7.3 Action Points as per National Clean Air Programme (NCAP) to control Air emission from the proposed Project (Industrial Emission) as per PgNo:7.5.3 ofNCAP-2019:

Our site is not covered in NCAP cities as project site is located within TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. As per the list of cities in the Smart Cities Mission (SCM) that are non-attainment cities under the National Clean Air Program (NCAP) in Tamil Nadu are only:

- Tiruchirapalli
- Thoothukudi.

(Source: https://pib.gov.in/PressReleasePage.aspx?PRID=1655203)

Though the project site is not NCAP area, we commit the control measures proposed above.



2.7.4 Noise Pollution

Major sources of noise generation in the unit during operational phase are classified into two categories:

- Stationary sources due to operation of heavy-duty machinery at the project site like Boilers, Compressors,
 ID fans, DG sets, Pumps etc.
- Mobile sources corresponding to mainly vehicular traffic for staff mobilization, materials, material transportation, liquid fuel transportation to project site, etc.

The impact of vibrations beyond the site would be negligible during normal operation phase. However, the impacts on workers engaged in the plant area would be considerable due to occupational exposure. The fixed major equipment/units such as air compressors, pumps, DG sets and ID fans etc., also generates vibrations during operational phase and may cause exposures to the workers/operators engaged at these units.

Mitigation Measures:

- The major noise generating equipment like Compressors, DG sets, Boiler Feed water pumps etc. will be enclosed in an acoustic enclosure designed for an insertion loss of 25dB(A) and silencers to other equipment etc.
- Major noise generating equipment will be designed with 85 dB (A) ensuring cumulative noise at 1.0 m remains at 85 dB (A).
- The occupational noise exposure to the workers in the form of eight hourly times weighted average will be maintained well within the prescribed Occupational Safety and Health Administration (OSHA) standard limits.
- Acoustic silencers will be provided in equipment wherever necessary.
- Acoustic design with sound proof glass paneling will be provided for critical operator cabins/control rooms
 of individual modules as well as central control facilities.
- Use of personal protective equipments/devices such as ear-muffs, ear plugs etc. will be strictly enforced for the workers engaged in high noise areas.
- 33.08% green belt will be developed within the industry.
- Ambient noise levels will be monitored at regular intervals during operational phase of the project.
 Workplace monitoring will also be carried out at regular intervals to ensure that noise levels are well within the standards prescribed by the Factories Act.

2.7.5 Water Pollution

Waste water Generation and Disposal Details

Construction Phase: Total Sewage generation will be 1.22 KLD. It will be treated through mobile Sewage Treatment Plant of 3 KLD and treated sewage will be reused for Green belt development within the plant.



Operation Phase: Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented

Table 2-24Liquid waste Management

S. No	Description	Proposed Quantity (KLD)	Final Disposal Points	
Cons	truction Phase			
1	Sewage	1.22	Will be treated in mobile STP (3 KLD) and treated sewage will be reused for greenbelt development	
Operation Phase				
1	Effluent	59.5	Effluent generation from process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE. RO permeate and MEE condensate will be reused for utilities and greenbelt. MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF.	
2	Sewage	4.6	Will be treated through packaged STP (6 KLD) and treated sewage will be reused for Greenbelt development. STP Sludge will be used as a manure for greenbelt.	

Process Description of STP

- The raw sewage gets collected to the packaged STP through a separation box where- in the solid waste and liquid waste are separated.
- The sewage then sent to the Moving bed chamber filled with Moving bed media which is provided with aeration through a small blower. The media fill in the aeration chamber is 50% of the volume.
- The aerated sewage will move to settling tank where suspended particles will be separated
- The treated water from packaged STP unit will be stored in Filter feed Tank from where it will be pumped to the Pressure Sand Filter & Activated Carbon Filter for the removal of suspended solids, colour & odour. The Filtered water is stored in the Treated water tank.
- Chlorination will be there for the purpose of disinfection.
- The Treated water will be utilized for green belt development.

The schematic diagram of process flow in STP is given in Figure 2-12.



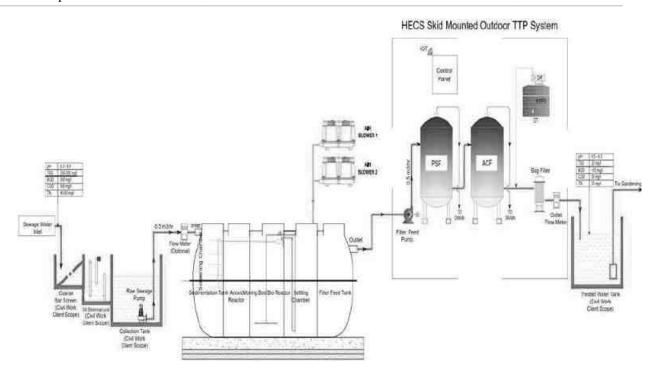


Figure 2-12Water STP Process Flow Diagram

Table 2-25Characteristics of treated sewage

Description	Quantity		Parameter					
	(KLD)	pН	TSS(mg/l)	TN(mg/l)	BOD (mg/l)	COD (mg/l)		
Domestic	4.6	6.0-8.0	200-300	40-60	250-300	400-500		
STP treated sewage	4.6	6.5-8.5	20	20	<10	50		

Effluent Treatment and Disposal

Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented.

Process Description of ETP, RO, MEE/ATFD

• The Effluent from various sources gets collected in the collection Chamber through bar screen chamber in order to remove the floating particles. Collection tank is provided with media for the removal of BOD / COD. The Effluent is then pumped to the oil skimmer chamber in order to remove the floating oil.



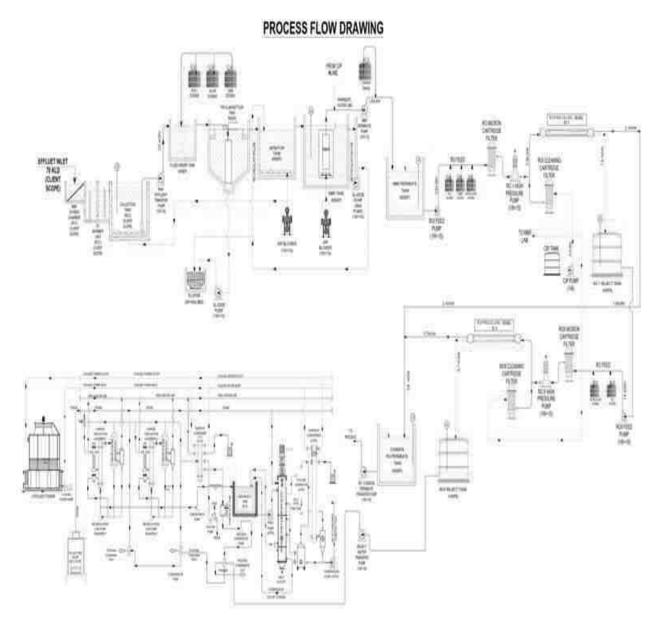
- The Effluent from various sources gets collected in the Equalization Tank through bar screen chamber in order to remove the floating particles. The Effluent is then pumped to the oil skimmer chamber in order to remove the floating oil.
- The Effluent from the Oil Skimmer tank is then sent to Flash Mixer tank provided with agitator mechanism. Coagulant & Flocculants dosing is done in the flash mixer tank. The Overflow from the Flash Mixer is sent to the Primary settling tank.
- The Primary Clarifier tank is provided with Settler internal where the sludge gets settled at the bottom of the tank. The overflow from the Primary Clarifier tank is sent to Anaerobic digester tank.
- Anaerobic digester tank is again provided with SAFF media for the removal of BOD / COD. The over flow from the Anerobic digester tank is sent to the Aeration tank.
- Air diffusion is done in the Aeration tank through Air blower & diffuser arrangement for biological growth.

 The Over flow from the Aeration tank is sent to the Secondary clari settler tank
- Secondary Clarisettler tank is provided with settler internal where the sludge gets settled at the bottom of the tank. The Overflow from the Secondary Clarisettler tank is sent to the Filter Feed tank.
- The Clear water is then pumped to the Pressure Sand Filter, Activated Carbon Filter & OzoneSystem in order to remove the Suspended solids, Colour, Odour & COD. The Filtered water is then stored in the Treated water tank for further process.

RO Plant

- The treated water is then used for RO feed tank
- The Effluent is then sent to 1st stage RO System with recovery of 80% respectively and RO Permeate is used for further process. RO Rejects is sent to the MEE Plant.
- From the MEE Plant, Condensate is combined with RO Permeate and used for further process and Concentrate from MEE is sent to ATFD and result in Salt.





Figure~2--13Water~ETP,~RO&MEE/ATFD~Process~Flow~Diagram

Table 2-26 Characteristics of raw and treated Effluent water

Description	Quantity (KLD)	Parameter					
		pН	TSS(mg/l)	TDS(mg/l)	BOD(mg/l)	COD(mg/l)	
ETP feed	59.5	6.0-8.0	200-400	800-1000	1300-1500	4000-4500	
ETP Outlet (Permeate)	59.5	6.0-8.0	<5	800-1000	<20	<200	
RO Permeate	48	5.0-6.0	<5	<100	<20	<200	
RO reject	11.5	7.0-8.0	<5	<5000	<20	<200	

2.7.6 Solid Waste Management

Municipal Solid waste

Municipal Solid Wastes generated will be segregated to organic and inorganic wastes. The organic wastes will be disposed to TANSIDCO Bins and inorganic waste will sell to TNPCB authorized vendors. Details are given in **Table 2-27**.

Table 2-27 Municipal Solid Waste Generation

S.No	Waste	Proposed (kg/day)	Total (kg/day)	Method of disposal
Operat	tions Phase (120 Nos)			
1	Organic	32.4	32.4	To Local TANSIDCO bins
2	Inorganic	21.6	21.6	To TNPCB Authorized Recyclers
3	STP Sludge	0.6	0.6	Used as a manure for greenbelt.
Total		54.6	54.6	-
<u> </u>	mation Dhasa (20 Nas), 12	5 IZ /1 (D: 1.1	1.1 1.T.A.NGID.C	10.1:)

Construction Phase (30 Nos): 13.5 Kg/day (Disposal through local TANSIDCO bins)

Note: As per CPHEEO norms - 0.45kg/capita/day

Paper/Card Board, dry leaves, grass, Dustbin collection, Metal scrap & wooden scrap will be recycled/ sent to authorize dealer.

Item Name	Proposed (MT/year)	Mode of disposal
Cartons, Paper and stationary scrap	0.5	Toscrapvendors

E-waste:

Tentative e-waste generated from the project site will be mainly from Admin block, Production Blocks, Engineering, Warehouses, Administration, and Toilets etc.,. It is mainly:

- 1. Fans
- 2. Light
- 3. Electrical items.
- 4. Defective equipments etc.

It will be storied in separate place and disposed through TNPCB authorized E-Waste recyclers

2.7.7 Hazardous Waste Management

The details of hazardous waste generation and handling/Management are givenin Table 2-28.

Table 2-28 Hazardous waste details

S.No	Description of Waste	Category as per HWM Rules 2016	QTY/Annum	Storage method	Method of disposal
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1	Used /Spent Oil	5.1	1 KL		Will be collected and disposed through TNPCB Authorised recycler
2	Waste or residues containing oil	5.2	1Ton	All the generated	Will be collected and disposed through TNPCB Authorized TSDF
3	Discarded Containers/Bags	33.2	4Ton	waste will be stored on Concrete	Will be collected and disposed through TNPCB Authorised recycler
4	MEE salt	37.3	16.5Ton (50 kg/day)	platform in leak Proof	
5	ETP Sludge	35.3	3.3Ton (10 kg/day)	Barrels in designated	Will be collected and
6	Off Specification Products (Doesn't Met by Specifications or standards)	28.3	2Ton	areas	disposed through TNPCB Authorized TSDF
7	Expiry Products/Chemicals	28.5	1.5Ton		

Hazardous waste will be segregated and stored under roofshed on raised platform. Proper leachate collection system and roof. Leachate, if any will be collected and treated in effluent treatment plant. Unit will take membership with TSDF and also Authorization from TNPCB after getting Environmental Clearance from SEIAA, Tamil Nadu.

2.7.8 Biomedical Waste management

Unit will provided Occupational Health Centre within their premises with facilities like bed and O₂ Generator. There will be a generation of biomedical waste and same will be disposed as mentioned below:

Waste Quanity Sl.No **Method of Disposal** Waste type Schedule (kg/month) Will be sent to TNPCB Authorized 1 Yellow Solid waste 4.34 common Biomedical waste Management Facility for Incineration Will be sent to TNPCB Authorized Contaminated common Biomedical waste Management 2 3.1 Red wastes Facility for Sterilization Will be sent to TNPCB Authorized waste sharps 3 White 0.186 common Biomedical waste Management including metals Facility for shredding & disposal Will be sent to TNPCB Authorized 4 blue Glassware 1.24 common Biomedical waste Management Facility for disinfection & recycling

Table 2-29Biomedical waste details

2.7.9 Potential Impacts & Mitigation Measures

Brief description of potential environmental impacts and mitigation measures is provided below:



Table 2-30Probable Environmental Impacts and mitigation measure

Project Activity	Likely Pollutants	Surround ing Environm ent	Media	Likely Impacts	Probable Mitigation Measures
Fuel storage, handling in stock yard & raw materials & finished product transportation	Dust		Air	 Degradation of surrounding air quality. Health hazards to local inhabitants. Reduced growth of vegetation that gets coated with dust. 	 Providing controlled excess air to ensure complete fuel combustion Provision of adequate APCM before stack. Raw materials & finished
Emission from process & utility Stack	PM, SO ₂ ,NOx, CO			Reduction in soil fertility due to pollutant deposition.	products will be kept covered during transportation.
Water Usage			Water	Resource Depletion	Maximize the usage of treated water and reduced fresh water consumption.
Treatment of wastewater from project activity		Industrial & Agricultur al	Water & Soil	 Degradation of water quality of receiving water bodies. Land degradation due to percolation. 	 Designing the efficient water water treatment systems and reusing the treated water based on its quality within the plant. Maintain ZLD facility.
Storage area runoff	water		Water & Soil	 Land degradation due to percolation. Degradation of water quality of receiving water bodies 	Suitable plant layout and provision of run off collection system
Due to Manufacturing Process, Transportation & storage of Products and Raw materials	Odour		Air/ water/ solid	 Health hazards due to hazardous chemical handling 	 Odor masking Authorized transportation system (TREM Card), Public liability insurance

2.8 Assessment of New and untested technology for the risk of technological failure

Omexa Formulary Pvt Ltd proposes to manufacture monoclonal antibodies/therapeutic proteins in a cost effective, more efficient path which will ultimately reduce the generation of waste. Manufacturing process involves various unit operations and processes. For the proposed products, currently we are implementing the Single Use technology, which will reduce the 70% of water consumption compared to the other Stainless steel technology, unit will adopt the latest and best technology available so far in the market. Moreover, the unit is very concerned and conscious



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about the product quality and equally about the environmental protection and resource conservation. The company will upgrade the technology as per requirement from time to time with the best as per the requirement.



CHAPTER – 3 DESCRIPTION OF ENVIRONMENT

3 DESCRIPTION OF ENVIRONMENT

This chapter depicts the establishment of baseline for valued environmental components, as identified in and around the proposed project "Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The primary baseline data monitored covered three (3) months i.e., from March to May 2024 and secondary data was collected from government and semi-government organizations published data. The primary baseline data has been generated by M/s. Hubert Enviro Care Systems (P) ltd, Chennai, NABL accredited MoEF&CC approved environmental testing laboratory for the following terrestrial environmental.

3.1 Study Area and Period

A 10 Km radial distance with the proposed project site as the epicentre has been identified as the General study area for assessing the baseline environmental status. The core study area is the project area and its immediate surroundings to the tune of 1.0 Km radius from the boundary. Further the Project Impact/Influence Area (PIA) is 10Km from the boundary of the project site which covers parts of Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The primary baseline data monitored covered three (3) months i.e., from March to May 2024 of Study Area.

3.2 Description of Study Area, components & Methodologies

As described in Chapter 1, the proposed project project-"Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility" at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. The Nearest Railway Station is RS ~4.31 (ESE) Tindivanam km from the project boundary. NH-77(Tindivanam-Krishnagiri)/NH179B(Chennai-Tindivanam-Harur)~0.37 km (S) from the project boundary. An overall idea of the study area with reference to the physical conditions are presented for better understanding in the following sections before proceeding into the section on the prevailing environmental conditions of the study area. The map showing the satellite image of the study area is given in Figure 3-1 and Topo Map of the study area is given in **Figure 3-2.**

- Meteorology: Temperature, Relative Humidity, Rainfall, Wind Speed & Direction- Refer
 Section 3.5
- Ambient Air Quality: Particulate matter <10 micron size (PM₁₀), Particulate matter <2.5 micron size (PM_{2.5}), Sulphur Dioxide (SO₂), Nitrogen Dioxide (NO₂), Carbon Monoxide (CO), Lead (Pb),Ozone (O₃), Benzene (C₆H₆), Benzo (a) pyrene (C₂₀H₁₂), Arsenic (As), Nickel (Ni) and Ammonia (NH₃)- Refer Section 3.6
- Ambient Noise Levels: Day equivalent noise levels, Night equivalent noise levels Refer
 Section 3.7

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- Water Quality: Groundwater Quality, Surface Water Quality Refer Section 3.8
- Soil Quality Refer Section 3.9
- Ecology Refer Section 3.10
- Social Economic Status Refer Section 3.11

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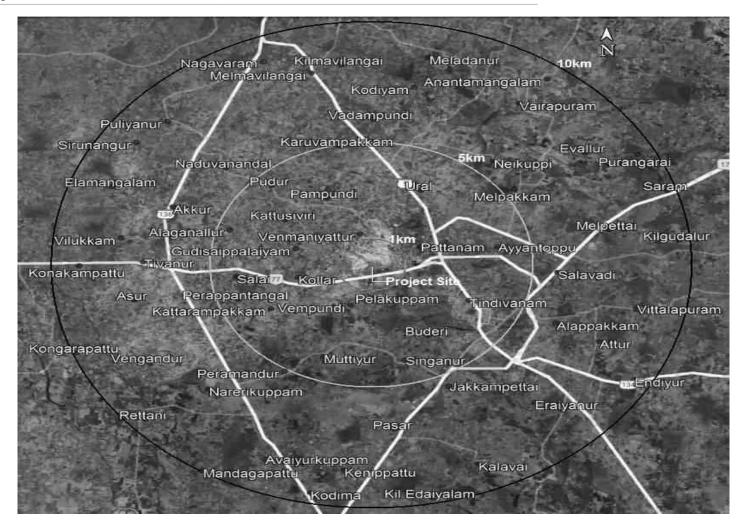


Figure 3-1Map showing the Satellite Image of the study Area of Project



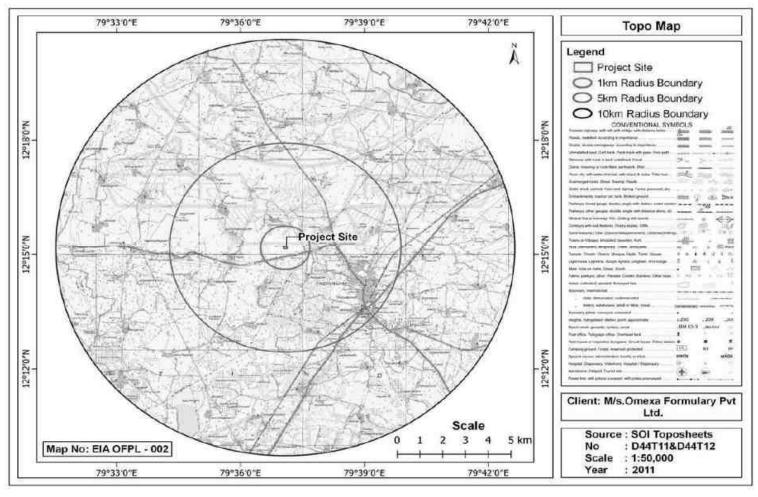


Figure 3-2Topo Map of the Study area



3.3 Environmentally/Ecologically Sensitive areas

This section details with the environmentally sensitive areas present within the project site and surrounding environs. It included national parks, state forest, essential habitats etc. The environmental sensitive areas covering an aerial distance of 15 km from the project boundary is given in **Table 3-1**

Table 3-1Environmentally Sensitive Areas within 15 km from Project Boundary

		1 able 3-1Environmentally Sensitive Areas within	y v				
S.No	Areas	Distance & Direction from project boundary					
1	Monuments &		~Dist	Direc			
1	Heritage Sites	Pallava Rock-cut shrine	7.79km	N			
		Sensitive places	~Dist (km)	Direc			
		W	aterbodies	,			
		Pelakuppam Lake	0.99	ESE			
		Pattanam Lake	1.59	NNE			
		Buderi Lake	2.13	SSE			
		Vempundi Lake	2.26	SW			
7)	Waterbodies &Reserve Forest	Melpakkam Lake	4.31	NE			
		Avaiyurkuppam Lake	7.36	SW			
		Kodiyam Lake	7.50	N			
		Saram Lake	7.97	ENE			
		Vilukkam Lake	8.21	W			
		Elamangalam Lake	8.60	WNW			
		Tondi Ar	8.75	SW			



		Saram R	8.91	ENE	
		Kondamur Ar	9.50	SE	
		Olakkur Lake	10.75	NE	
		Sankaraparani R/Varaha N	10.85	WSW	
		Etanemali Lake	10.98	NW	
		Ongur Channel	14.05	ENE	
		Nallur Lake	14.68	N	
		Reserved Forest			
		Sevur RF	12.39	Е	
		School	~Dist(km)	Direc	
		Sri Rajarajeswari Matric Hr Sec School	0.48	SE	
		Pattanam Panchayat Union Middle School	2.17	ENE	
		Kollar Goverment Higher Secondary School	2.46	WSW	
		Singanur Goverment ADW Higher Secondary School	4.46	SSE	
		Agoor Government Higher Secondary School	6.64	WNW	
		College	~Dist(km)	Direc	
3 Man	made Structures	nade Structures P.V.Polytechnic College		SSW	
		Thiru A Govindhasamy Goverment Arts College	0.53 4.37	ENE	
		University College of Engineering Tindivanam		4.38	ENE
		St. Ann's College of Arts And Science	5.97	SE	
		National College of Arts and Science	7.22	Е	
		Hospitals	~Dist(km)	Direc	
		Kollar Goverment PHC	2.48	W	
		Tindivanam Goverment Hospital	3.75	ESE	



Muppuli Goverment PHC	7.34	SSW
Endiyur Goverment PHC	9.74	ESE
Vellimedu Pettai Goverment PHC	9.94	NNW
Government Buildings	~Dist(km)	Direc
Avaraipakkam Sub Registrar Office	1.88	Е
Tindivanam Taluk Office	3.94	SE
Tindivanam Municipality Office	4.21	ESE
Tindivanam Sub Collector Office	4.89	SSE
Tindivanam Fire Station	5.57	SE
Religious Places	~Dist(km)	Direc
Shri Ragavendrar Temple	0.32	S
Sri Raja Rajeswari Arulvakku Siddhar Peedam	0.49	SE
Sri Lakshminarasimha Temple	3.7	ESE
Om Thinthirineesvarar Temple	4.05	ESE
Our Lady of Seven Dolors Church	4.87	SE
Poyyamozhi Vinayagar Temple	6.52	W
Sri Nidheeswarar Temple	10.83	SSE
Masjid E Aqusa	10.88	S
Neminathar Jain Alayam	11.05	NW
Sri Mailam Murugan Temple	13.49	S
Industries	~Dist(km)	Direc
Cheyyar SEZ Developers Private Limited	0.41	SSE
Pioneer Cold Store & Cladding Pvt Ltd	0.62	NE
Sri Ram Enterprises	0.68	NNE
JRMB Auto Technologies Private Limited	0.76	N
Dharshini Engineering Pvt Ltd	0.82	N
Stellar Pipes	0.84	NNE
SAF Petroleum	1.25	NNE



		Kals rises India Pvt Ltd		1.31	NNE
		Shree Kubera Vinayagar Modern Rice Mill		5.52	Е
		Kanishka Granites		6.09	Е
		Horizon Packs Pvt. Ltd		6.59	Е
		Mini Star Engineering Pvt Ltd		6.7	Е
		Jayanthi Agro Industries	8.08	SE	
		Senthaiyappa Modern Rice Mill		8.4	SE
		Prabakar Food Tech		8.89	SE
		KMC Rice Industry		9.11	SE
		KK Leathers		9.14	SE
		NCC Agro Industries		10.49	W
		Karuna Industries		10.5	SE
		Sulochana Engineering		10.64	ESE
		Suja shoe Industries Pvt ltd		14.79	ENE
4	State, National boundaries	Nil			
5	Nearest Highway/Railway	Nearest Railway Station - Tindivanam ~4.31 km (ESE) NH-77(Tindivanam-Krishnagiri)/NH179B(Chennai-Tind	divanam-Harur)~0	.37 km (S)	
6	Nearest Airport	Puducherry Airport ~37.48 km (SSE)			
7	Defence installations	Nil			
		Villages	~Dist	Dire	Population
		Hamlet(Periyar Ninaivu Samathuvapuram-Pattanam)	0.74km	NE	240
	Normant Williams and	Venmaniyattur	1.16km	N	1,350
8	Nearest Villages and Population	Pelakuppam	1.39km	SSE	1,610
	1 opulation	Vempundi	1.47km	SSW	1,843
		Pattanam	1.53km	ENE	2,896
		Tindivanam	2km	ESE	72,796



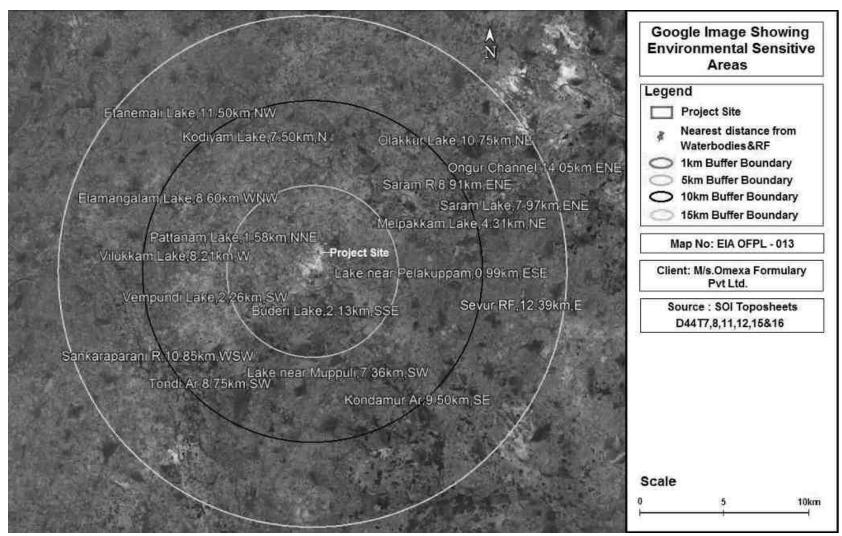


Figure 3-3Environmental sensitive areas covering within 15 km from project boundary



3.4 Physical Conditions of PIA district

In this section, the physical conditions of PIA district are discussed in general and wherever possible references to the conditions prevailing in the study area in particular are also provided. The physical conditions are discussed as under:

- District profile
- > Drainage, land use, geology, Physiographic profile
- > Natural resources
- > Climatic conditions, seismic zone characteristics and natural hazard.

3.4.1 PIA District Profile

Viluppuram district is located between 11^o and 35^o Northern Latitude and 78^o 38' and 80^o Eastern Longitude. It is bordered on the north by Kancheepuram district and Tiruvannamalai district, on the south by Cuddalore district and east by Union Territory of Puducherry. According to district authorities, the total geographical area of the district is 7194 sq kms.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(Ref: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

3.4.2 Climatic Conditions

The climate of Viluppuram district is fairly dry and on the whole healthy. The temperature is moderate. The maximum and minimum temperature in the district is 36°C and 21°C respectively. The rainfall is more in the coastal area compared to interior areas. An average, about 93.82% of the rainfall is received during NorthEast and South West monsoons. Normally the district does not get heavy rainfall with the exception of Marakkanam and Vanur blocks. The rainfall is moderate in Kandamangalam and Koliyanur blocks, it isscanty in Kallakkurichi and Sankarapuram blocks.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(**Ref**: Directorate of Census Operations-TamilNadu, "DistrictCensusHandbook-2011, ViluppuramDistrict", Series-34 Part XII-A)

3.4.3 Natural Resources of PIA District

3.4.3.1 Flora & Fauna

The coastal regions —containing the casuarinas plantations, sand dunes, the mangroves and scrub jungle. This includes the whole of Pitchavaram, Pitchavaram extension and Killai Reserved Forests.

The lateritic region- containing the extensive cashew plant at ion and dry evergreen forestcovering Kangiruppum Bit I and II, Velangulam, Ammeri, Narimanam, Semakottai and Extension, Kallamedu and Kuttady Reserved Forests.

The inland plains region - containing the eucalyptus and miscellaneous fuel plantations and the thorny scrub jungles atAlwarmalai, Varanjaram, Porasakurichi, Magarur, Katt umailur, Nangur, Krishnapuram, Thottapadi, Kottalamalai, Melpalangur, Mallapuram and Poosapadi Reserved Forests.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(Ref:DirectorateofCensusOperations-TamilNadu,"DistrictCensusHandbook-2011,ViluppuramDistrict", Series-34 Part XII-A)

3.4.3.2 ForestResources

Gingee and Kalrayan hills are the two major hills in the district. Forest areas in the district constitutes about 14% of the total area of the district which spread in the areas bordering Salem, Dharmapuri and Tiruvannamalai districts with divisions of reserve forest, interface forest and social forest. Teak, rose and sandal trees are found in the hills. In Kalrayan hills and Gingee areas some medicinal plants are grown. In the social forest areas, trees raised are mainly for firewood and paper making. Babul, Eucalyptus and Casuarina are found to be grown in the district. The main activities of forest department are protection and preservation of the existing natural forests and wild animals such as Spotted Deer, Antelope, Sloth Bear etc., and also development of the degraded forests.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B
DCHB VILUPPURAM.pdf

(Ref:DirectorateofCensusOperations-TamilNadu, "DistrictCensusHandbook-2011, ViluppuramDistrict", Series-34 Part XII-A)

3.4.3.3 Irrigation

Intensive and extensive cultivation of land depends mainly on the availability of water. The rivers in Viluppuram district are not perennial. So, the major sources of irrigation are tube wells and open dug wells. Lower anaicut, Tirukkoyilur anaicut, Ellis Chuoltry anaicut and reservoir are the important irrigation projects in the district.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(Ref:DirectorateofCensusOperations – TamilNadu, "DistrictCensusHandbook-2011, ViluppuramDistrict", Series-34 Part XII-A)

3.4.3.4 Agricultural Resources

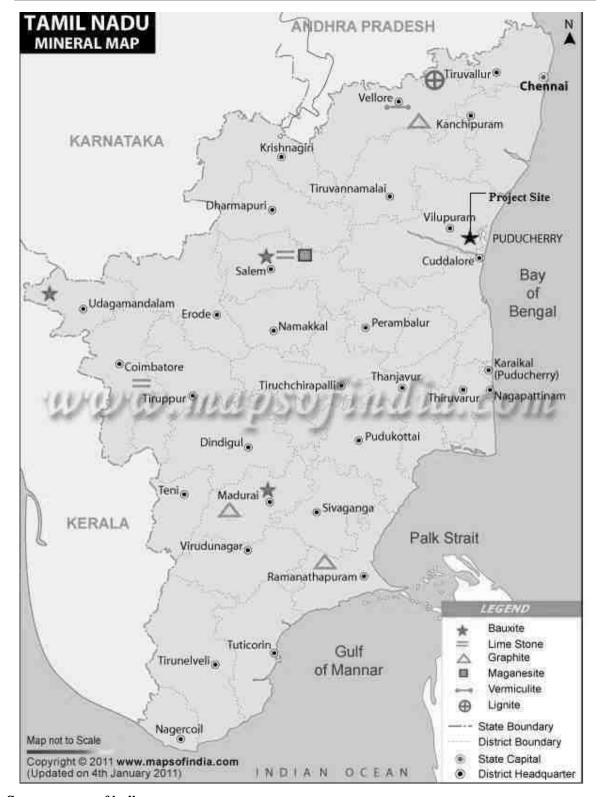
Agriculture is the mainstayof the people in the district. Except Gingee and Kalrayan hills, the entire district is characterized by plains. Major portion of the plains is utilized for agricultural purpose. The major crops in the district are paddy, groundnut, cotton, sugarcane, tapioca and cumbu. Paddy is the important food crop cultivated over an extent of 148454 hectares in the district during 2009-10. Among pulses, black grams andred grams are the most important varieties grown over an extent of 17276 and 519 hectares respectively. During 2009-10, nearly 19763 hectares were used for the production of pulses in the district.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(Ref: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

3.4.3.5 Mineral Resources

The major portion of Viluppuram district is covered by mineral deposits like silica sand, lime stone, black graniteand bluemetal. Silicasand is foundin Agaram reserve forest in Tindivanam taluk. Fine clay deposits are found in large numbers in Tindivanam taluk. Inferior grade sedimentary limestone deposit is found in Vanur taluk. Gingee, Kallakkurichi, Tindivanam, Tirukkoyilur, Ulundurpettai, Vanur and Viluppuram taluks has rich sources of export quantity of black granite. Multicoloured granites are found in Gingee, Kallakkurichi and Viluppuram taluks. The mineral map of Tamilnadu is shown in Figure 3-4.



Source: maps of india

Figure 3-4 Mineral Map of Tamilnadu

3.4.4 Land Use & Land Cover

Total geographic area of Villupuram district is 7254.50 Sq.Km. Urban Built-up area is 44.12 Sq.Km and Rural Built-up area is 246.08 Sq.Km. Details of land use/land cover statistics for Villupuramdistrict were given in **Table 3-2**and Land cover pattern of Villupuramdistrict is given in **Figure 3-5.** Land Use map of Villupuramis given in **Figure 3-6.**

Table 3-2 District land use/land cover statistics (2015-16) for Villupuram district

S.	Table 3-2 District land use/land cover sta	Areain	Areain	Areain	Total
No	DivisionofLandUse/LandCover	Sq.Km	Acres	Ha	Area%
1	Built-up,Urban	44.12	10902.27	4412	0.61
2	Built-up,Rural	246.08	60807.60	24608	3.39
3	Built-up,Mining	33.96	8391.69	3396	0.47
4	Agriculture, Cropland	3609.55	891937.85	360955	49.76
5	Agriculture,Plantation	252.31	62347.06	25231	3.48
6	Agriculture,Fallow	1435.24	354654.98	143524	19.78
7	Forest, Evergreen/Semievergreen	56.79	14033.09	5679	0.78
8	Forest, Deciduous	561.07	138643.20	56107	7.73
9	Forest, Forest Plantation	132.83	32822.96	13283	1.83
10	Grass/Grazing	3.81	941.47	381	0.05
11	Barren/unculturable/Wastelands,Salt Affectedland	32.95	8142.11	3295	0.45
12	Barren/unculturable/Wastelands,Gullied/Ravin ousLand	5.54	1368.96	554	0.08
13	Barren/unculturable/Wastelands,Scrubland	83.27	20576.43	8327	1.15
14	Barren/unculturable/Wastelands,Sandy Area	9.59	2369.74	959	0.13
15	Barren/unculturable/Wastelands,Barren rocky	13.97	3452.06	1397	0.19
16	Wetlands/WaterBodies,CoastalWetland	4.06	1003.25	406	0.06
17	Wetlands/WaterBodies,River/Stream/canals	110.19	27228.50	11019	1.52
18	Wetlands/WaterBodies,Resorvoir/Lakes/Ponds	619.17	153000.00	61917	8.53
	Total	7254.5	1792623.22	725450	100.00

Source: https://bhuvan-app1.nrsc.gov.in/thematic/thematic/index.php

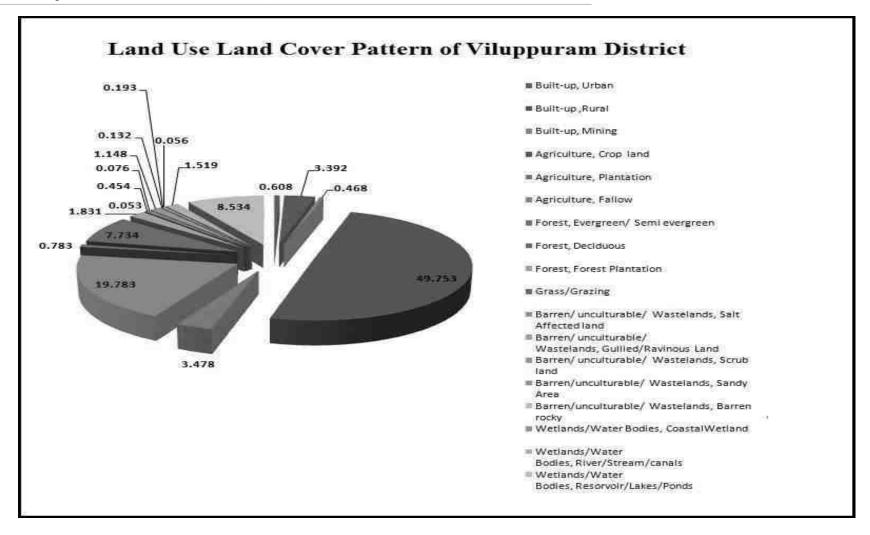
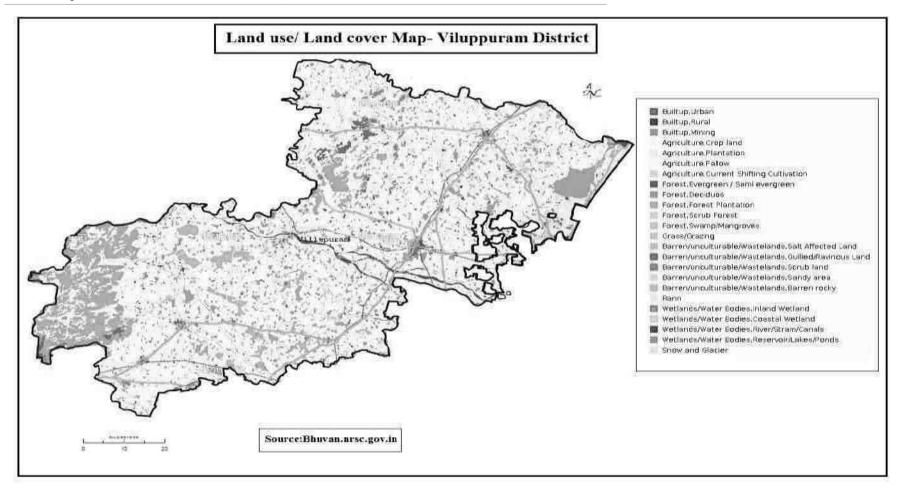


Figure 3-5Land use pattern of the Villupuram district





 $\textbf{\textit{Source:}} \underline{\textit{https://bhuvan-app1.nrsc.gov.in/thematic/thematic/index.php}}$

Figure 3-6Land use map of the VillupuramDistrict



3.4.4.1 Land Use and Land Cover of the Study Area

Total Project Study area is 320.66 Sq.km. The Land Use Pattern is given in Table 3-3. The Land Use Pattern and Land Use Map of the Study area are given in Figure 3-7& Figure 3-8 respectively.

Table 3-3 Land Use Pattern of the Study Area

Description	%	Sq.Km	Acres	Hec
Crop land	60.45	193.83	47896.36	19383
Fallow	18.03	57.80	14282.67	5780
Tanks / Lakes / Ponds	11.54	37.01	9145.36	3701
Plantation	3.86	12.39	3061.63	1239
Rural	3.01	9.66	2387.03	966
Urban	1.46	4.68	1156.45	468
Salt affected land	0.99	3.18	785.79	318
Scrub land	0.33	1.06	261.93	106
River / Stream / Canals	0.23	0.74	182.86	74
Barren rocky	0.06	0.19	46.95	19
Mining	0.04	0.12	29.65	12
Total	100.00	320.66	79236.69	32066

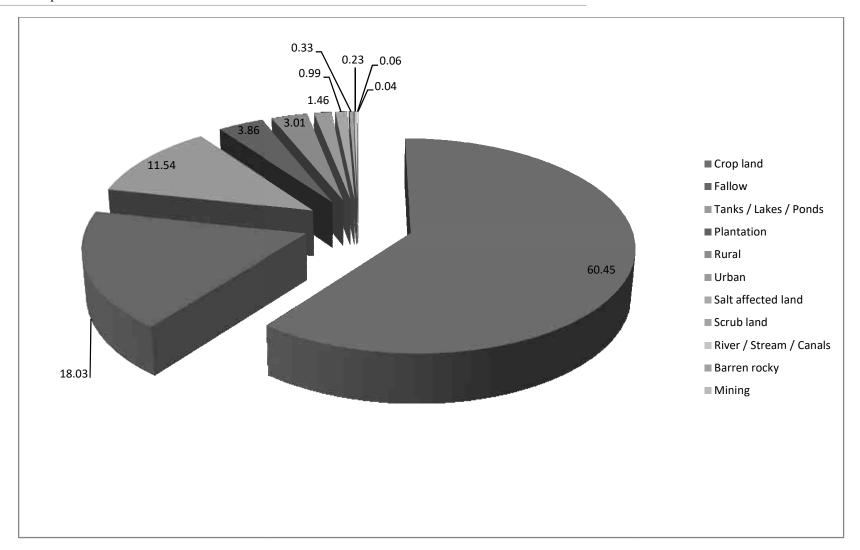


Figure 3-7Land Use Pattern of the Study Area



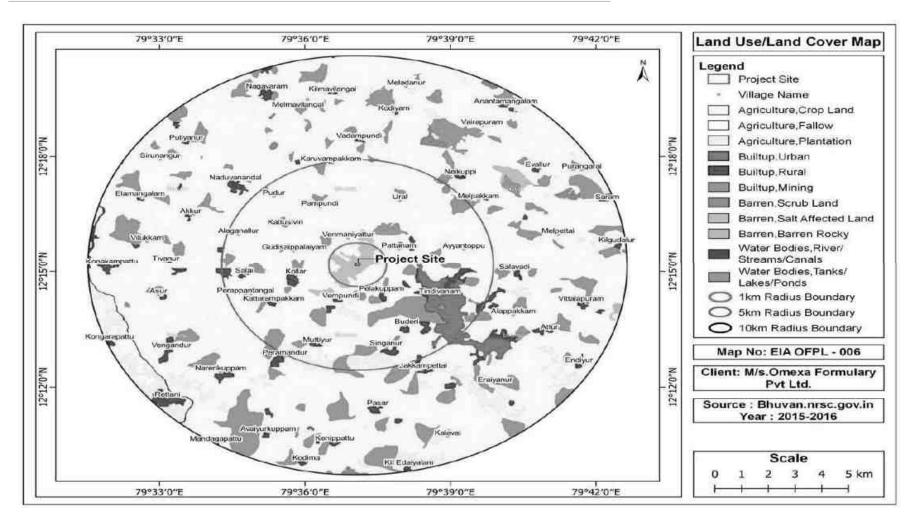


Figure 3-8Land Use Map of the Study Area



3.4.5 Topography

Thegreaterpart of the district iscoveredbythemetamorphicrocksbelonging to Gneissicformations. The district has also three types of sedimentary rocks belonging to different geological periods. The Kalrayan hills on the north represent a continuous range of hills covered with some thorny forests and vegetation. The most beautiful hill of the district is Gingee hills. The residual and denudational hills are common in Thirukoilur, Kallakurichi and Gingee taluks. Structural hills are noticed on the western part of the district. The shallow pediments and buried pediments are quite common in the central part of the district. The Physical map of Tamilnadu is given as **Figure 3-9** and contour map of the study area is given as **Figure 3-10**.

Source: https://spc.tn.gov.in/DHDR/Vlupuram_dt.pdf

Ref:State planning Comission—TamilNadu, "DistrictHumanDevelopmentReport-2017, Viluppuram District")

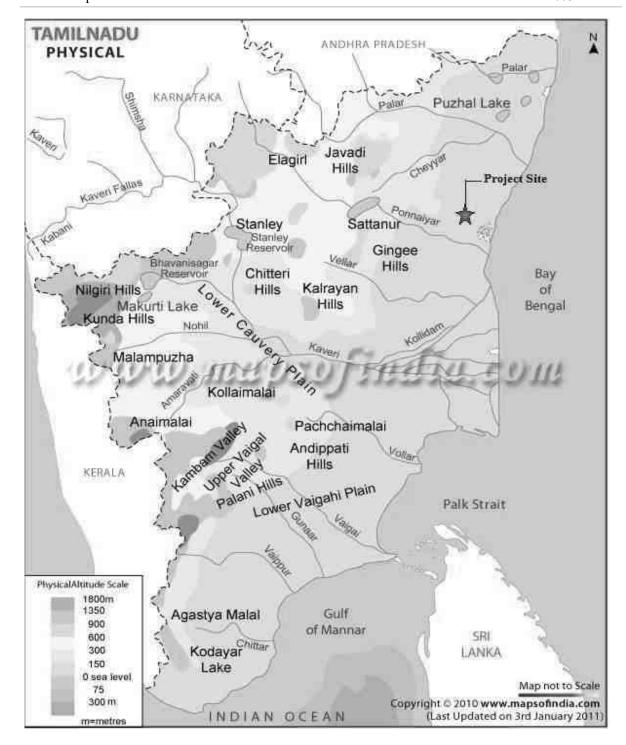


Figure 3-9Physical Map of Tamil Nadu

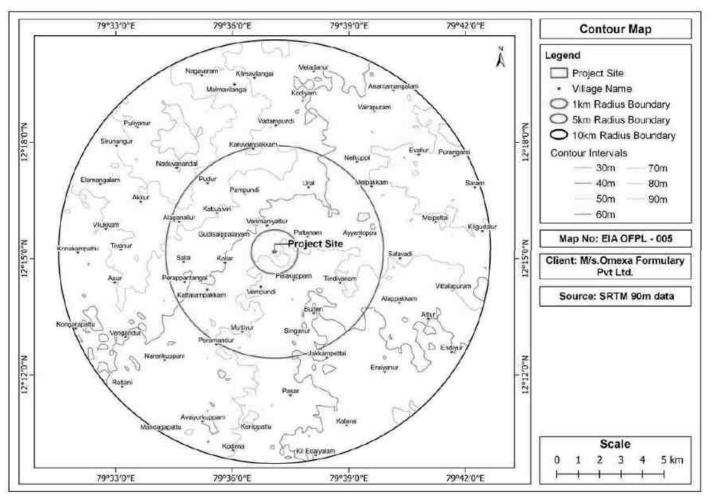


Figure 3-10Contour Map of Study Area



3.4.6 Geomorphology of PIA district

The residual hills and denudational hills are common in Tirukoilur, Kallakurichi and Gingee taluks. Structural hills are noticed in the western part of the district. The shallow pediments and buried pediments are common in the central part of the district. Coastal areas are having older and younger flood plains and also beach landforms at places. The ground slope is gentle towards coast. The valley fill near Villupuram is thick, which forms main ground water discharge zone. Lineaments are restricted to parts of Kallakurichi and Sankarapuram areas and productive fractures are noticed in select pockets. The crystalline sedimentary contact fault is having sympathetic fractures in hard rocks but mostly they are dry fractures. The Geomorphology Map of the Viluppuram District is shown as **Figure 3-12.**

Source: http://cgwb.gov.in/District Profile/TamilNadu/VILUPPURAM.pdf

3.4.6.1 Geomorphology of the Study Area

The total Geographical area of the study area is 320.49 Sq.Km. The Geomorphology of the study area is given in **Table 3-4** and Geomorphology pattern and Geomorphology Map of the study area is given in **Figure 3-11** and **Figure 3-13** respectively.

Table 3-4 Geomorphology of the Study Area

S.No.	Description	%	sq.Km	Acr	Hec
1	Denudational Origin-Pediment-PediPlain Complex	88.23	282.91	69908.48	28291
2	Waterbodies	11.77	37.75	9328.21	3775
	Total	100.00	320.66	79236.69	32066

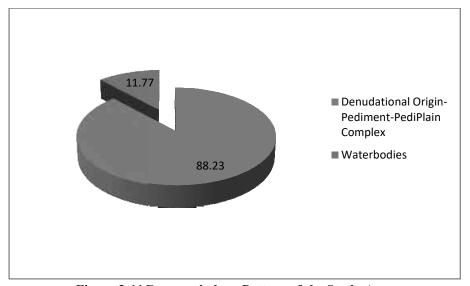


Figure 3-11Geomorphology Pattern of the Study Area

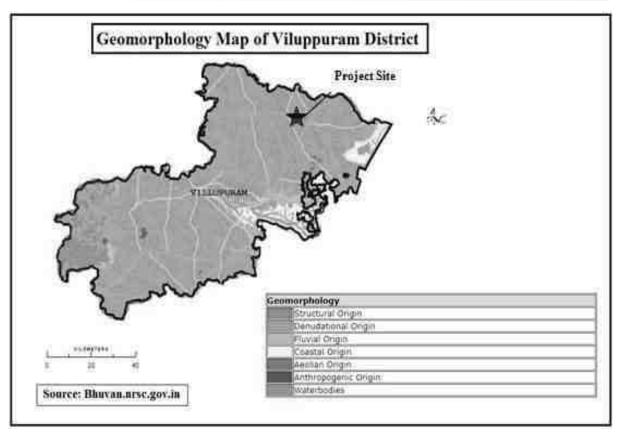


Figure 3-12Geomorphology Map of Villupuram District

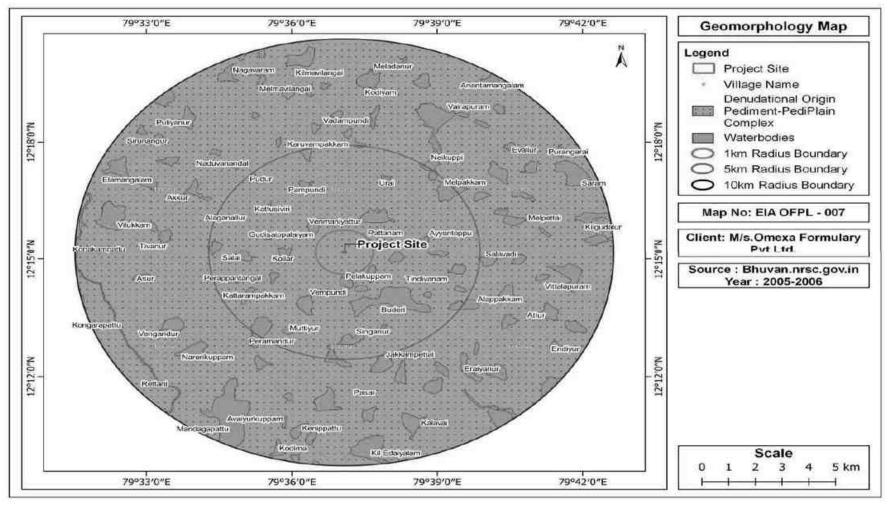


Figure 3-13 Geomorphology Map of the Study Area



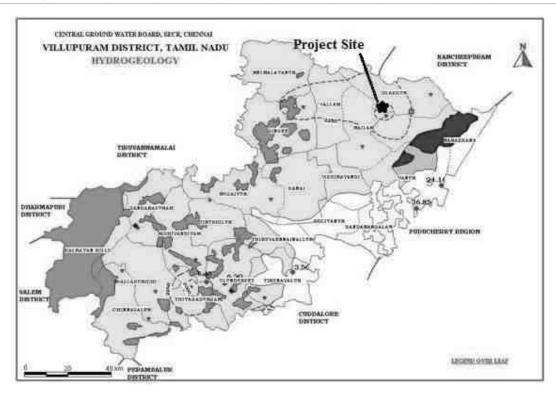
3.4.7 Hydrogeology of PIA district

Villupuram district is underlain by crystalline metamorphic complex in the western part of the district and sedimentary tract in eastern side (Plate-II). The thickness of sediments exceeds 600m near southern part of the district. Groundwater occurs under phreatic and semi-confined conditions in consolidated formations, which comprises weathered and fractured granites, gneisses and charnockites whereas in unconsolidated sedimentary rocks the groundwater occurs in phreatic, semi-confined conditions in Vanur sandstone, Kadapperi kuppam formation and Turuvai limestone. The district is having rocky outcrops in major part of Kallakurichi, Sankarapuram and Tirukoilur taluks. The weathering is highly erratic and the depth of abstraction structures is controlled by the intensity of weathering and fracturing. The depth of wells varies from 6.64 to 17m bgl and water levels in observation wells tapping shallow aquifers varied from 0.74 to 9.7 m bgl during pre monsoon (May 2006) and it varies from 0.7 to 4.45 mbgl during post monsoon (January 2007). During pre monsoon, the depth to water levels in the range of >2 to 5 m bgl in major part of the district, in the range of >5 -10 m bgl in western and southeastern parts of the district and range of 0-2 m bgl were recorded in two isolated pockets (Plate –III). During post monsoon the depth to water levels range of >2 to 5 m bgl exists in major part of the district, range of 0 - 2 m bgl prevails in central and northeastern parts of the district and range of >5 - 10 m bgl were recorded in two isolated pockets in the southwestern and north western parts of the district (Plate –IV).

The depth to piezometric surface ranged from 2.8 to 11.25 m bgl during Pre monsoon and 0.5 to 6.35 m bgl during post monsoon. The ground water is being developed my means of dug wells, bore wells and tube wells. The diameter of the well is in the range of 7 to 10 m and depth of dug wells range from 15 to 18 m bgl depending on the weathered thickness and joints. The dug wells yield up to 11ps in summer months and few wells remains dry. The yield is adequate for irrigation for one or two crops in monsoon period. The yield of bore wells in favorable locations vary from <1 to 61ps. The valley fills, intersection of lineaments, particularly, in the western part along the foot hills of Kalrayan hills are reported to have potential pockets suitable for dug wells and bore wells. The area of contact between crystalline and sedimentary formations has variable yield prospects. The cretaceous formations are very compact and yield prospects are low. The dug wells of 6 m diameter and 10 m bgl depth in sandy tracts give about 3.51ps. The yield of tube wells in the sedimentary formation ranges from 2.4 to 371ps. The hydrogeology map of Villupuram District is given in Figure 3-14.

Source: http://cgwb.gov.in/District Profile/TamilNadu/VILUPPURAM.pdf

Ref:GovernmentofIndia,MinistryofWaterResources,CentralGroundWaterBoard,SouthEasternCoastalRegion Chennai,"DistrictGroundWaterBrochureViluppuram District"



LEGEND PLATE -VI DISTRICT – VILLUPURAM

	Wells Feasible	Rigs Suitable	Depth of Well (m.bgl)	Discharge (LPM)	Suitable Artificial Recharge Structures		
	Dug Cum Bore Well Tube Well	Manual Direct Rotary	10 - 50 75 - 100	150 - 450	Recharge Tube Wells / Recharge Shaft		
Soft Rock Aspetier							
Sirt Rock Aspeter	Dug Well Fiber Point-Well Tuhe Well	Manual Hand Bore Direct Rotary	H-12 10-15 100-150	500 - 250	Rain Water Harvesting / Chock Dams / Percolation Funds / Gabion Structures Recharge Table Wells		
Hard Book Agents	Dug Well Bore Well	Minual	100 - 300	10.460	Cleck Dams Percolation Fonds		
Hard Rick Agenter	Dug Cum Bore Well Bore Well	Manual + DTH DTH	15 + 100 60 - 300	60-180	Percedation Ponds		
	Hore Well	EYTH	190 - 300	130 - 300	Percolation Pends		
Hard Reck Against					<u> </u>		
	District Boundary			Block Beambay			
m	Block Headquarter			Block Headquart	er .		
5	Water Level-Pre-Mono 1990-2002) mbgl	oon (Decadal Mean	fal Meun Et (Microsiemens / em af 25				
$\overline{}$	River	-		Lincament			
	Norate Greater Than S Limit (45 mgl)	faxemum Permissible		Hilly Ares			

Figure 3-14Hydrogeology Map of Villupuram District

3.4.8 Drainage Pattern in PIA district

Ponnaiyar, Malattar and Gadilam arethemajor riversdraining the district. Ponnaiyar Riverflows from northwest to east in the district. Manimukta nadi originates in Kalrayan hills and drains the southern part of the district.

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Pambaiyar and Varaganadhi originate in the uplands of the district and join Bay of Bengal. Varaganadhi is also known as Gingee River and drains the parts of GingeeandVanurtaluksofthisdistrict.MalattarandGadilamriversalsooriginateintheuplands within the district and flow eastwards to Cuddalore district. All the rivers are phemeral in nature and carry only floodwater during monsoon period. The drainage pattern is mostly parallel to sub parallel and drainage density is very low. There are small reservoirs across rivers namely Gomukhi, Vedur and Mahanathur. The drainage map of the Study Area is given as Figure 3.15.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_330_PART_B_DC HB_VILUPPURAM.pdf

(Ref: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

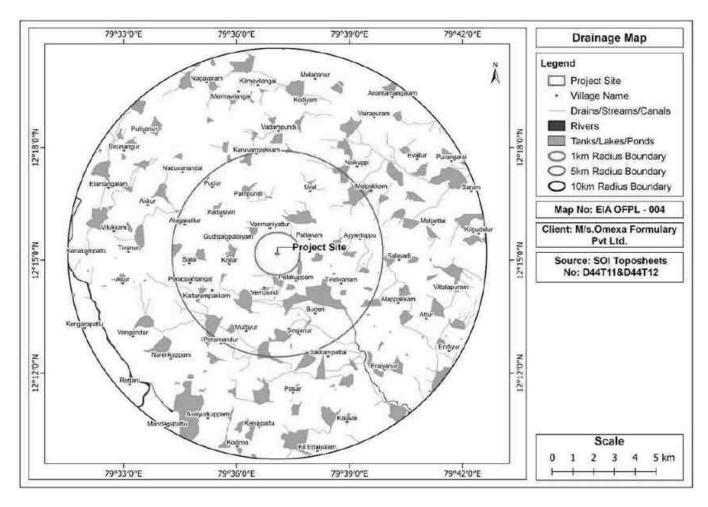


Figure 3-15Drainage Map of study area

3.4.9 Geology

The hills are found in the western part of the district and they are Kalrayan and Ginjee hills falling under Kallakurichi and Ginjee taluks respectively. Plain terrain occurs in the middle part of this district, while the coastal plains lie in the eastern part of the district in and around Marakanam and Vanur taluks. The Geological map of Tamilnadu is given as **Figure 3-16.**

Source: http://cgwb.gov.in/District Profile/TamilNadu/VILUPPURAM.pdf

(Ref: Government of India, Ministry of Water Resources, Central Ground Water Board, South Eastern Coastal Region Chennai, "District Ground Water Brochure Viluppuram District")

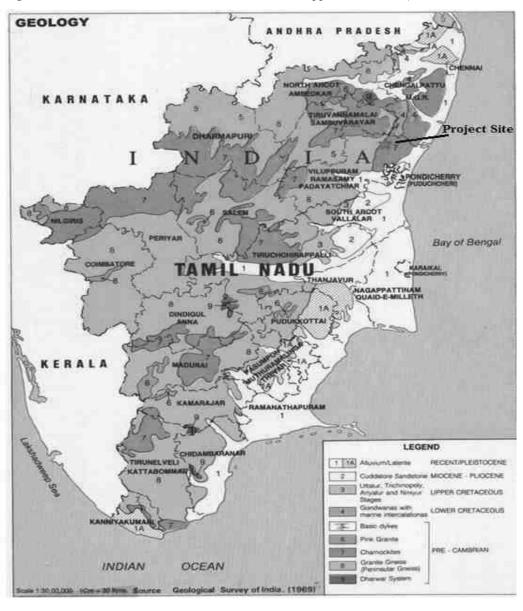


Figure 3-16Geology Map of Tamilnadu

3.4.10 Seismicity

As per Earthquake hazard map of Tamil nadu, the project location/study area falls in Zone II, which is categorized as a Low Damage Risk Zone. The Earthquake hazard map of Tamil Nadu is shown in **Figure 3-17.**

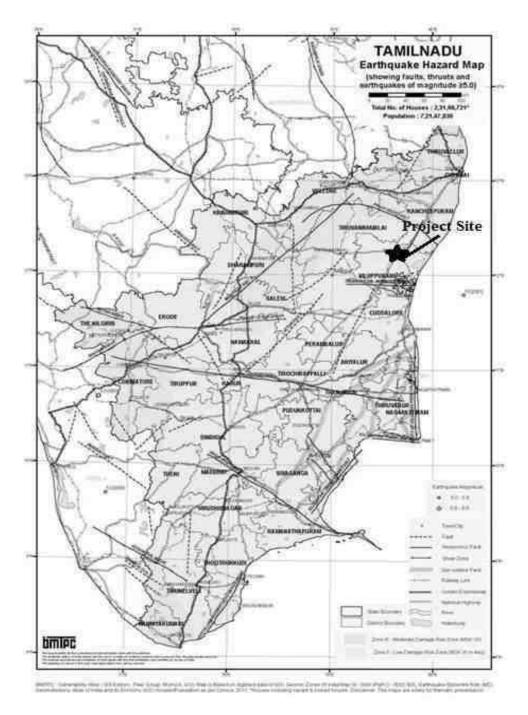


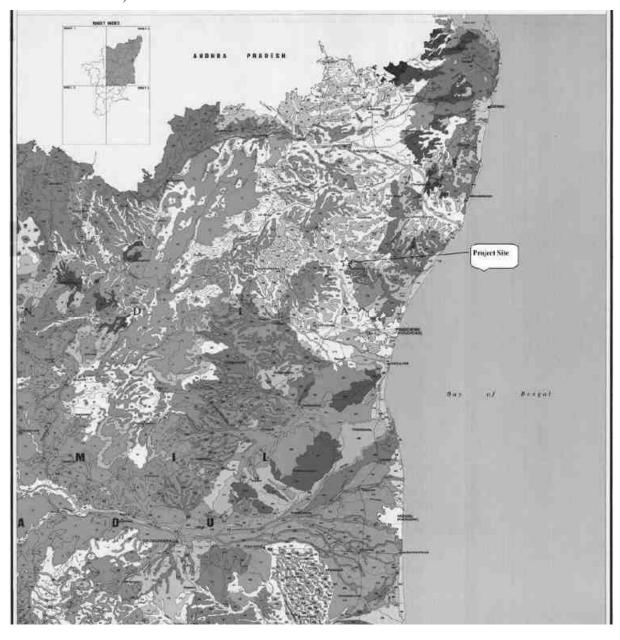
Figure 3-17Seismicity Map of Tamil Nadu

3.4.11 Soils in PIA District

The soils in the district are mainly red soil, sandy loam and black cotton soil. Alluvial soils are found in eastern side bordering coastal areas. Black soils are confined to low ground in select pockets in Vanur taluk. The Soil map of Tamil naud is given in **Figure 3-18.**

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DC HB_VILUPPURAM.pdf

(**Ref**:Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)



(Source: TN Agri University)

Figure 3-18 Soil map of Tamil nadu

3.4.12 Natural Hazards in PIA District

As any other coastal environment, coast of Villupuram district also gets affected with regular erosion and accretion. Sea level rise and elevation in sea surface temperature are also seen hereas the consequences of global climate change. It has been ascertained from the available information that only 8 taluks and 22 blocks were affected by flood in the years 1992-94 and affected by cyclone in the years 1993-94. Banana cultivation faces the cyclone havoc most frequently. The Wind Hazard Map of Tamil Nadu is given in **Figure 3-19**.

Source: http://tnenvis.nic.in/files/VILLUPURAM%20.pdf

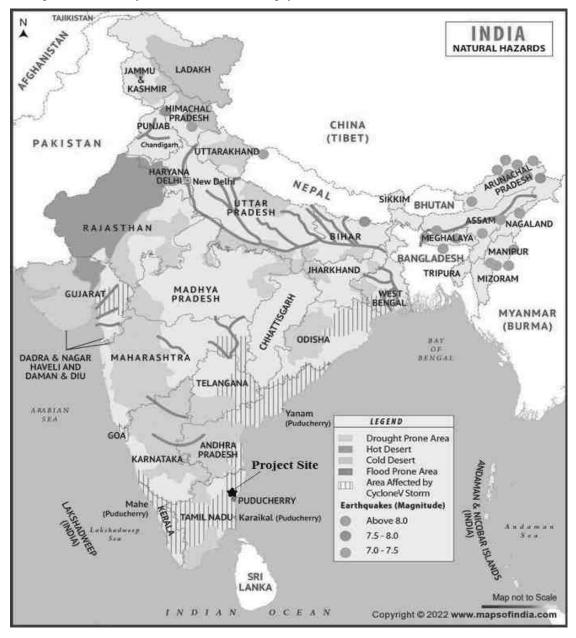


Figure 3-19 Natural hazard Map of India

3.5 Establishment of Baseline for valued environmental components

3.5.1 Air Environment

Baseline ambient air quality assessment gives the status in the vicinity of site and is an indispensable part of environmental impact assessment studies. Significant changes, in predominant winds and weather conditions are observed in winter, summer and post-monsoon seasons apart from the local topographic influences. The baseline status of air environment in the study area is assessed through a systematic air quality surveillance programme

3.5.2 Meteorological Conditions

The regional air quality is influenced by the meteorology of that region. The principal weather parameters that influence the concentration of the air pollutants in the surroundings are wind speed, wind direction and temperature. The meteorological data is useful for proper interpretation of the baseline data.

3.5.3 Meteorological Data Collection

Available secondary data pertaining to the meteorological parameters was obtained from the IMD Climatological tables. In addition, baseline meteorological data was generated during the study period of **March** to **May 2024**. The methodology adopted for monitoring surface observations is as per the standard norms laid down by Bureau of Indian Standards (BIS) i.e. IS:8829 and India Meteorological Department (IMD).

3.5.4 General Meteorological Scenario based on IMD Data

The nearest India Meteorological Department (IMD) station located to project site is Puducherry. The Climatological data of Puducherry (11°55' N and 79°50'E)published by the IMD, based on daily observations at 08:30 and 17:30 hour IST for a 30 year period (1991-2020), is presented in the following sections on the meteorological conditions of the region. The monthly variations of the relevant meteorological parameters are reproduced in **Table 3-5**.

Table 3-5 Climatological Summary – Puducherry (1991-2020)

Month	Temp(°C)		Rainfall Rela Humid		1		Mean Wind Speed	Predominant Wind Directions (From)*			
	Daily Max.	Daily Min.	Total (mm)	No. of days	08:30	17:30	08:30	17:30	(Kmph)	08:30	17:30
Jan	30.1	20.6	31	1.4	87	73	25.2	25.4	5.5	N	NE
Feb	31.2	21.4	8.1	0.9	85	71	26.5	26.4	4.9	NW	NE
Mar	32.7	23.6	9.9	0.6	82	72	29.5	29.4	4.5	NW	SE
Apr	34.4	26.2	9.2	0.4	78	76	32.7	33.4	5.4	S	SE
May	36.9	27.1	52	1.7	73	74	31.9	34.9	6.5	SW	SE
Jun	37.1	26.9	58.8	2.7	69	66	29.4	31.8	6.3	SW	S
Jul	36.1	26.2	80.5	4.8	73	64	29.1	30.6	5.9	SW	SE

Aug	35.2	25.6	130.7	6.6	76	68	29.4	31.8	5.4	SW	SE
Sep	34.4	25.2	131.7	6.8	80	75	30.3	32.0	4.9	SW	SE
Oct	32.6	24.4	229.3	9.6	85	79	30.9	31.3	4.0	NW	SE
Nov	30.5	22.8	351	11.1	89	82	29.2	29.3	4.8	N	NE
Dec	29.6	21.4	242	6.2	89	78	26.7	26.7	5.7	N	NE
Max.	37.1	27.1	351	11.1	89	82	32.7	34.9	6.5	An	nual
Min.	29.6	20.6	8.1	0.4	73	64	25.2	25.4	4.0		minant
Annual Avg/Total.	33.4	24.3	942	50.8	81	73	29.2	30.2	5.3		lirection ith East

As per the above IMD climatological Data given in **Table 3-5**, the observations drawn are as follows:

- ➤ Highest Daily maximum temperature is 37.1°C and the Lowest daily minimum temperature is 29.6°C were recorded in the months of June and December respectively
- Maximum and minimum relative humidity of 89% and 73% were recorded in the months of November, December and May, June respectively.
- Maximum and minimum rainfall of 351.0 mm and 0.4 mm was recorded in the months of November and April respectively.
- Maximum and minimum Mean wind speed is 6.5 km/hr and 4 km/hr was recorded in the months of May and October respectively. Annual Wind predominant pattern is South West.

3.5.5 Meteorological Scenario during Study Period

The meteorological scenario in and around the project site is an essential requirement during study period for proper interpretation of baseline air quality status. Meteorological data was collected during the study period March 2024 to May 2024 and is presented in Table 3-6. The wind rose for the study period is given as Figure 3-20.

Table 3-6 Meteorological Data for the Study Period (March 2024 to May 2024)

S. No	Parameter	Observation
		Max. Temperature: 41°C
1	Temperature	Min. Temperature: 24°C
		Avg. Temperature: 31.15°C
2	Average Relative Humidity	73.36%
3	Average Wind Speed	3.61m/s
4	Predominant Wind Direction	South East

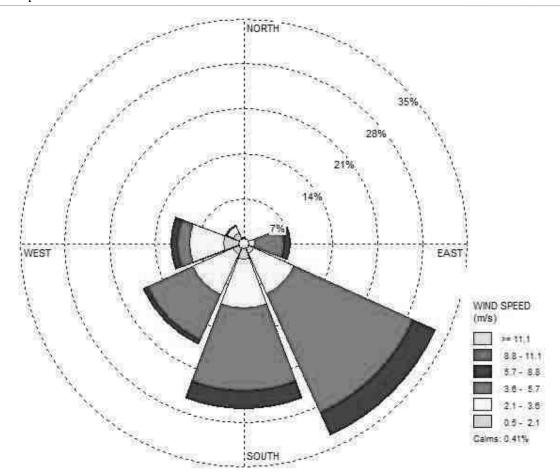


Figure 3-20Wind rose during study period (March 2024 to May 2024)

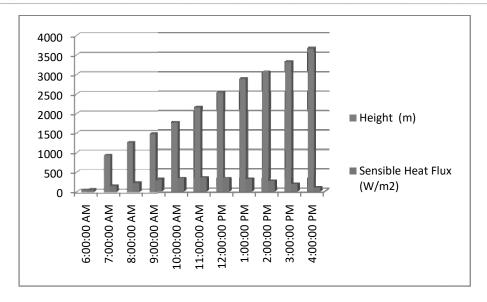
3.5.6 Atmospheric Inversion

Atmospheric inversion level at the project site was monitored; the results observed at the site during the study period are as follows:

- Average atmospheric temperature: 31.15°C
- Average Relative humidity: 73.36%
- Average Wind speed:3.61 m/s

The daily inversion level calculated based on the average temperature and average wind speed at the project site and the maximum inversion height is derived by the graph plotted based on the average temperature and average wind speed. The daily inversion level at the project site varies from 50 to 3673 m during 6 AM to 4 PM, the maximum recorded at 3673 m during May 2024. This is shown in the following **Note:**

Figure 3-21.



Note:

Figure 3-21Atmospheric inversion level at the project site

3.6 Ambient Air Quality

The selection criteria for monitoring locations are based on the following:

- > Topography/Terrain.
- Meteorological conditions Upwind and Downwind locations.
- Residential and sensitive areas within the study area.
- Representatives of regional background air quality/pollution levels
- Representation of likely impacted areas.

3.6.1 Ambient Air Quality Monitoring Stations

To evaluate the baseline air quality of the study area, Eight (08) monitoring locations have been identified as per annual wind predominance of Puducherry from IMD data (1991-2020). The wind predominance during study period (March to May 2024 is from South East). AAQ monitoring locations are selected based on Annual wind predominance, map showing the AAQ monitoring locations is given in Figure 3-22 and the details of the locations are given in Table 3-7.

Table 3-7 Details of Ambient Air Quality Monitoring Locations

Station Code	Location	Type of Wind	Distance(~km) from Project boundary	Azimuth Directions
AAQ1	ProjectSite	-	0.23	ESE
AAQ2	Ural	c/w	3.08	NNE
AAQ3	Tindivanam	c/w	3.38	ESE
AAQ4	Pelakuppam	u/w	1.43	SE
AAQ5	Vempundi	c/w	2.31	SSW
AAQ6	Kollar	c/w	2.25	WSW
AAQ7	Kattusiviri	d/w	3.14	NW
AAQ8	pudur	d/w	4.52	NW

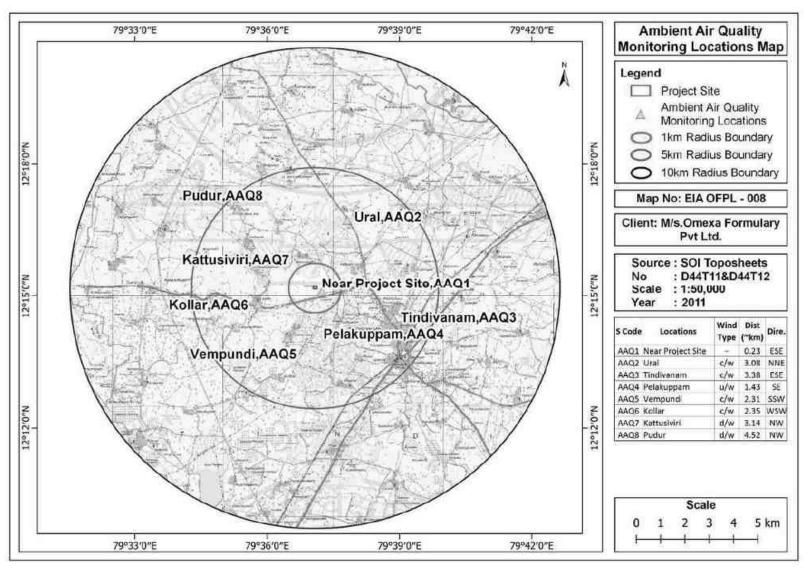


Figure 3-22Map showing the Air monitoring locations



3.6.2 Ambient Air Quality Monitoring Techniques, Frequency and Methodology

Ambient air quality was monitored twice in a week for One (01) season (shall cover 12 weeks), i.e. during (March to May 2024). PM10, PM2.5, SO2, NOx, CO, Pb, O3, NH3, C6H6, Ni were monitored. Sampling was carried out as per Central Pollution Control Board (CPCB) monitoring guidelines at each location. Analytical methods used for analysis of parameters are given in **Table 3-8**

Table 3-8 Analytical Methods for Analysis of Ambient Air Quality Parameters

S.No	Parameters	Analytical method	NAAQ sta	indards: 2009	Sampling Time		
1	Sulphur Dioxide (SO ₂), µg/m ³	IS:5182(Part-2):2001 (Reaff:2006)	50 (Annual)	80(24 Hours)	24 Hours		
2	Nitrogen Dioxide (NO ₂), μg/m ³	IS: 5182 (Part - 6): 40 (Annual) 80 (24 Hours)		80 (24 Hours)	24 Hours		
3	Particulate Matter (PM _{2.5}), µg/m ³	IS: 5182 (Part - 23): 2006	40 (Annual)	60 (24 hours)	24 Hours		
4	Particulate Matter (PM ₁₀), μg/m ³	IS:5182 (Part– 23): 2006	60 (Annual)	100 (24 hours)	24 Hours		
5	CO mg/m ³	IS:5182(Part– 10):1999 (Reaff:2006)	2 (8 hours)	4 (1hour)	8 Hours		
6	Pb μg/m ³	IS:5182(Part– 22):2004 (Reaff:2006)	0.5(Annual)	1(24 hours)	24 Hours		
7	O_3 , $\mu g/m^3$	IS: 5182 (Part – 9): 1974	100(8hours)	180 (1hour)	8 Hours		
8	NH_3 , $\mu g/m^3$	APHA(air) 2nd edition (Indophenol- blue method)	100(Annual)	400(24 hours)	8 Hours		
9	Benzene, μg/m ³	IS:5182(Part– 11):1999 (RA:2009)	5 (Annual)	5 (Annual)	24 Hours		
10	Benzo (a) pyrene, ng/m ³	IS:5182(Part– 12):2004 (RA:2009)	1 (Annual)	1 (Annual)	24 Hours		
11	Arsenic, ng/ m ³	APHA (air) 2nd edition	6 (Annual)	6 (Annual)	24 Hours		
12	Nickel ng/ m ³	In house method (AAS method) based on CPCB guidelines volume 1	20(Annual)	20(Annual)	24 Hours		

3.6.2.1 Results and Discussions

The variations of the pollutants PM10, PM2.5, SO2, NOx, CO, Pb, O3, NH3, C6H6, Ni,Benzo(a)Pyrene, Arsenic&Nickel are compared with National Ambient Air Quality Standards (NAAQS), MoEF&CC Notification, November 2009. Ambient Air Quality Monitoring Data (March to May 2024) for the study area is given in **Table 3-9** and trends of measured ambient concentration in the study area were graphically represented in **Figure 3-23**.



Table 3-9 Summary of the average baseline concentrations of pollutants

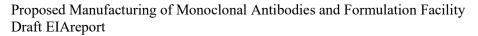
			Locations							
Parameters	Conc.	NAAQ Standards	Near Project Site	Ural	Tindivana m	Pelakuppa m	Vempundi	Kollar	Kattusivir i	pudur
			A1	A2	A3	A4	A5	A6	A7	A8
	Min.		34.50	36.18	41.73	31.11	32.64	32.24	30.24	32.98
PM ₁₀ Conc. (µg/m³)	Max.	100	49.17	51.56	59.48	44.34	46.52	45.95	43.10	47.01
	Avg.	(24Hours)	41.38	43.38	50.05	37.31	39.14	38.66	36.27	39.55
	98th'tile		48.89	51.26	59.13	44.08	46.25	45.68	42.85	46.73
	Min.		19.98	19.60	23.25	19.15	19.24	18.27	18.18	17.86
PM _{2.5} Conc. (μg/m ³)	Max.	60	28.48	27.93	33.13	27.30	27.42	26.04	25.91	25.45
	Avg.	(24Hours)	23.97	23.50	27.88	22.97	23.07	21.91	21.80	21.42
	98th'tile		28.31	27.77	32.94	27.14	27.26	25.89	25.76	25.31
	Min.		7.35	7.60	8.74	7.32	7.84	7.08	8.00	8.35
GO G (. / . 3)	Max.	80	10.47	10.83	12.46	10.44	11.17	10.09	11.40	11.90
SO ₂ Conc. (μg/m ³)	Avg.	(24Hours)	8.82	9.12	10.49	8.79	9.41	8.50	9.60	10.02
	98th'tile		10.41	10.77	12.39	10.38	11.11	10.03	11.33	11.83
	Min.		17.17	16.71	18.19	16.52	17.08	16.53	16.19	16.44
NO ₂ Conc. (μg/m ³)	Max.	80	24.47	23.81	25.92	23.55	24.35	23.56	23.07	23.43
	Avg.,	(24Hours)	20.59	20.04	21.81	19.82	20.49	19.83	19.42	19.72
	98th tile		24.32	23.67	25.77	23.41	24.21	23.43	22.94	23.30
Lead(Pb) (μg/m³)	Avg.	1 (24 hour)	BLQ (LOQ 0.05)	BLQ (LOQ 0.05)	BLQ(LOQ 0.05)	BLQ (LOQ 0.05)	BLQ(LOQ 0.05)	BLQ (LOQ 0.05)	BLQ (LOQ 0.05)	BLQ(LOQ 0.05)
Carbon monoxide (CO) (mg/m³)	Avg.	4 (1hour)	0.69	0.62	0.72	0.64	0.7	0.69	0.63	0.71
OzoneO ₃ (μg/m³)	Avg.	180 (1hour)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ (LOQ10)	BLQ(LO Q10)	BLQ(LOQ 1 0)	BLQ(LO Q 10)	BLQ(LO Q10)	BLQ(LOQ 1 0)



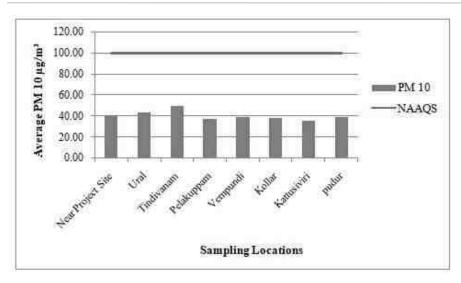
Benzene(C ₆ H ₆)(μg/ m ³)	Avg.	5(Annual)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)
Benzo (a) Pyrene (C ₂₀ H ₁₂ (a)) (ng/m ³)	Avg.	1(Annual)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)	BLQ (LOQ 1)
Arsenic (As) (ng/m³)	Avg.	6 (Annual)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)	BLQ (LOQ 2)
Nickel as Ni (ng/m³)	Avg.	20(Annual	BLQ(LO Q 10)	BLQ(LO Q 10)	BLQ(LOQ 10)	BLQ(LOQ 10)	BLQ(LOQ 10)	BLQ(LO Q 10)	BLQ(LOQ 10)	BLQ(LOQ 10)
Ammonia(NH ₃) (μg/m ³)	Avg.	400(24 hour)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)	BLQ(LO Q10)

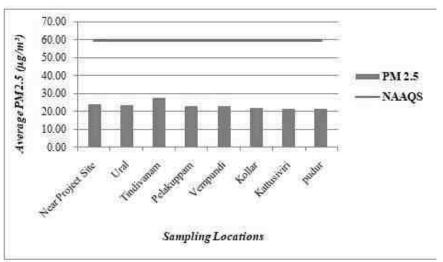
Note: BLQ (Below LimitOf Quantification), LOQ (Limit Of Quantification)

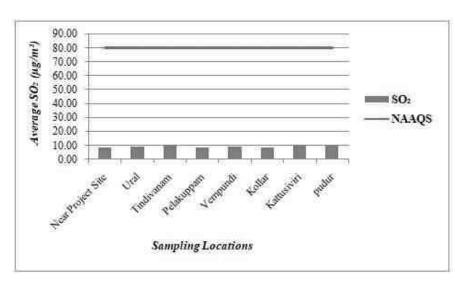




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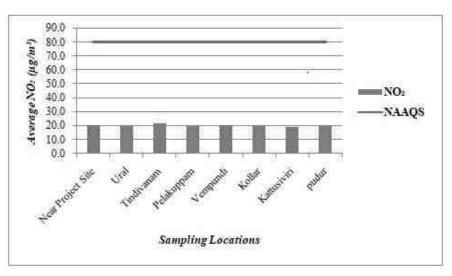


Figure 3-23Graphical representation of ambient concentration in the study area



3.6.2.2 Observations

The ambient air quality has been monitored at 8 locations as per NAAQS, 2009 within the study area. The results obtained are summarised as below:

- The average baseline levels of PM₁₀ vary from 36.27 to $50.05 \mu g/m^3$.
- The average baseline levels of PM_{2.5} vary from 21.42 μ g/m³ to 27.88 μ g/m³.
- The average baseline levels of SO_2 vary from $8.50 \mu g/m^3$ to $10.49 \mu g/m^3$.
- The average baseline levels of NO₂vary from 19.42 μ g/m³ to 21.81 μ g/m³

3.7 Noise Environment

The prevailing ambient noise level at a particular location is nothing but the resultant (total) of all kinds of noise sources existing at various distances around that location. The ambient noise level at a location varies continuously depending on the type of surrounding activities.

Ambient noise levels have been established by monitoring noise levels at Eight (08) locations in and around 10Km distance from project area during the study period using precision noise level meter. The noise monitoring locations in the study area were selected after giving due consideration to the various land use categories. The land use categories include commercial, residential, rural and sensitive areas. Noise levels were recorded on an hourly basis for one complete day at each location using pre-calibrated noise levels. Map showing noise monitoring locations is **Figure 3-24**.

3.7.1 Results and Discussions

Based on the recorded hourly noise levels at each monitoring location, the day equivalent (Ld) and night equivalent (Ln) were calculated;

- Ld: Average noise levels between 6:00 hours to 22.00 hours.
- Ln: Average noise levels between 22:00 hours to 6.00 hours.

The comparison of day equivalent noise levels (Ld) and night equivalent noise levels (Ln) with the respective CPCB stipulated noise standards for various land use categories are shown in the **Table 3-10**.



Table 3-10 Day and Night Equivalent Noise Levels

S. N		Location Code	Distance(~k m) from	Azimuth	Noiselevel in dB(A) Leq			PCB ndard	Environmental
0	Location		Project bound ary	Direction	Day	Night	Lday (Ld)	LNight (Ln)	Setting
1	ProjectSite	N1	Within	the site	54.6	49.3	75	70	Industrial
2	Pattanam	N2	1.67	ENE	47.6	42.5	55	45	Residential
3	Tindivanam	N3	3.09	ESE	52.8	43.6	55	45	Residential
4	Pelakuppam	N4	1.57	SSE	45.4	41.9	55	45	Residential
5	Kollar	N5	2.38	WSW	49.7	43.2	55	45	Residential
6	Gudisaippalaiyam	N6	2.35	WNW	50.2	43.5	55	45	Residential
7	Kattuvisiri	N7	3.14	NW	51.5	40.4	55	45	Residential
8	Venmaniyathur	N8	1.34	N	48.8	41.7	55	45	Residential

3.7.1.1 Observations

It is observed that the day equivalent and night equivalent noise levels at all locations are within prescribed CPCB standards

- In Industrial area (Project site), day time noise level was about 54.6 dB (A) and 49.3 dB(A) during night time, which is within prescribed limit by CPCB for Industrial area (75 dB(A) Day time & 70 dB(A)Night time).
- In Residential area day time noise levels varied from 45.4 dB (A) to 54.6 dB (A) and night time noise levels varied from 40.4 dB(A) to 43.6 dB(A) across the sampling stations. The field observations during the study period indicate that the ambient noise levels in Residential area are within the limit prescribed by CPCB for Residential area (55 dB (A) Day time & 45 dB(A) Night time).



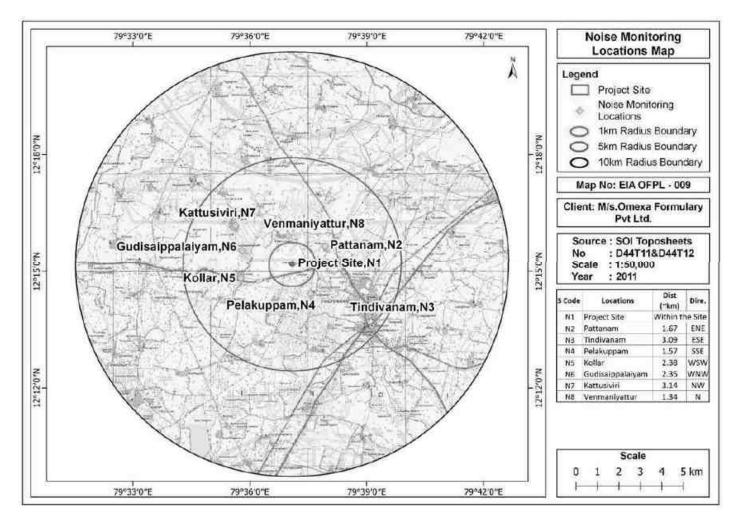


Figure 3-24Map showing the Noise Monitoring locations

3.8 Water Environment

3.8.1 Surface Water Resources

The Ponnaiyar, the Malattar and the Gadilam are the major rivers draining the district. The Ponnaiyar River flows from northwest to eastin the district. The Manimukta nadioriginates in Kalrayan hills and drains the southern part of the district. The Pambaiyarand the Varaganadhi originatein theuplandsofthedistrictand join Bayof Bengal. The Varaganadhi is also knownas the Gingee River and drains the parts of Gingee and Vanurtaluks of this district. The Malattar and Gadilam rivers also originate in the uplandswithin the district and flow eastwards to Cuddalore district. All the rivers are ephemeralin nature and carry only floodwater during monsoon period. The drainage pattern is mostly parallel to sub parallel and drainage density is very low. There are small reservoirs across rivers namely Gomukha, Vedur and Mahanathur.

Source: http://cgwb.gov.in/District Profile/TamilNadu/VILUPPURAM.pdf

(Ref:GovernmentofIndia,MinistryofWaterResources,CentralGroundWaterBoard,SouthEasternCoastalRegion Chennai,"District Ground Water Brochure Viluppuram District")

3.8.2 Surface Water Quality Assessment

Water quality monitoring and assessment can be used to determine ambient water quality, the extent and causes of a water quality problem, or to measure the effectiveness of best management practices being implemented in water system. Monitoring helps to determine the trends in the quality of the aquatic environment and the impact due to the release of contaminants, other anthropogenic activities, and/or by waste treatment operations (impact monitoring). To establish the baseline status of water environment, the representative sampling locations for surface water within a radial distance of 10Km from project site have been selected as per CPCB guidelines of Water Quality Monitoring through an adequate survey of the project area. Test methods used for the analysis of water quality parameters is given in **Table 3-11**.

Table 3-11 Test methods used for the analysis of water quality parameters

Sl. No	Parameter Measured	Test Method
1.	Turbidity	IS 3025(Part - 10):1984
2.	рН	IS:3025 (Part - 11): 1983
3.	Electrical Conductivity	IS:3025 (Part - 14): 1983
4.	Total Dissolve Solids	IS: 3025:1(Part - 16) 1984
5.	Total Suspended Solids	IS 3025 (Part - 17) 1984
6.	Total Alkalinity as CaCO3	IS:3025,1 (Part - 23) 1986
7.	Total Hardness as CaCo3	IS:3025 (Part - 21) 1983
8.	Sodium as Na	IS:3025,5(Part - 45) 1993
9.	Potassium as K	IS:3025,5(Part - 45) 1993
10.	Calcium as Ca	IS 3025 (Part - 40):1991
11.	Magnesium as Mg	IS 3025 (Part - 46) 1994
12.	Chloride as cl	IS 3025 (Part - 32):1988

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Sl. No	Parameter Measured	Test Method
13.	Sulphate as SO4	IS 3025(Part - 24):1986
14.	Nitrate as NO ₃	ASTM (Part - 31)1978
15.	Fluorides as F	IS 3025 (Part - 60):2008
16.	Cyanide as Cd	IS 3025 (Part-27):1986
17.	Arsenic as As	IS 3025:(Part-37):1988
18.	Cadmium as Cd	IS 3025 (Part - 41)1991
19.	Chromium, Total	IS:3025 (Part - 52) 2003
20.	Lead as Pb	IS:3025 (Part - 47) 1994
21.	Manganese as Mn	IS 3025:(Part - 59):2006
22.	Mercury as Hg	IS 3025 (Part48):1994
23.	Nickel as Ni	IS 3025:(Part-54):2003
24.	Selenium as Se	IS 3025 Part (56)2003
25.	Zinc as Zn	IS:3025 (Part - 49) 1994
26.	Dissolved Oxygen (DO)	IS:3025 (Part - 38)1989
27.	BOD, 3 days @ 27°C as O ₂	5210B APHA22nd Edn 2012
28.	Chemical Oxygen Demand as O ₂	IS:3025 (Part-58)-2006

Table 3-12 Details of Surface water sampling locations

S.No	Location	Location Code	Distance in Km	Direction
1	PattanamLake	SW1	1.60	N
2.	Melapakkam Lake	SW2	4.86	ENE
3	Lake near Pelakuppam	SW3	1.21	Е
4	BuderiLake	SW4	4.02	SE
5	Kondamur lake	SW5	9.60	S
6	VembudiLake	SW6	3.02	SSW
7	TondirAr	SW7	8.94	WSW
8	VenmaniyathurLake	SW8	1.41	WNW

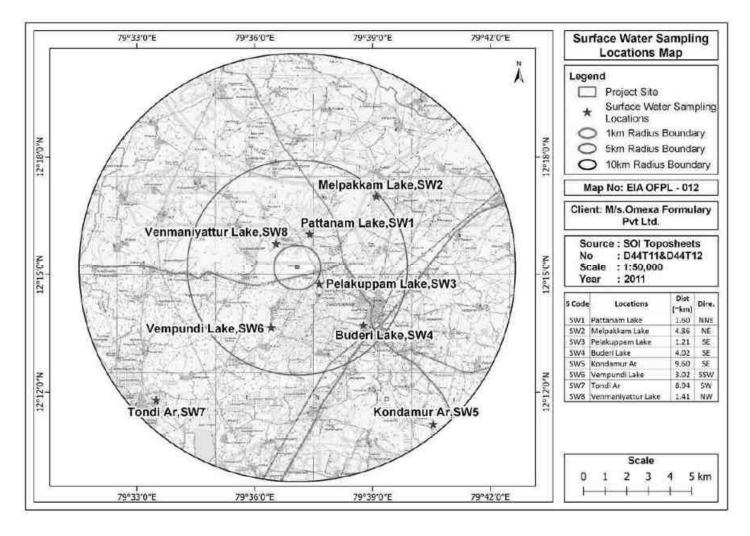


Figure 3-25Map showing the surface water monitoring locations

Table 3-13 Surface water Monitoring Results

S.No	Parameter	Unit	Surface water standard s (IS 2296	Pattanam Lake	Melapakkam Lake	Lake near Pelakuppam	Buderi Lake	Kondamur lake	Vembudi Lake	TondirAr	Venmaniyathur Lake
			Class-A	SW 1	SW 2	SW 3	SW 4	SW 5	SW 6	SW 7	SW 8
1	pH(at 25°C)		6.5-8.5	7.41	7.49	7.62	7.55	7.45	7.69	7.74	7.34
2	Turbidity	NTU	1	4.6	5.4	6.2	4.9	5.7	6.8	6.1	5.2
3	Electrical Conductivity	μS/cm	-	720	705	690	783	850	694	713	721
4	Total Dissolved Solids	mg/l	500	415	423	401	445	473	400	395	409
5	Total Suspended Solids	mg/l	-	58	44	39	42	26	35	46	52
6	Total Alkalinity as CaCO ₃	mg/l	-	117	108	133	141	158	92	100	141
7	Total Hardness as CaCO ₃	mg/l	300	231	184	231	180	265	175	193	192
8	Sodiumas Na	mg/l	-	46	64	51	69	67	61	55	63
9	PotassiumasK	mg/l	-	3	4	3	5	5	4	4	3
10	CalciumasCa	mg/l	-	46.6	39.05	49.76	38.59	42.77	47.63	41.62	39.26
11	MagnesiumasMg	mg/l	-	15.66	16.63	19.63	15.55	23.17	15.82	16.88	12.99
12	ChlorideasCl	mg/l	250	102.6	112.5	106.46	122.6	138.5	126.9	113.7	107.3
13	SulphateasSO ₄	mg/l	400	44.6	55.7	48.6	53.6	55.4	49.5	45.2	41.8
14	NitrateasNO3	mg/l	20	11.2	9.81	9.67	8.97	9.53	9.14	10.63	9.64
15	FluoridesasF	mg/l	1.5	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
<u> </u>		8		Q0.2)	Q0.2)	0.2)	Q0.2)	Q0.2)	Q0.2)	Q0.2)	0.2)
16	Cyanide	mg/l	0.05	BLQ(LO Q0.01)	BLQ(LO Q0.01)	BLQ(LOQ 0.01)	BLQ(LO Q0.01)	BLQ(LO Q0.01)	BLQ(LO Q0.01)	BLQ(LO Q0.01)	BLQ(LOQ 0.01)
				BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ
17	Arsenic	mg/l	0.05	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)	(LOQ 0.005)



18	Cadmium as Cd	mg/l	0.01	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
10	Cadillulli as Cu	ilig/i	0.01	Q0.001)	Q0.001)	0.001)	Q0.001)	Q0.001)	Q0.001)	Q0.001)	0.001)
10	CI : T . I	/1	0.05	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
19	Chromium,Total	mg/l	0.05	Q0.01)	Q0.01)	0.01)	Q0.01)	Q0.01)	Q0.01)	Q0.01)	0.01)
20	I 1 DI	/1	0.1	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
20	Lead as Pb	mg/l	0.1	Q0.005)	Q0.005)	0.005)	Q0.005)	Q0.005)	Q0.005)	Q0.005)	0.005)
21	Manganese as Mn	mg/l	0.5	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
	Triangunese us iviii	mg r	0.5	Q0.05)	Q0.05)	0.05)	Q0.05)	Q0.05)	Q0.05)	Q0.05)	0.05)
22	Mercury	mg/l	0.001	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
22	iviciculy	mg/i	0.001	Q 0.0005)	Q 0.0005)	0.0005)	Q0.0005)	Q 0.0005)	Q 0.0005)	Q 0.0005)	0.0005)
23	Nickel as Ni	~/1		BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
23	Nickei as Ni	mg/l	-	Q0.01)	Q0.01)	0.01)	Q0.01)	Q0.01)	Q0.01)	Q0.01)	0.01)
24	C-1	/1	0.01	BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
24	Selenium as Se	mg/l	0.01	Q0.005)	Q0.005)	0.005)	Q0.005)	Q0.005)	Q0.005)	Q0.005)	0.005)
25	7.	/1		BLQ(LO	BLQ(LO	BLQ(LOQ	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LO	BLQ(LOQ
25	Zinc	mg/l	-	Q0.1)	Q0.1)	0.1)	Q0.1)	Q0.1)	Q0.1)	Q0.1)	0.1)
26	Dissolved Oxygen	mg/l	6	6.1	6.3	6.6	5.7	6.1	5.9	6.4	6.5
27	Chemical Oxygen Demand as O2	mg/l	-	16	12	10	22	16	18	12	13
	BOD, 3days@27°C as O2	mg/l	2	4	2	2	5	3	4	2	4

(Note: BLQ – Below Limit of Quantification; LOQ – Limit Of Quantification)

3.8.2.1 Results and Discussions

Surface water sample results are discussed below:

- Water sampling results are compared with Surface water standards IS 2296:1992.
- pH in the collected surface water samples varies between 7.34to7.74.
- The Total Dissolved Solids (TDS) value of collected surface water sample ranges from 395mg/l to 473mg/l.
- The Total hardness value of the collected surface water sample ranges between 175 mg/l to 265 mg/l.
- BOD value of surface water varies from 2 mg/l to 5 mg/L
- COD value of surface water varies from 10 to 22 mg/l.

Surface water standards (IS2296:1992) given in below table.

Table 3-14Surface water Standards IS 2296:1992

S.No	Parameters	Unit	A	В	C	D	E
1.	Turbidity	NTU					
2.	рН		8.5	8.5	8.5	8.5	8.5
3.	Conductivity	μS/cm				1000	2250
4.	Total Dissolved Solids	mg/l	500		1500		2100
5.	Total Suspended Solids	mg/l					
6.	Alkalinity as CaCO ₃	mg/l					
7.	Total Hardness as CaCo ₃	mg/l	300				
8.	Calcium as Ca	mg/l					
9.	Magnesium as Mg.	mg/l					
10.	Sodium Na	mg/l					
11.	Potassium	mg/l					
12.	Chloride as Cl	mg/l	250		600		600
13.	Sulphate as SO4	mg/l	400		400		1000
14.	Nitrate as NO ₃	mg/l	20		50		
15.	Fluorides as F	mg/l	1.5	1.5	1.5		
16.	Cyanide	mg/l	0.05	0.05	0.05		
17.	Arsenic	mg/l	0.05	0.2	0.2		
18.	Cadmium	mg/l	0.01		0.01		
19.	Chromium, Total	mg/l	0.05	0.05	0.05		
20.	Lead	mg/l	0.1		0.1		
21.	Nickel	mg/l					
22.	Zinc	mg/l	15		15		

S.No	Parameters	Unit	A	В	C	D	E
23.	Manganese	mg/l	0.5				
24.	Selenium	mg/l	0.01		0.05		
25.	Mercury	mg/l	0.001				
26.	Dissolved Oxygen	mg/l	6	5	4	4	
27.	COD	mg/l					
28.	BOD	mg/l	2	3	3		

Class A – Drinking water without conventional treatment but after disinfection.

Class B – Water for outdoor bathing.

Class C – Drinking water with conventional treatment followed by disinfection.

Class D – Water for fish culture and wild life propagation.

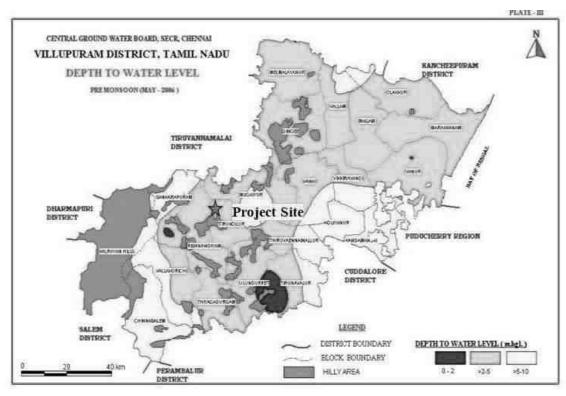
Class E – Water for irrigation, industrial cooling and controlled waste disposal

3.8.3 Ground Water Resources

Ground water development is very high in the district. There are number of dug wells and dug cum bore wells in the hard rock areas while tube wells are common in the sedimentary areas. The average draft of dug wells in hard rock areas is of the order of 1.2 ha.m./year. The extraction of ground water by shallow tube wells in the eastern part of the district is of the order of 2.5ha.m./year. The average command area for dug well and bore well in the district is 2ha and 3 ha respectively. The hard rock areas in select pockets with valley fills and lineaments are having appreciable groundwater potential. At many pockets, the command areas are the main potential groundwater zones, The yield prospects are good in select pockets of Villupuram, Sankarapuram and Kallakurichi areas where as it is very poor in Tirukoilur, Ulundurpet, Gingee and Tindivanam taluks. The massive granites in Gingee and Tindivanam taluks do not favour even bore wells. The augmentation of well yield by horizontal and extension bores is successful in part of Kallakurichi and Tirukoilur areas. The crystalline sedimentary contact zones have thicklimestone capping followed byproductive granular zones, which are tapped, bynumber of cavity wells of 40 to 60 m bgl depth giving 7 to 10 lps discharge. The tube wells can yield about 70 to 200 m3/hr and can sustain pumping for 10 hrs a day. The Depth to water level during Pre Monsoon & Post Monsoon for Viluppuram District, Tamil Nadu, is given in Figure 3-26

Source:http://cgwb.gov.in/District Profile/TamilNadu/VILUPPURAM.pdf

(Ref: Government of India, Ministry of Water Resources, Central Ground Water Board, South Eastern Coastal Region Chennai, "District Ground Water Brochure Viluppuram District")



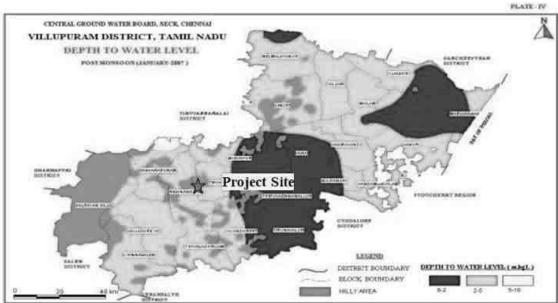


Figure 3-26 Depth to water level during Pre-Monsoon & Post Monsoon in Villupuram District

3.8.3.1 Ground Water Quality

LECO

Groundwater is the principal source for domestic and drinking purposes in almost all villages near the study area. The quality of the groundwater received is influenced by pollution of soil and air, industrial and domestic waste disposal, organic components, pathogenic microorganisms, application of fertilizers and pesticides in agriculture, etc. Total Eight (08) ground water monitoring locations were identified for assessment in different villages around the project site based on the usage of sub surface water by the settlements/ villages in the study area. The groundwater results are compared with the desirable and permissible water quality standards as per IS 10500 (2012) for drinking water. Groundwater quality monitoring locations and results are given in Table 3-15 and Table 3-16. A map showing the groundwater monitoring locations is given in Figure 3-27.

Table 3-15 Details of Groundwater Quality Monitoring Locations

S.No	Location	LocationCode	Distancein ~Km	Direction
1	ProjectSite	GW1	0.57	Е
2	Ural	GW2	3.05	NNE
3	Tindivanam	GW3	3.10	ESE
4	Pelakuppam	GW4	1.65	SSE
5	Kollar	GW5	2.35	WSW
6	Gudisaippalaiyam	GW6	2.25	WNW
7	Kattuvisiri	GW7	3.14	NW
8	Venmaniyathur	GW8	1.31	N

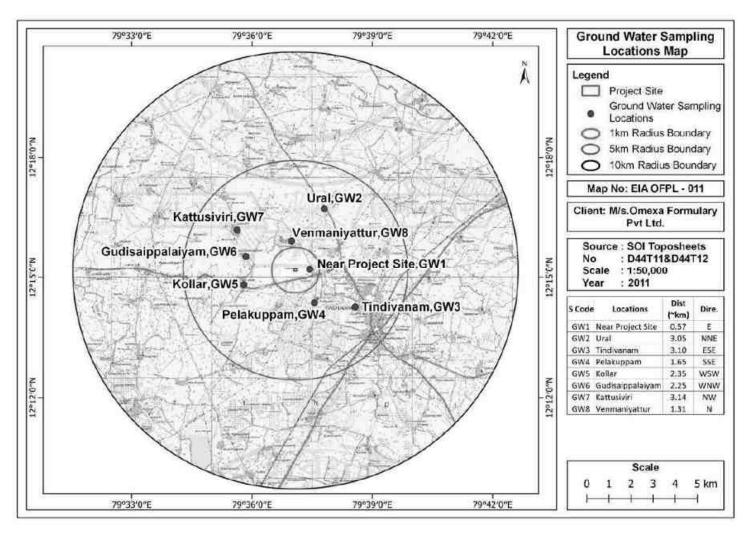


Figure 3-27Map showing the groundwater monitoring locations



Table 3-16 Ground Water Monitoring Results

SL No	Parameters	Unit	Drinkin Standard 201	(IS10500: 12)	Project Site	Ural	Tindivana m	Pelakupp am	Kollar	Gudisaippalai yam	Kattuvi siri	Venmaniyat hur
110			Permissible Limit	Acceptable Limit	GW1	GW2	GW3	GW4	GW5	GW6	GW7	GW8
1	Colour	Haze n	15	5	BLQ(LO Q1)	BLQ(LOQ1)	BLQ(LOQ1	BLQ(LO Q1)	BLQ(L O Q1)	BLQ(LO Q1)	BLQ(LO Q1)	BLQ(LO Q1)
2	Turbidity	NTU	5	1	BLQ (L OQ0.1)	BLQ(LOQ 0.1)	BLQ(LOQ 0.1)	BLQ(LO Q0.1)	BLQ(LO Q0.1)	BLQ(LO Q0.1)	BLQ(L O Q0.1)	BLQ(LO Q0.1)
3	рН	-	NR	6.5-8.5	7.6	7.2	7.4	7.01	6.91	7.5	7.6	7.5
4	Electrical Conductivity	μS/c m	-	-	800	792	810	787	815	792	803	808
5	Total Dissolved Solids	mg/l	2000	500	692	702	750	680	650	680	710	675
6	Total suspended olids	mg/l	-	-	BLQ(L O Q1)	BLQ(LO Q1)	BLQ(LOQ 1)	BLQ(LO Q1)	BLQ(LO Q1)	BLQ(LO Q1)	BLQ(L O Q1)	BLQ(LO Q1)
7	Total Alkalinity as CaCO ₃	mg/l	600	200	150	145	172	133	149	156	160	140
8	Total Hardness as CaCO ₃	mg/l	600	200	232	243	236	240	226	232	229	228
9	Sodium as Na	mg/l	-	-	105.2	109.5	125.3	98.5	72	112.4	73	77
10	Potassium as K	mg/l	-	-	12	13	10	18	11	16	13	17
11	Calcium as Ca	mg/l	200	75	65	64	62	69	80.6	66	66	63



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12	Magnesium as Mg	mg/l	100	30	19	25	18	20	22	21	21	20
13	Chloride	mg/l	1000	250	180	201	206	165	170	168	146	149
14	Sulphate SO ₄	mg/l	400	200	37.5	35.4	36.4	40.6	42.5	43.3	44.7	39.8
15	Nitrate as NO ₃	mg/l	NR	45	5.9	5.2	6.6	15.6	10.3	11.4	6.9	5.5
16	Phosphate as PO ₄	mg/l	1	-	BLQ(LO Q 0.02)	BLQ(LOQ 0.02)	BLQ(LOQ 0.02)	BLQ(LOQ 0.02)	BLQ(L OQ 0.02)	BLQ(LOQ 0.02)	BLQ(LO Q 0.02)	BLQ(LOQ 0.02)
17	Fluorides as F	mg/l	1.5	1	0.32	0.39	0.40	0.31	0.35	0.33	0.30	0.31
18	Cyanide	mg/l	NR	0.05	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(L OQ 0.01)	BLQ(LOQ 0.01)	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)
19	Arsenic as As	mg/l	0.05	0.01	BLQ(LO Q 0.005)	BLQ(LOQ 0.005)	BLQ(LOQ 0.005)	BLQ(LOQ 0.005)	BLQ(L OQ 0.005)	BLQ(LOQ 0.005)	BLQ(LO Q 0.005)	BLQ(LOQ 0.005)
20	Boron as B	mg/l	1.0	0.5	BQL(LO Q 0.1)	BQL(LOQ 0.1)	BQL(LOQ 0.1)	BQL(LOQ 0.1)	BQL(L OQ 0.1)	BQL(LOQ 0.1)	BQL(LO Q 0.1)	BQL(LOQ 0.1)
21	Cadmium as Cd	mg/l	NR	0.003	BQL(LO Q 0.001)	BQL(LOQ 0.001)	BQL(LOQ 0.001)	BQL(LOQ 0.001)	BQL(L OQ 0.001)	BQL(LOQ 0.001)	BQL(LO Q 0.001)	BQL(LOQ 0.001)
22	Chromium as Cr	mg/l	NR	0.05	BQL(LO Q 0.01)	BQL(LOQ 0.01)	BQL(LOQ 0.01)	BQL(LOQ 0.01)	BQL(L OQ 0.01)	BQL(LOQ 0.01)	BQL(LO Q 0.01)	BQL(LOQ 0.01)
23	Copper as Cu	mg/l	1.5	0.05	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(L OQ 0.01)	BLQ(LOQ 0.01)	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)
24	Lead as Pb	mg/l	NR	0.01	BLQ(LO Q 0.005)	BLQ(LOQ 0.005)	BLQ(LOQ 0.005)	BLQ(LOQ 0.005)	BLQ(L OQ 0.005)	BLQ(LOQ 0.005)	BLQ(LO Q 0.005)	BLQ(LOQ 0.005)
25	Manganese as Mn	mg/l	0.3	0.1	BLQ(LO Q 0.05)	BLQ(LOQ 0.05)	BLQ(LOQ 0.05)	BLQ(LOQ 0.05)	BLQ(L OQ 0.05)	BLQ(LOQ 0.05)	BLQ(LO Q 0.05)	BLQ(LOQ 0.05)



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26	Mercury	mg/l	NR	0.001	BLQ(LO Q 0.0005)	BLQ(LOQ 0.0005)	BLQ(LOQ 0.0005)	BLQ(LOQ 0.0005)	BLQ(L OQ 0.0005)	BLQ(LOQ 0.0005)	BLQ(LO Q 0.0005)	BLQ(LOQ 0.0005)	
27	Nickel as Ni	mg/l	NR	0.02	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(LOQ 0.01)	BLQ(L OQ	BLQ(LOQ 0.01)	BLQ(LO Q 0.01)	BLQ(LOQ 0.01)	

BLQ(LOQ

0.005

BLQ(LOQ

0.005

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BLQ(LOQ

0.005

0.01) BLQ(L

OQ

0.005

BLQ(LOQ

0.005

(Note: BLQ – Below Limit of Quantification; LOQ – Limit Of Quantification; NR – No Relaxation)

BLQ(LO

Q 0.005

0.01

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NR



Selenium as

Se

mg/1

28

BLQ(LO

Q 0.005

BLQ(LOQ

0.005

3.8.3.2 Results and discussions

A summary of analytical results are presented below:

- The pH of the collected ground water sample ranges from 6.91-7.6
- The concentrations of Chloride in the collected ground water sample ranges from 146 to 206 mg/l.
- Total Dissolved Solids (TDS) value of the collected ground water sample varies from 650 mg/l to 750 mg/l.
- Total hardness of the collected ground water sample ranges from 226 mg/l to 243 mg/l.

3.9 Soil quality

Soil quality monitoring locations & results are given in **Table 3-17**& **Table 3-18**. Map showing the soil monitoring locations is given in **Figure 3-28**.

Table 3-17 Soil Quality Monitoring Locations

S.No	Location	Location Code	Distance in ~Km	Direction
1	ProjectSite	S1	With in the site	
2	Pattanam	S2	1.67	ENE
3	Tindivanam	S3	3.09	ESE
4	Pelakuppam	S4	1.57	SSE
5	Kollar	S5	2.38	WSW
6	Gudisaippalaiyam	S6	2.35	WNW
7	Kattuvisiri	S7	3.14	NW
8	Venmaniyathur	S8	1.34	N

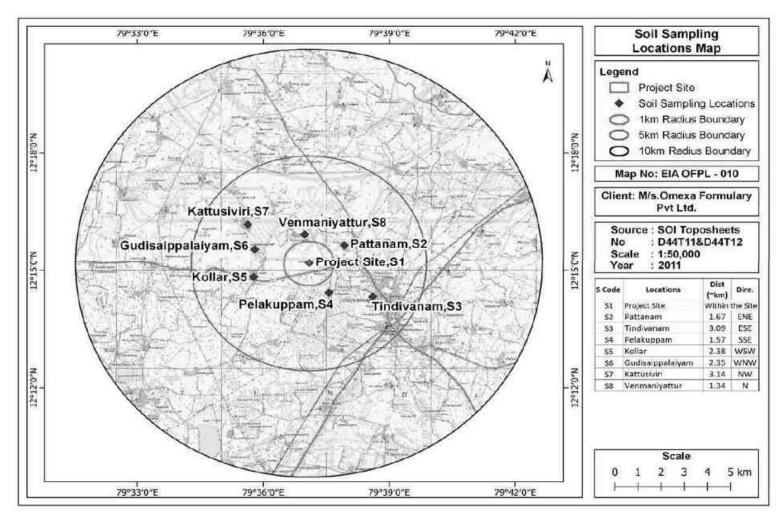


Figure 3-28Map showing the soil monitoring locations

Table 3-18 Soil Quality Monitoring Results

Sl. N	Parameters	Units	Project Site	Patanam	Tindivana m	Pelakuppam	Kollar	Gudisaippalaiya m	Kattuvisiri	Venmaniyath ur
0			S1	S2	S3	S4	S5	S6	S7	S8
1	SoilTexture	-	Sandyloam	Loam	SandyLoam	Loam	Sandyloam	Clayloam	Sandyclay loam	Sandyclay loam
2	Sand	%	59.26	44.32	63.66	48.47	59.88	39.47	69.58	71.26
3	Silt	%	23.97	40.69	23.62	37.39	31.69	32.59	6.24	2.2
4	Clay	%	10.66	13.26	9.56	15.23	9.56	29.63	21.65	23.16
5	pН	-	7.05	6.66	7.35	7.19	6.86	7.39	7.56	6.55
6	Electrical conductivity	μS/cm	316	281	306	296	342	346	293	276
7	NitrogenasN	mg/kg	98.6	102.6	93.2	116.8	102.8	88.2	83.5	95.3
8	Phosphorus	mg/kg	4.2	4.1	4.2	5.3	4.4	3.7	3.6	4
9	Potassium	mg/kg	46.2	44.3	42.8	50.3	46.3	37.5	38.4	40
10	Boron	mg/kg	BLQ(LOQ 0.1)	BLQ(LOQ0.	BLQ(LOQ0.	BLQ(LOQ .1)	BLQ(LOQ 0.1)	BLQ(LOQ0.1)	BLQ(LOQ .1)	BLQ(LOQ .1)
11	Cadmium	mg/kg	BLQ(LOQ 0.1)	BLQ(LOQ0.	BLQ(LOQ0.	BLQ(LOQ0.	BLQ(LOQ0.	BLQ(LOQ0.1)	BLQ(LOQ0.	BLQ(LOQ0.1)
12	Porosity	-	0.43	0.45	0.43	0.45	0.43	0.77	0.42	0.42
13	Water Holding Capacity	%	20	32	20	32	19	18	16	16.5

Note: BLQ: Below Limit of Quantification; LOQ: Limit Of Quantification



3.9.1 Results and Discussions

Summary of analytical results

- pH of the soil samples ranged from 6.55 to 7.56.
- Conductivity of the soil samples ranged from 276to346 μS/cm.
- Nitrogen content ranged from 83.5 to116.8 mg/kg.
- Phosphorous ranged from 3.6 to 5.3 mg/kg.
- Potassium content ranges from 37.5 to 50.3 mg/kg.

3.10 Biological Environment

An ecological study of the ecosystem is essential to understand the impact of industrialization and urbanization on existing flora and fauna of the study area. Studies on various aspects of ecosystem play an important role in identifying sensitive issues for under taking appropriate action to mitigate the impact, if any. The biological study was under taken as a part of the EIA study report to understand the present status of ecosystem prevailing in the study area, to compare it with past condition with the help of available data, to predict changes in the biological environment as a result of present activities and to suggest measures for maintaining its health. Secondary information was collected to study the flora & fauna in 10 km radius. Some of the information was gathered from the local habitants. All the collected data were classified to interpret the impact of pollution on the flora and fauna of that region. All the available information was recorded about the wild plants and cultivated crop plants.

During primary and secondary information, following aspects were considered for ecological studies:

- ❖ Assessment of present status of flora and fauna;
- ❖ Identification of rare and endangered species of plants and animals (if any);
- ❖ Identification of ecologically sensitive areas within the study area;
- ❖ Assessment of Aquatic Ecology with specific reference to aquatic birds and plankton resources.

3.10.1 Methodology

Terrestrial investigations for flora and fauna records were collected by secondary information like research article, periodicals, floras and forest checklist.

3.10.2 Floral

- Plants species were identified based on their specific diagnostics characters of family, genus and species using available floral, other related literature.
- Besides the identification of plant species, information was collected on the vernacular names and uses of plants made by local inhabitants.

Faunal Study

Secondary information collected from published government data etc.

- ❖ List of the endangered and endemic species as per the schedule of The Wildlife Protection Act, 1972.
- ❖ Emphasis is given to identify avifauna and mammals to determine the presence and absence of Schedule-1 species, listed in The Wildlife Protection Act 1972, as well as in Red List of IUCN.

3.10.2.1 Floristic composition within the study area

For primary and secondary information based on a total 80 species under 32 family found in the study area. The detailed list of plant species found in each quadrat provided in below table.

Table 3-19Checklist of floral diversity in and around the area

S.No	Species	Family	Common Name	Habit	IUCN
1.	Abrus precatorius	Fabaceae	Kundumani	Shrub	NA
2.	Abutilon indicum	Malvaceae	Perun thuthi	Shrub	NA
3.	Acacia nilotica	Mimosaceae	Karuvelam	Tree	LC
4.	Acacia planifrons	Mimosaceae	Kodaivelam	Tree	NA
5.	Acalypha indica	Euphorbiaceae	Kuppaimeni	Herb	NA
6.	Acanthospermum hispidum	Compositae		Herb	NA
7.	Achyranthes aspera	Amaranthaceae	Nayurivi	Herb	NA
8.	Aegle marmelos	Rutaceae	Vilvam	Tree	NA
9.	Aerva lanata	Amaranthaceae	Sirupeelai	Shrub	NA
10.	Aerva persica	Amaranthaceae	Perumpeelai	Shrub	NA
11.	Aeschynomene aspera	Fabaceae	Thakkai	Shrub	NA
12.	Ageratum conyzoides	Compositae	Poom pillu	Herb	NA
13.	Alloteropsis cimicina	Poaceae		Grass	NA
14.	Alternanthera sessilis	Amaranthaceae	Ponnanganni	Herb	NA
15.	Anisomeles indica	Labiatae		Herb	NA
16.	Annona squamosa	Annonaceae	Seetha	Tree	NA
17.	Arachis hypogaea	Fabaceae	Verkadalai	Herb	NA
18.	Argemone mexicana	Papaveraceae	Braman Thandu	Herb	NA
19.	Aristida adscensionis	Poaceae		Grass	NA
20.	Aristida hystrix	Poaceae		Grass	NA
21.	Aristolochia bracteolata	Aristolochiaceae	Aduthinnappalai	Herb	NA
22.	Barleria acuminata	Acanthaceae	Vellai kurinji	Shrub	NA
23.	Barleria longiflora	Acanthaceae		Shrub	NA
24.	Barleria noctiflora	Acanthaceae	Barleria	Shrub	NA
25.	Boerhavia diffusa	Nyctaginaceae	Mookarattai	Herb	NA
26.	Carissa carandas	Apocynaceae	Kalaa, Perun kala	Shrub	NA
27.	Cassia fistula	Caesalpiniaceae	Kondrai	Tree	NA
28.	Celosia argentea	Amaranthaceae	Pannai keerai	Herb	NA
29.	Cissus quadrangularis	Vitaceae	Pirandai	Shrub	NA
30.	Citrullus colocynthis	Cucurbitaceae	Peikkumatti	Herb	NA
31.	Citrus aurantifolia	Rutaceae	Elumichai	Tree	NA
32.	Cleome viscosa	Capparidaceae	Nai kadugu	Herb	NA
33.	Coccinia grandis	Cucurbitaceae	Kovai	Climber	NA

34. Croton bonplandianum Euphorbiaceae Rail poondu Herb 35. Cyperus bulbosus Cyperaceae — Sedge 36. Eclipta prostrata Compositae Karisaalai Herb 37. Euphorbia antiquorum Euphorbiaceae Sadura-kalli Tree 38. Evolvulus alsinoides Convolvulaceae Vishnukarandi Herb 39. Ficus benghalensis Moraceae Aala maram Tree 40. Ficus religiosa Moraceae Arasu Tree 41. Indigofera linnaei Fabaceae Herb 42. Indigofera tinctoria Fabaceae Avuri, Neeli Herb	NA
36. Eclipta prostrata Compositae Karisaalai Herb 37. Euphorbia antiquorum Euphorbiaceae Sadura-kalli Tree 38. Evolvulus alsinoides Convolvulaceae Vishnukarandi Herb 39. Ficus benghalensis Moraceae Aala maram Tree 40. Ficus religiosa Moraceae Arasu Tree 41. Indigofera linnaei Fabaceae Herb 42. Indigofera tinctoria Fabaceae Avuri, Neeli Herb	NA NA NA NA NA NA NA
37.Euphorbia antiquorumEuphorbiaceaeSadura-kalliTree38.Evolvulus alsinoidesConvolvulaceaeVishnukarandiHerb39.Ficus benghalensisMoraceaeAala maramTree40.Ficus religiosaMoraceaeArasuTree41.Indigofera linnaeiFabaceaeHerb42.Indigofera tinctoriaFabaceaeAvuri, NeeliHerb	NA NA NA NA NA
38.Evolvulus alsinoidesConvolvulaceaeVishnukarandiHerb39.Ficus benghalensisMoraceaeAala maramTree40.Ficus religiosaMoraceaeArasuTree41.Indigofera linnaeiFabaceaeHerb42.Indigofera tinctoriaFabaceaeAvuri, NeeliHerb	NA NA NA NA
39.Ficus benghalensisMoraceaeAala maramTree40.Ficus religiosaMoraceaeArasuTree41.Indigofera linnaeiFabaceaeHerb42.Indigofera tinctoriaFabaceaeAvuri, NeeliHerb	NA NA NA
40.Ficus religiosaMoraceaeArasuTree41.Indigofera linnaeiFabaceaeHerb42.Indigofera tinctoriaFabaceaeAvuri, NeeliHerb	NA NA
41. Indigofera linnaei Fabaceae Herb 42. Indigofera tinctoria Fabaceae Avuri, Neeli Herb	NA
42. Indigofera tinctoria Fabaceae Avuri, Neeli Herb	
	NA
42 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	1
43. <i>Ipomoea pes-caprae</i> Convolvulaceae Kudhirai Kulambu Creeper	NA
44. Jatropha gossypifolia Euphorbiaceae Kaatu-amanakku Shrub	NA
45. Justicia adhatoda Acanthaceae Adathodai Shrub	NA
46. Justicia simplex Acanthaceae Herb	NA
47. Lagenaria siceraria Cucurbitaceae Surakkaai Climber	NA
48. Lantana camara Verbenaceae Unnichedi Shrub	NA
49. Leucaena leucocephala Mimosaceae Soundil Tree	NA
50. Merremia hederacea Convolvulaceae Herb	NA
51. Nyctanthes arbor-tristis Nyctanthaceae Parijaatham Tree	NA
52. Ocimum americanum Labiatae Ganjaankorai Herb	NA
53. Phyllanthus amarus Euphorbiaceae Kizha-nelli Herb	NA
54.Pongamia pinnataFabaceaePunga maramTree	NA
55. Portulaca oleracea Portulacaceae Kari keerai Herb	NA
56. Prosopis juliflora Mimosaceae Velikkaathaan Tree	NA
57. Rhynchosia viscosa Fabaceae Climber	NA
58. Ricinus communis Euphorbiaceae Amanakku Shrub	NA
59. Rivea hypocrateriformis Convolvulaceae Boodhikeerai Climber	NA
60. Ruellia tuberosa Acanthaceae Herb	NA
61. Senna auriculata Caesalpiniaceae Avaram Shrub	NA
62. Senna occidentalis Caesalpiniaceae Peiyavarai Tree	NA
63. Sida acuta Malvaceae Malai thangi Herb	NA
64. Sida cordata Malvaceae Pazhampaasi Herb	NA
65. Sida cordifolia Malvaceae Nilatutthi Herb	NA
66. Solanum americanum Solanaceae Manatakkali Herb	NA
67. Solanum torvum Solanaceae Chundai Shrub	NA
68. Solanum trilobatum Solanaceae Thoodhuvalai Climber	NA
69. Spermacoce hispida Rubiaceae Nathaichoori Herb	NA
70. Tamarindus indica Caesalpiniaceae Puliya maram Tree	NA
71. Tectona grandis Verbenaceae Thekku Tree	NA
72. Tephrosia purpurea Fabaceae Kozhinji Undershrub	NA
73. Terminalia catappa Combretaceae Badam Tree	NA
74. Thespesia populnea Malvaceae Poovarasu Tree	NA
75. Tinospora cordifolia Menispermaceae Seenthilkodi Climber	NA
76. Tridax procumbens Asteraceae Vettukayapoonduthalai Herb	NA
77. Vitex negundo Verbenaceae Nochi Tree	NA

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78.	Waltheria indica	Sterculiaceae	Chempoodu	Herb	NA
79.	Wrightia tinctoria	Apocynaceae	Vetpaalai	Tree	NA
80.	Ziziphus mauritiana	Rhamnaceae	Illandhai	Tree	NA

Source:

- 1. Flora of Tamil Nadu. Botanical survey of India. 1983.
- 2. IUCN Status: https://www.iucnredlist.org/

3.10.2.2 Fauna Diversity

A checklist faunal species such as birds, reptiles, amphibians and butterfly species based on secondary information. As per the Wild Life Act (1972) those animals, which have been enlisted in the schedules of the Wildlife Act, have been presented below. The schedules are based on the species namely, rare, endangered, threatened, vulnerable etc. According to the threat of extinction, Schedule-I contains those species which need topmost priority, while II, III, IV and V have lesser degree of threat. Most of the avi-fauna has been listed in Schedule–IV. As per the list of avi-faunal species, these are mostly local migrant species only. Secondary information for Fauna diversity were collected to cross check with relevant literatures (Smith 1933-43, Ali and Ripley 1983, Daniel 1983, Prater 1993, Murthy and Chandrasekhar 1988). Alist of fauna was either spotted or reported from the study area is given in **Table 3-20**.

Table 3-20List of Faunal diversity IUCN Status

S.No	Scientific Name	Common Name	Family	IUCN	WPA
1.	Acridotheres tristis	Common Myna	Sturnidae	LC	Sch IV
2.	Anthus rufulus	Paddyfield pipit	Motacillidae	LC	Sch IV
3.	Apus affinis	House Swift	Apodiformes	LC	Sch IV
4.	Ardea alba	Great Egret	Ardeidae	LC	Sch IV
5.	Ardea cinerea	Grey Heron	Ardeidae	LC	Sch IV
6.	Ardeola grayii	Indian Pond Heron	Ardeidae	LC	Sch IV
7.	Bubulcus ibis	Cattle Egret	Ardeidae	LC	Sch IV
8.	Calidris minuta	Little Stint	Scolopacidae	LC	Sch IV
9.	Centropus sinensis	Greater Coucal	Cuculidae	LC	Sch IV
10	Ciconia episcopus	Asian Woolly-necked Stork	Ciconiidae	NT	Sch IV
11	Cinnyris asiaticus	Purple Sunbird	Nectariniidae	LC	Sch IV
12	Circus aeruginosus	Eurasian Marsh-Harrier	Accipitridae	LC	Sch IV
13	Columba livia	Rock Pigeon	Columbidae	LC	Sch IV
14	Copsychus saularis	Oriental Magpie Robin	Muscicapidae	LC	Sch IV
15	Coracias benghalensis	Indian roller	Coraciidae	LC	Sch IV
16	Corvus splendens	House Crow	Corvidae	LC	Sch IV
17	Cyornis tickelliae	Tickell's blue flycatcher	Muscicapidae	LC	Sch IV
18	Dendrocygna javanica	Lesser Whistling-Duck	Anatidae	LC	Sch IV
19	Dicaeum erythrorhynchos	Pale billed flowerpecker	Dicaeidae	LC	Sch IV
20	Dicrurus macrocercus	Black Drongo	Dicruridae	LC	Sch IV
21	Egretta garzetta	Little Egret	Ardeidae	LC	Sch IV
22	Elanus caeruleus	Black-winged Kite	Accipitridae	LC	Sch IV
23	Eudynamys scolopaceus	Asian Koel	Cuculidae	LC	Sch IV
24	Euodice malabarica	Indian silverbill	Estrildidae	LC	Sch IV
25	Fulica atra	Eurasian Coot	Rallidae	LC	Sch IV

26	Gallinula chloropus	Eurasian Moorhen	Rallidae	LC	Sch IV
		Brahminy Kite	Accipitridae	LC	Sch I
		White-throated kingfisher	Alcedinidae	LC	Sch IV
	Halcyon smyrnensis Lonchura punctulata	Scaly-breasted Munia	Estrildidae	LC	Sch IV
	Merops orientalis	Green Bee-eater	Meropidae	LC	Sch IV
	*	Little cormorant	Phalacrocoracidae	LC	Sch IV
32	Milvus migrans	Black Kite	Accipitridae	LC	Sch IV
		White browed Wagtail	Motacillidae	LC	Sch IV
	Mycteria leucocephala	Painted Stork	Ciconiidae	NT	Sch IV
	Nycticorax nycticorax	Black-crowned Night-Heron	Ardeidae	LC	Sch IV
	Orthotomus sutorius	Common tailorbird	Cisticolidae	LC	Sch IV
37	Ortygornis pondicerianus	Grey francolin	Phasianidae	LC	Sch IV
	Passer domesticus	House Sparrow	Passeridae	LC	Sch IV
	Pelecanus philippensis	Spot-billed Pelican	Pelecanidae	NT	Sch IV
		Great Cormorant	Phalacrocoracidae	LC	Sch IV
	Phalacrocorax fuscicollis	Indian Cormorant	Phalacrocoracidae	LC	Sch IV
	Plegadis falcinellus	Glossy Ibis	Threskiornithidae	LC	Sch IV
	<u> </u>	Plain prinia	Cisticolidae	LC	Sch IV
		Ashy Prinia	Cisticolidae	LC	Sch IV
	Pseudibis papillosa	Red-naped Ibis	Threskiornithidae	LC	Sch IV
	Psittacula krameri	Rose-ringed Parakeet	Psittaculidae	LC	Sch IV
47	Pycnonotus cafer	Red-vented Bulbul	Pycnonotidae Pycnonotidae	LC	Sch IV
		Indian Robin	Muscicapidae	LC	Sch IV
	•	Common Tern	Laridae	LC	Sch IV
	Sternula albifrons	Little Tern	Laridae	LC	Sch IV
	· ·	Spotted Dove	Columbidae	LC	Sch IV
	Streptopelia decaocto	Eurasian collared dove	Columbidae	LC	Sch IV
	Streptopelia senegalensis	Laughing Dove	Columbidae	LC	Sch IV
	Sturnia pagodarum	Brahminy Starling	Sturnidae	LC	Sch IV
55		Little Grebe	Podicipedidae	LC	Sch IV
	Thalasseus bengalensis	Lesser Crested Tern	Laridae	LC	Sch IV
57	Threskiornis melanocephalus	Black-headed Ibis	Threskiornithidae	NT	Sch IV
	Tringa erythropus	Spotted Redshank	Scolopacidae	LC	Sch IV
	Vanellus indicus	Red-wattled Lapwing	Charadriidae	LC	Sch IV
	Vanellus malabaricus	Yellow-wattled Lapwing	Charadriidae	LC	Sch IV
Mamm		Tene w watered Eap wing	Charachitace		Sell I v
S.No	Common Name	Scientific Name	Family	IUCN	WPA
5.110	Common Traine	Scientific (value	1 uniny	Tociv	Schedule
1	Five striped Palm squirrel	Funambulus pennantii	Sciuridae	LC	Sch IV
2	Field Rat	Rattus argentiventer	Muridae	LC	Sch V
3	Indian hare	Lepus nigricollis	Leporidae	LC	Sch V
4	Wild boar	Sus scrofa	Suidae	LC	Sch V
Butter		Sus ser oju	Saraue	LC	Sen v
1	Baronet	Euthalia nais	Nymphalidae	NT	Schedule IV
2	Blue tiger	Tirumala limniace	Nymphalidae	LC	Schedule IV
3	Pioneer	Belenois aurota	Pieridae	LC	Schedule IV
					Schedule IV
4	Common Crow	Euploea core	Nymphalidae Pieridae	LC	
5	Common Emigrant	Catopsilia pomona	rieridae	NT	Schedule IV

6	Common evening brown	Melanitis leda	Nymphalidae	LC	Schedule IV
7	Common grass yellow	Eurema hecabe	Pieridae	LC	Schedule IV
8	Common jezebel	Delias eucharis	Pieridae	NT	Schedule IV
9	Common leopard	Phalanta phalantha	Nymphalidae	LC	Schedule IV
10	Common lime	Papilio demoleus	Papilionidae	NT	Schedule IV
11	Common mormon	Papilio polytes	Papilionidae	NT	Schedule IV
12	Danaid eggfly	Hypolimnas misippus	Nymphalidae	LC	Schedule IV
13	Great eggfly	Hypolimnas bolina	Nymphalidae	NT	Schedule IV
14	Grey pansy	Junonia atlites	Nymphalidae	NT	Schedule IV
15	Lemon pansy	Junonia lemonias	Nymphalidae	NT	Schedule IV
16	Mottled Emigrant	Catopsilia pyranthe	Pieridae	NT	Schedule IV
17	Pale Grass Blue	Pseudozizeeria maha	Lycaenidae	NT	Schedule IV
18	Peacock pansy	Junonia almana	Nymphalidae	LC	Schedule IV
19	Plain tiger	Danaus chrysippus	Nymphalidae	LC	Schedule IV
Reptil	es				
1	Oriental Garden lizard	Calotes versicolor	Agamidae	LC	Schedule IV
2	Indian Rat Snake	Ptyas mucosa	Colubridae	LC	Schedule II
3	Russels Viper	Daboia russelii	Viperidae	LC	Schedule II
4	Peninsular Rock Agama	Psammophilus dorsalis	Agamidae	LC	Schedule IV
5	Checkered keelback	Xenochrophis piscator	Colubridae	LC	Schedule II

LC- Least Concern, NT- Near Threatened, EN- Endangered, NE-Not Evaluated, DD -Data Deficient, VU-Vulnerable, IUCN- International Union for Conservation of Nature.

3.10.2.3 Microflora

Microflora of soil is an integral part of soil Organic Matter. Soil bacteria and fungi are the start of the soil food web that supports other organisms. Bacteria constitute the most abundant groups of microorganisms in soil and the fungal population of soils constitutes a very heterogenous group of organisms. The bacterial genera Nocardia, Streptomyces and Micromonospora belong to order actinomycetes (aerobic and heterotrophic) are capable of degrading many complex organic substances and consequently play an important role in building soil fertility. The soil food web is interconnected matrix of invisible (fungi, bacteria, protozoa, nematodes) and visible (earthworms, beetles, arthopods) creatures that have a whole host of functions which creates a healthy ecosystem for plant growth. Various microorganisms were isolated from different soil samples collected. Thus the population of total bacteria in rhizosphere was reported to be highest as compared as to non-rhizosphere. The majority of the bacteria were reported to be Bacillus and Micrococcus Species. The total fungal population densities were also decreased in non-rhizosphere while the highest fungal population was observed in rhizosphere. The majority of fungi were reported to be Aspergillus niger, Aspergillus fumigatus, Penicillum species and Fusarium species. A number of diazotrophs bacteria have abilities to fix Nitrogen, some strains may relieve deficiencies where there is an inadequate application of N fertilizers. Many heterotrophic bacteria live in the soil and fix significant levels of Nitrogen including Azotobacter, Azospirillum and Rhizobium. N fixing microorganisms are globally noteworthy due to

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the fact as they provide only natural biological source of fixed N in the biosphere. The population count of Azotobacter was also more in rhizosphere than non-rhizosphere sites.

3.10.2.4 Methodology

a) Microbial analysis of soil: Earthworms

Microbial analysis of soil was done by Media preparation, Autoclaving, Serial Dilution, Inoculation of the media for Isolation of organisms, Colony counting and identification of the same.

Earthworms: The soil core was dug out and the warms were hand sorted according to the method described by Lewis and Taylor (1968). The worms were sorted according to their species and kept separately in polythene bags containing the mother soil taken from the collection site. Care was taken while digging so as to avoid damaging earthworms or killing them. The worms were preserved in 5-10% formalin solution following the method suggested by Julka (1993) in the laboratory.

b) Microscopic observation and Identification

The microscopic observations of diatom isolates were carried out at 40x and 100x magnification using compound microscope (Olympus). The diatom flora was identified based on the taxonomic criteria as described by Cramer, (1984), Jensen, (1985), Krammer and Lange-Bertalot, (1988) and Benson, (1998).

Order **Family** Genera **Species** Octochaetidae Dichogaster Dichogasterbolaui Glossocolecida Pontoscolexcorethrurus(Muler) **Pontoscolex** Perionyx excavatus (Muler) Perionyx Megascolecide *Perionyx sansibaricus*(Muler) Haplotaxida Lampito Lampitomauritii (Knberg) Eudrilus Eudriluseugenia(Kinbeg) Eudrilidae Polypheretima Polypheretimaelongata Octochaetidae Octochaetonona Octochaetona serrata (Gates) Drawidawillsi (Michaelsen) Moniligastrida Moniligastridae Drawida Drawida lamella (Gates)

Table 3-21List of Earthworms

Table 3-22List of Diatoms

No	Species	Family	Sub Family	
1.	Calonies sp.			
2.	Pinnularia sp.	Naviculaceae Naviculoide		
3.	Gomphonema sp.	1 va v Todiacodo		
4.	Gyrosigma sp.			

5.	Navicula sp.		
6.	Stauroneis sp.		
7.	Nitzchia sp.	Nitzschiaceae	
8.	Cocconeis sp.	Acanthaceae	
9.	Acanthes sp.	Acammaccac	
10.	Fragillaria sp.		
11.	Tabularia sp.	Fragillariaceae	
12.	Synedra sp.	Tagmanacac	
13.	Cyclotella sp.		Coscinodiscaceae
14.	Neidium sp.	Nediaceae	Cosemodiscaccae

Source: Anand, N. 1998. Indian freshwater microalgae. Shiva offset Press, Dehradun,India

3.10.3 Conservation Plan and Budget Allocation

The Conservation Plan would focus on conservation of habitats of Schedule-I species identified during the study. We identified 1 IUCN red list bird species in the study area i.e. 10 km buffer area.

Fauna

S.No	Common Name	Species Name	IUCN	WPA 1972
Birds			,	
1	Brahminy Kite	Haliastur indus	LC	Schedule I

The budgetary provision has been made for implementation of wildlife conservation measures. Project proponent will allocate Rs.5,35,000 towards the conservation plan for implementing the following activities with the help of and in consultation with the Forest Department.

- **Bird species** Brahminy Kite
 - Capacity Building: Capacity building program on protection would be of high significance. Creation of awareness among local people as well as employees about the importance of protecting the habitat and foraging grounds.
 - Anti-Poaching Plan: Poaching being one of the causes for depletion of wildlife in general and it being one of the main reasons for the poor faunal assemblage, it is necessary to increase protection for the RET species. The people living in the surrounding area should be rewarded for timely information about disturbing and/or poaching of the bird more specifically the threatened species.
 - Habitat Improvement: Sufficient food, water resources, vegetation cover, and breeding sites must be available at the release location.
- The proponent has proposed a sum of Rs. 5,35,000/-for the conservation plan under the following heads:

S.No	Work or Activity	Approximate Cost. Rs.
5.110	WOLK OF ACTIVITY	Approximate Cost. Rs.

		Year 1	Year 2	Year 3	Year 4	Year 5
1	Monitoring birds	105,000/-	105,000/-	52,500/-	-	-
2	Birds monitoring tools	1,00,000/-	-	-	-	-
3	Environmental awareness programme	24,000/-	24,000/-	24,000/-	24,000/-	24,000/-

(Not including water supply, grass seed collection and plantation)

Management of Biological Environment

- Greenbelt will be developed all along the boundary of the installation by choosing fast growing and resistant varieties suitable to the soil conditions in the site (native plants) and special care will be taken to maintain it.
- Survival rate of the planted trees will be closely monitored in the green belt and the trees which could not survive should be counted.

	Following Plants will be planted on the periphery of Project area								
S.No	Botanical name	Common Name	Key future of Tree						
1	Albizia lebbeck	Vagai	A middle-sized deciduous tree with a spreading crown.						
2	Azadicrta Indica	Vembu	It is adapted to various climate zones.						
3	Dalbergia latifolia	Eeitti	It is common on deep loams or clays containing lime.						
4	Ficus benghalensis	Allamaram	Nesting and food purpose for wildlife						
5	Ficus relegiosa	Arasamaram	It is tolerant to various climate zones.						
6	Madhuca longifolia	Illupai	A large deciduous shapely, long lived tree						
7	Pongamia pinnata	Pungaimaram	Dust reduce						
8	Pterocarpus marsupium	Vengai							
9	Syzygiumcumini	Naval	It is tolerant to temprature resistant.						
10	Termanilia arjuna	Maruthu	It is reducing soil erosion						

Environmental Sensitivity:

As per MoEF&CC guideline,15 km radius from the project site is considered as a study area for evaluating environmental sensitivity. The description of the environmental sensitivity of the site is given below;

The project area covering 15 km radial distance did not reveal any notified/ protected ecologically sensitive area including national park, sanctuary, Elephant and Tiger reserves. There are not any sanctuaries or national park or reserve/ protected forest within study area of 15 km radius.

• Impact on Biological Environment

No wildlife sanctuary, national park or biospheres reserve is located within the study area.

Impact on Wildlife

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There is no National Park, Wildlife Sanctuary, Biosphere Reserve, Wildlife corridors and Tiger/Elephant Reserve found within 10 km radius of the project site.

Impact on Flora

Plantation will be developed in the undeveloped area as per plantation programme. These activities will help to improve the floral cover of the area. The greenery and plantation development will eventually attract micro fauna, birds etc in the area. Assistance will be taken from local forest department in selection of species of plants so that green coverage may improve fast. The varieties would include those plants, which are suitable to the area.

Impact on Fauna

The study area is in non-forest land where presence of fauna is very rare. As such, there will be no adverse impact of the plant unit activity on fauna around the plant unit area.

Green Belt Development

The proposed green belt in the plant unit area will be designed taking into consideration the availability of area as the efficacy of green belt in pollution control mainly depends on width of green belt, distance from pollution sources, site of the habitat from working place and tree height & density. While considering the above aspects due care will be taken for selecting suitable characteristics plant species as those fast growing and evergreen trees, trees with large leaf area, locally suitable plant species, those resistant to specific pollutant and those which would maintain the regional ecological balance, soil and hydrological conditions. The plantation work for green belt development will be carried in consultation with a local forest department which will help minimizing adverse impact on the flora found in the area.

3.11 Socio Economic Aspects

Socio-economic Profile: The socio-economic study of the project area is to determine how a proposed project will affect or change the lives of current or future residents of the geographical area.

Methodology: To conduct door-to-door surveys and interact with people in the project area, transect walk study in the project area. The interference is arrived at by extrapolation of secondary data with the current situation (primary data).

A transect walk is a mapping exercise that uses a systematic walk along a defined path within a community with local people. It is a participatory research method that explores environmental and social resources, conditions, and systems by listening, asking, observing, and producing a transect diagram alongside community members.

(Ref:Keller S. Transect Walk-)

District Profile:

The District is situated in the northern part of Tamil Nadu. The boundaries of the district are Tiruvannamalai and Kanchipuram districts in the North, Cuddalore, Kallakurichi districts in the South and Dharmapuri, Salem districts in the west and Puducherry and Bay of Bengal in the east.

As per 2011 census, the total population of the combined district is 3463284, of which 17.45 lakhs are males and 17.18 lakhs are females. The urban population was 509876 and rural population was 2953408 as per census 2011. Thus, 85.28 percent of the total population reside in rural areas, while only 14.72 percent of the total population is urban based. This suggests that the degree of urbanization in the district is lesser when compared to the state average which stands at 48.45 percent.

The major crops are Paddy and Pulses.

3.11.1 Socio Economix Aspects

A socio-economic study was undertaken in assessing aspects which are dealing with social and cultural conditions, and economic status in the study area. The study provides information such as demographic structure, population dynamics, infrastructure resources, and the status of human health and economic attributes like employment, per-capita income, agriculture, trade, and industrial development in the study area. The study of these characteristic helps in identification, prediction and evaluation of impacts on socio-economic and parameters of human interest due to proposed project activities and its developments. The parameters are:

- Demographic structure
- Infrastructure Facility
- Economic Status
- Health status
- Cultural attributes

Awareness and opinion of people about the project and Industries in the area shows some important Social Indicators of Villupuram District in Tamil Nadu.

Table 3-23Social Indicators of Villupuram District

S.No	Social Indicators	Viluppuram(Combined)
1	Decadal growth rate %	16.84
2	Urban population %	15.01
3	Sex ratio(per 1000 males)	987
4	Population density (Persons per square Km)	481
5	Scheduled caste population %	31.54
6	Scheduled tribe population %	0.23
7	Literacy rate %	72.08
8	Work Participation rate %	41.57
9	Main Workers %	72.37
10	Marginal Workers %	27.63
11	Cultivators %	10.04

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12	Agricultural labourers %	51.35
13	Workers in household industries %	1.72
14	Other workers %	36.89

Source: https://censusindia.gov.in/census.website/data/handbooks

3.11.1.1 Population and Household Size

The total population of the district was 3458873 in 2011 census. Of this, the rural population was 2939785 and the urban population returned with 519088 persons. The number of statutory towns and non - statutory towns by size and class of population. The district constituted with 18 statutory towns (3Municipalities and 15Town Panchayats) and one CensusTown.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH 2011 3306 PART B DCHB

VILUPPURAM.pdf

(**Ref**: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

3.11.1.2 Population Density and Sex Ratio

The sex ratio of the population is calculated for number of females for every 1000 males, irrespective of age. The child sex ratio is calculated in the same manner for the children aged upto 6 years. The sex ratio of the district was 987 and the State was 996.

The population density is an indicator for the assessment of the development of the area and the people. The population density of the district in 2011 was 481 per sq.km, lower than State density of 555.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(**Ref**: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

3.11.1.3 Scheduled Castes and Scheduled Tribes

The Scheduled Caste population in Tamil Nadu is 20% and Scheduled Tribe is 1.1% to the total population. The Scheduled Caste population in the district is higher (29.4%) than the State and therural and urban percentages are 31.5% and 17.5% respectively. The Scheduled Tribe population percentage in the district was 2.2% both in 2001 and 2011.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(**Ref**: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A)

3.11.1.4 Education & Literacy

The literacy rate of the district was 71.9%, lower than the literacy level of the State 80.1%. The literacy rate for males was higher than females. The male literacy was 80.5% and female literacy was 63.2%. The rural and urban literacy in the district has recorded significant disparity. The rural literacy was 61% in 2001 which has marginally increased to 69.6% in 2011. The urban literacy in the district was 80.3% in 2001 and 84.7% in 2011. The urban literacy in the district has seen significant increase in 2011 census compared to 2001 census. The accessibility of Primary and Upper Primary education has increased the literacy rate as well as reducing the dropout rate. **Table 3-24** Show the details of education infrastructures in Viluppuram District.

Table 3-24 Education Infrastructures in Viluppuram District

T	Total scho	ools	Rural Schools		
Typeofschool	Government	Private	Government	Private	
Primary	1357	475	1281	394	
Primary+Upper Primary	421	66	399	46	
P+UP+Secondary+Higher Secondary	5	61	3	35	
UPonly	15	12	15	9	
UP+Secondary+HigherSecondary	178	38	150	25	
P+ UP+ Secondary	9	60	5	49	
UP+Secondary	190	35	183	25	

Source: http://udise.in/Downloads/Publications/Documents/District Report Cards-2016-17-Vol-II.pdf])

3.11.1.5 Employment and Livelihood

The main workers among the workers constituted 74% and the marginal workers of both categories were with 26%. The non-workers to the total population was 58.4%, who were 51. 2% in 2001 census. The male participation is higher than the female participation within main workers and marginal workers, whereas the female dominates in the non-workers category with 74.2%.

Source: https://censusindia.gov.in/nada/index.php/catalog/1105/download/3434/DH_2011_3306_PART_B_DCHB_VILUPPURAM.pdf

(**Ref**: Directorate of Census Operations-Tamil Nadu, "District Census Handbook-2011, Viluppuram District", Series-34 Part XII-A).

3.11.2 Social Economic Profile of the study area

The villages and towns covering 10 km radius from the boundary of the project site is taken for the study. **Table 3-25** shows the list of locations which comes under the study area.

Table 3-25 Population profile within study area

Sl. No	Name	Households	Total Population	Male	Female	Children below 6	Scheduled Caste	Scheduled Tribe
0 to 5	km			,	,			
Villup	uram District-Tindivanam	taluk						
1	Buderi	199	844	440	404	95	450	0
2	Karuvapakkam	273	1059	539	520	118	239	6
3	Kattusiviri	409	1775	861	914	221	129	33
4	Kollar	655	2802	1385	1417	261	1551	5
5	Neykuppi	275	1077	539	538	153	1070	0
6	Palakuppam	376	1610	809	801	159	1325	0
7	Pampundi	277	1206	615	591	135	422	0
8	Pattanam	721	2896	1457	1439	307	758	141
9	Tindivanam (M)	17088	72796	36338	36458	7664	12078	354
10	Ural	621	2578	1288	1290	281	198	3
11	Vempundi	426	1843	960	883	226	1221	0
12	Venmaniyathur	271	1350	691	659	155	401	0
5 to 10) km							
Villup	uram District-Tindivanam	taluk						
13	Alapakkam	296	1250	583	667	140	656	10
14	Ammanambakkam	106	391	201	190	40	222	0
15	Asur	408	1716	860	856	216	650	0
16	Attur	360	1473	746	727	158	602	17
17	Avanampattu	177	703	387	316	89	417	0
18	Deevanur	462	2065	1014	1051	263	952	7
19	Endiyur	773	3103	1556	1547	308	0	0
20	Evalur	191	832	424	408	71	345	0
21	Ilamangalam	248	1063	541	522	106	160	25



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22	Iraiyanur	907	3869	1919	1950	418	1192	1
23	Jaggampettai	328	1411	703	708	139	911	0
24	Kalpakkam	102	391	199	192	38	148	0
25	Karanavur	282	1165	585	580	97	540	184
26	Kenipattu	184	723	350	373	65	188	0
27	Kilgudalur	231	879	427	452	93	519	0
28	Kilkaranai	142	567	296	271	70	435	0
29	Kilmalayanur	146	571	276	295	73	119	199
30	Kilmavilangai	264	1000	500	500	100	94	0
31	Kodiam	370	1460	722	738	129	330	0
32	Kodima	227	956	473	483	127	0	0
33	Mannampoondi	94	386	198	188	43	83	15
34	Manoor	886	3550	1793	1757	312	625	91
35	Manur	1513	6290	3114	3176	648	1806	5
36	Meladhanur	236	910	454	456	111	506	0
37	Melpakkam	416	1652	828	824	167	870	13
38	Melpettai	205	827	400	427	79	541	0
39	Muppuli	177	783	377	406	76	0	28
40	Naduvanandal	613	2412	1236	1176	247	436	59
41	Nagavaram	156	649	315	334	78	649	0
42	Nettiyur	283	1323	666	657	133	590	0
43	Panchalam	273	1072	500	572	142	581	0
44	Peramandur	1079	4635	2288	2347	484	1844	59
45	Perapari	75	273	139	134	29	157	0
46	Pulaiyur	160	711	354	357	82	266	0
47	Puliyanur	441	1872	904	968	180	888	58
48	Purangarai	228	1006	502	504	110	571	6
49	Salavadi	598	2467	1218	1249	270	319	129
50	Sattanur	115	482	246	236	31	213	0
51	Singanur	731	3255	1572	1683	343	2496	0



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52	Sitteripattu	152	659	329	330	76	202	0
53	Taniyal	233	1013	494	519	137	688	67
54	Tengapakkam	42	159	80	79	16	62	0
55	Vadampundi	330	1379	692	687	195	468	52
56	Vairapuram	547	2161	1091	1070	258	1011	108
57	Varagapattu	105	406	201	205	54	0	246
58	Vilukkam	710	2799	1412	1387	289	1274	41
59	Vittalapuram	449	1985	1013	972	204	1140	9
	Total	38642	162540	81100	81440	17309	46608	1971

(Source: Census 2011)



3.11.2.1 Employment and livelihood

The majority of the population in the study area comes under other working categories. Agriculture cannot be the main sustenance for most farmers, so they have dual professions. Farming is mostly seasonal, involving other livelihood activities like business, non-agriculture labour, agriculture labour and other service sectors. Fragmentation of landholding leads to the adoption of additional occupations.

People were welcoming industries as they would fetch more employment opportunities. As the education standard has improved, they expect job opportunities in their native places. Women were more eager to participate in economic generation and independence. Skill development is required for a productive work force. Summaries of employment and livelihood within the study are given in **Table 3-26.**

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Table 3-26 Summaries of Employment and Livelihood within the study area

Table 3-26 Summaries of Employment and Livelihood within the study area												
						Agricultur	e Workers	S		sehold	Other	Workers
S.No	Name	Total	Main	Marginal	Culti	vators	Agri. L	abourers	Industry	Workers	Other World	
5.110	Name	Workers	Workers	Workers	Main	Marginal	Main	Marginal	Main	Marginal	Main	Marginal
0 to 5	km								_			
Villup	ouram District-Tind	livanam ta	luk									
1	Buderi	354	293	61	181	4	61	27	8	5	43	25
2	Karuvapakkam	584	536	48	67	5	336	9	35_	20	98	14
3	Kattusiviri	898	732	166	520	19	113	121	10	18	89	8
4	Kollar	1379	1120	259	103	29	669	176	9	6	339	48
5	Neykuppi	536	532	4	29	0	371	2	2	0	130	2
6	Palakuppam	660	348	312	14	9	222	248	9	18	103	37
7	Pampundi	860	753	107	477	18	30	6	8	0	238	83
8	Pattanam	1489	1043	446	351	4	445	389	8	4	239	49
9	Tindivanam (M)	24415	21273	3142	595	51	672	431	465	207	19541	2453
10	Ural	1564	1045	519	146	216	685	252	6	7	208	44
11	Vempundi	909	892	17	146	0	542	3	6	0	198	14
12	Venmaniyathur	952	856	96	631	14	187	9	3	3	35	70
5 to 10	0 km											
Villup	ouram District-Tind	livanam ta	luk									
13	Alapakkam	482	402	80	46	3	191	30	13_	0	152	47
14	Ammanambakkam	266	240	26	73	2	120	22	2	1	45	1
15	Asur	1031	75	956	3	70	1	816	0_	3	71	67
16	Attur	679	608	71	81	1	336	7	10	7	181	56
17	Avanampattu	397	192	205	23	3	144	141	3	7	22	54
18	Deevanur	1110	789	321	288	10	272	282	13	3	216	26
19	Endiyur	1536	1186	350	526	14	262	271	13	8	385	57
20	Evalur	447	447	0	110	0	200	0	0	0	137	0
21	Ilamangalam	673	377	296	199	0	155	278	0	0	23	18



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22	Iraiyanur	1609	1244	365	151	7	145	231	5	19	943	108
23	Jaggampettai	743	682	61	170	1	376	39	10	5	126	16
24	Kalpakkam	244	243	1	0	0	232	1	0	0	11	0
25	Karanavur	707	584	123	169	0	287	120	1	0	127	3
26	Kenipattu	451	433	18	129	1	203	17	0	0	101	0
27	Kilgudalur	472	401	71	91	1	211	64	2_	0	97	6
28	Kilkaranai	345	295	50	105	8	104	12	11	0	75	30
29	Kilmalayanur	373	373	0	272	0	99	0	0	0	2	0
30	Kilmavilangai	513	222	291	49	38	69	234	0	2	104	17
31	Kodiam	800	476	324	203	17	124	273	3	19	146	15
32	Kodima	457	342	115	72	12	179	87	1	1	90	15
33	Mannampoondi	194	101	93	59	6	1	80	0	0	41	7
34	Manoor	2171	2144	27	636	5	1352	10	15	0	141	12
35	Manur	2442	2061	381	321	16	339	138	20	16	1381	211
36	Meladhanur	469	280	189	143	0	67	182	0	2	70	5
37	Melpakkam	864	752	112	118	4	513	99	6	0	115	9
38	Melpettai	430	407	23	12	1	291	8	1	4	103	10
39	Muppuli	544	537	7	34	3	410	0	3_	0	90	4
40	Naduvanandal	1190	746	444	235	72	266	335	10	0	235	37
41	Nagavaram	387	386	1	35	1	280	0	0	0	71	0
42	Nettiyur	648	639	9	91	1	275	4	4_	0	269	4
43	Panchalam	567	540	27	17	1	456	19	3	0	64	7
44	Peramandur	2184	1589	595	472	6	670	505	11_	1	436	83
45	Perapari	120	120	0	46	0	55	0	6	0	13	0
46	Pulaiyur	434	358	76	44	4	187	50	23	3	104	19
47	Puliyanur	934	901	33	241	2	521	7	7	1	132	23
48	Purangarai	483	215	268	37	0	115	240	4	2	59	26
49	Salavadi	1011	1004	7	181	1	602	2	5	0	216	4
50	Sattanur	213	131	82	39	6	15	66	0	0	77	10
51	Singanur	1617	560	1057	15	6	140	504	7	240	398	307



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52	Sitteripattu	400	148	252	83	2	18	246	0	0	47	4
53	Taniyal	572	525	47	34	1	415	45	3	0	73	1
54	Tengapakkam	103	92	11	4	0	86	9	0	0	2	2
55	Vadampundi	713	705	8	42	0	566	5	0	0	97	3
56	Vairapuram	887	845	42	220	5	348	24	3	0	274	13
57	Varagapattu	206	31	175	0	22	0	114	0	2	31	37
58	Vilukkam	1618	1066	552	45	6	945	525	31	0	45	21
59	Vittalapuram	1129	1049	80	247	6	656	62	24	3	122	9
	Total	70465	56966	13499	9471	734	17632	7877	842	637	29021	4251

(Source: Census 2011)

3.11.2.2 Educational infrastructure within study area

The district has good primary and secondary education infrastructure in urban and rural areas. The people around the study area are well connected to educational infrastructures. The following **Table 3-27** shows the literates, and the percentage within the study area.

Table 3-27 Details of literates and the percentage within the study area

Villupur	Villupuram District-Tindivanam taluk											
1	Buderi	844	530	317	213	62.80	314	123	191	37.20		
2	Karuvapakkam	1059	766	423	343	72.33	293	116	177	27.67		
3	Kattusiviri	1775	1182	641	541	66.59	593	220	373	33.41		
4	Kollar	2802	1957	1079	878	69.84	845	306	539	30.16		
5	Neykuppi	1077	633	350	283	58.77	444	189	255	41.23		
6	Palakuppam	1610	1202	639	563	74.66	408	170	238	25.34		
7	Pampundi	1206	842	477	365	69.82	364	138	226	30.18		
8	Pattanam	2896	1770	1026	744	61.12	1126	431	695	38.88		
9	Tindivanam (M)	72796	56920	29987	26933	78.19	15876	6351	9525	21.81		
10	Ural	2578	1653	939	714	64.12	925	349	576	35.88		
11	Vempundi	1843	1018	598	420	55.24	825	362	463	44.76		
12	Venmaniyathur	1350	874	515	359	64.74	476	176	300	35.26		

0 to 5 km

Villupuram District-Tindivanam taluk



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13	Alapakkam	1250	248	144	104	19.84	369	132	237	29.52
14	Ammanambakkam	391	1000	564	436	255.75	143	57	86	36.57
15	Asur	1716	892	505	387	51.98	716	296	420	41.72
16	Attur	1473	450	287	163	30.55	581	241	340	39.44
17	Avanampattu	703	2092	1202	890	297.58	253	100	153	35.99
18	Deevanur	2065	600	341	259	29.06	769	286	483	37.24
19	Endiyur	3103	316	176	140	10.18	1011	354	657	32.58
20	Evalur	832	693	397	296	83.29	232	83	149	27.88
21	Ilamangalam	1063	486	271	215	45.72	325	124	201	30.57
22	Iraiyanur	3869	512	292	220	13.23	1106	414	692	28.59
23	Jaggampettai	1411	355	213	142	25.16	434	199	235	30.76
24	Kalpakkam	391	306	168	138	78.26	75	23	52	19.18
25	Karanavur	1165	696	407	289	59.74	472	188	284	40.52
26	Kenipattu	723	988	562	426	136.65	237	79	158	32.78
27	Kilgudalur	879	588	332	256	66.89	367	135	232	41.75
28	Kilkaranai	567	251	151	100	44.27	212	83	129	37.39
29	Kilmalayanur	571	4775	2571	2204	836.25	265	108	157	46.41
30	Kilmavilangai	1000	551	309	242	55.10	304	93	211	30.40
31	Kodiam	1460	1009	575	434	69.11	472	160	312	32.33
32	Kodima	956	647	332	315	67.68	368	141	227	38.49
33	Mannampoondi	386	605	322	283	156.74	135	47	88	34.97
34	Manoor	3550	1576	935	641	44.39	1369	556	813	38.56
35	Manur	6290	386	225	161	6.14	1515	543	972	24.09
36	Meladhanur	910	693	367	326	76.15	359	145	214	39.45
37	Melpakkam	1652	2791	1565	1226	168.95	643	253	390	38.92
38	Melpettai	827	185	101	84	22.37	180	68	112	21.77
39	Muppuli	783	481	258	223	61.43	178	55	123	22.73
40	Naduvanandal	2412	1188	646	542	49.25	836	301	535	34.66
41	Nagavaram	649	759	407	352	116.95	263	90	173	40.52
42	Nettiyur	1323	286	165	121	21.62	416	167	249	31.44



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43	Panchalam	1072	2424	1225	1199	226.12	379	133	246	35.35
44	Peramandur	4635	412	239	173	8.89	1844	723	1121	39.78
45	Perapari	273	761	386	375	278.75	88	38	50	32.23
46	Pulaiyur	711	62	31	31	8.72	230	96	134	32.35
47	Puliyanur	1872	814	473	341	43.48	684	258	426	36.54
48	Purangarai	1006	1166	665	501	115.90	247	95	152	24.55
49	Salavadi	2467	213	132	81	8.63	990	412	578	40.13
50	Sattanur	482	2090	1108	982	433.61	196	81	115	40.60
51	Singanur	3255	1368	761	607	42.03	831	347	484	25.53
52	Sitteripattu	659	1477	806	671	224.13	247	90	157	37.48
53	Taniyal	1013	2181	1237	944	215.30	252	108	144	24.88
54	Tengapakkam	159	881	451	430	554.09	97	49	48	61.01
55	Vadampundi	1379	2763	1505	1258	200.36	565	219	346	40.97
56	Vairapuram	2161	977	504	473	45.21	995	426	569	46.04
57	Varagapattu	406	907	499	408	223.40	193	69	124	47.54
58	Vilukkam	2799	1296	728	568	46.30	709	304	405	25.33
59	Vittalapuram	1985	738	417	321	37.18	617	252	365	31.08
	Total	162540	116282	62948	53334	71.54	46258	18152	28106	28.46

Source: Census 2011



3.11.2.3 Health facilities within the study area

The majority of people visit nearby Hospitals/health services provided by the Government which are all within 2 to 3 Km distance. Apart from Govt hospitals private clinics are also available in the project area. The area has got good public health facilities at easily reachable distances. The Sub Centres and Primary Health Centres are available. Tindivanam, Villupuram and Puducherry are nearer towns for any major health issues. While we surveyed people, there were no major illnesses found. The natural ambience and stress-free lifestyle provided them healthy life. Even for any minor ailments they contact medical facilities immediately as it is very accessible to them. The incidents of institutional delivery are high due to awareness, education, economic development, and proximity to the health delivery system. The Infant mortality rate and the maternal mortality rate have significantly reduced.

Village **Community Health Centre Primary Health Centre Primary Health Sub Centre** Buderi 0 0 0 0 0 0 Karuvapakkam Kattusiviri 0 0 1 Kollar 0 1 0 0 0 1 Neykuppi Palakuppam 0 0 0 Pampundi 0 0 0 0 0 1 Pattanam Ural 0 0 1 Vempundi 0 0 0 Venmaniyathur 0 0 0

Table 3-28 Details of Public Health Services in 5 Km radius

3.11.2.4 Summary

The Socioeconomic profile of the study area shows that the majority of people in the study area work in non-agricultural sector, however in rural area majority of the people in the rural area depends on agricultural sector. They have good educational infrastructures and the people in the study area are well connected to the educational infrastructures. The average literacy rate of the study area is 71.54%. The people in the study area are well connected to Government primary health centres and Primary health sub-centres. Socio-economic indicators within the study area given in Table 3-29.

Table 3-29 Summary of Socioeconomic indicators within the study area

S.No	Particulars	Study area	Unit
1	Number of villages in the Study Area	59	Nos.
2	Total Households	38642	Nos.
3	Total Population	162540	Nos.
4	Children Population (<6 Years Old)	17309	Nos.
5	SC Population	46608	Nos.
6	ST Population	1971	Nos.
7	Total Working Population	70465	Nos.
8	Main Workers	56966	Nos.

9	Marginal Workers	13499	Nos.
10	Cultivators	10205	Nos.
11	Agricultural labours	25509	Nos.
12	Household Industries	1479	Nos.
13	Other Workers	33272	Nos.
14	Literates	116282	Nos.

Source: Census 2011

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CHAPTER – 4 ANTICIPATED ENVIRONMENTAL IMPACTS AND MITIGATION MEASURES

4 ANTICIPATED ENVIRONMENTAL IMPACTS AND MITIGATION MEASURES

4.1 Details of Investigated Environmental Impacts due to project location, possible accidents, project design, project construction, regular operations, final decommissioning or rehabilitation of a completed project

4.1.1 Impact Identification & Evaluation

Once identified anticipated impacts are analyzed and evaluated based on available information, the method used for evaluating the overall importance of impacts is based on four fundamental criteria:

- Nature (positive or negative, and direct or indirect);
- Duration (temporary or permanent);
- Area extent (regional, local, or isolated); and
- Intensity (low, moderate, or high).

These criteria enable the determination of the overall importance or significance (low, moderate, or strong negative/positive) of each impact identified. Even if a particular evaluation is merely based on a value judgment rather than quantitative data that is not available, the methodology enables the establishment of acceptable levels and defines necessary mitigation and monitoring measures to minimize or eliminate impacts.

4.1.1.1 Nature of Impact

Nature of the impact can be described as positive or negative. Positive impacts enhance the quality or facilitate access to baseline socioeconomic and environmental elements as described in the above chapter, while negative impacts degrade their quality or limit access. Impacts are also described as direct or indirect. A direct impact appears as an immediate result of a project activity, such as the damage to vegetation caused by the development of project land. An indirect impact arises from a project activity at the secondary level, such as the enhanced opportunities for economic development enabled by the project.

4.1.1.2 **Duration of Impact**

The duration of an impact can be temporary or permanent. Careful attention has been made to distinguish between the duration and the source of the impact. For example, a source of impact of short duration (such as turbidity of river water caused by storm runoff from the construction site during construction) can exert an impact of permanent duration on the downstream environment (sedimentation of the riverbed). The presence and operation of the infrastructure works generally impose impacts of permanent duration.

The duration of impact can be classified as below:

Construction Phase: 1-2 years;

The immediate community within the radius of 5 km will be affected. However the impact will be mainly as below:

Traffic Impacts:

• Caused by vehicular movements of men, materials and machineries.

Air quality impacts:

• Due to construction activities viz. dust and particulates

Water Quality impacts:

- Due to runoff during rainy time of construction materials.
- Sewage generation and its disposal.

Noise Quality impacts:

• Caused by vehicular movements of men, materials and machineries.

Area Extent of Impact

The aerial extent of an impact refers to its area of influence and can be regional, local, or isolated to a particularly small and well defined area. An impact of regional extent exerts an influence far beyond the surroundings of the project area. And lastly, an isolated impact is limited in extent to a small, readily defined area or experienced by a small number of individuals.

Intensity of Impact

The intensity of an impact concerns the scale or size of the impact on socioeconomic and environmental elements such as the productivity of natural habitat, a community, or the utilization of resources. Intensity is evaluated as low, moderate or high. Impacts are evaluated as a function of how they affect the overall integrity of elements and their vulnerability to degradation or loss in value.

4.1.1.3 Project Planning & Design

The most important phase of the project is to get the strategic planning of the project components to ensure the following;

Processes which require less water

The planning Phase should draw

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- Water requirement
- Wastewater generation & management
- ➤ Power requirement & source
- Ancillary facilities proposed for the Industrial Area

To ensure the prevention of sources of pollution, reduce the pollutant concentration and enable the operation schedule to manage the effects of pollution.

4.1.2 Environmental Impacts during Construction Phase

The impacts on Air, Noise, Water, Soil, and Ecology of the surrounding environment due to the activities carried out during the construction phase are discussed below;

Impact assessment during the construction phase of the project is of importance as the construction activities lead to adverse effects on the environment on a short term basis. The major activities that

are undertaken during this phase are civil works, mechanical works, machinery works and transportation works.

During the construction phase, the following activities among many are considered to be important towards creating environmental impacts:

- Site preparation (fencing, boundary & clearing of site).
- Excavation, backfilling and levelling
- Hauling and dumping of earth materials & construction spoils.
- Foundation works.
- Fabrication erection of Steel structures such as, Tanks, Pipelines and Sheds.
- Construction of internal roads drains & water supply.
- Painting and finishing.
- Cleaning, landscaping and plantations.

4.1.2.1 Loss of Vegetation

During Construction there will be essentially entail the removal and loss of some, if not most, of the existing trees and underlying grassland at the project site, and the permanent erection of block and steel concrete structures associated within the project site new infrastructures. This would constitute a loss of alternative land use, an irreversible commitment of land resources and thus a direct long-term impact. The site is not extensively or heavily vegetated prior to construction and did not support any significant ecological habitats or fauna. Therefore, the impacts from erecting the new buildings are considered to be insignificant in terms of habitat loss. Impact mitigation is not required during the construction phase. Landscaping of the site, after building completion, will see the introduction of plants and trees that should offset any negative impacts associated with the removal and loss of existing trees at the project site.

The numbers and types of vegetation to be introduced during the landscaping exercise are expected to be greater and more diverse than presently obtained, and these are expected to play a greater role in terms adding ecological value and attracting birds and other terrestrial fauna during the operational phase of the project, apart from being more pleasing aesthetically.

4.1.2.2 Impact on Drainage Pattern

The overall topography of the proposed expanion site will be radically changed by the erection of buildings and this will bring moderately significant change in the existing pattern of surface drainage. Mainly, the impact will arise from the creation of impermeable surfaces (roofs, pavements, etc.,) and the corresponding reduction in the amount percolation in the soil and capacity of the site to absorb rainfall.

4.1.2.3 Erosion of Cleared Area

Vegetation clearance and excavation works related to construction will expose soils in the affected areas which could leave them vulnerable to erosion by surface run-off and create the threat of turbidity and sediment deposition in drains & nearby rivers. The topography of the site and the

pervious nature of the soil will cause erosive surface flows during the construction works before landscaping and drainage works reduce the susceptibility to soil erosion. Significant surface features such as gullies, streams or rivers in close proximity to the site that could be affected by soil erosion.

4.1.2.4 Impacts of Material Transportation

The various materials required for construction (e.g. Steel, sand, Blocks, Lumber, Marl, Asphalt, etc.) will be obtained from sources elsewhere and transported to the site. Transportation of these materials, typically in over-laden and sometimes uncovered trucks, usually result in noise pollution. In the case of fine earth materials, dusting and spillages occur on the roadways between source and site. Dusting degrades local air quality and material spillages worsen road driving conditions and increase the risk of road accidents. These occurrences represent indirect, short-term, reversible, negative impacts on public health and safety related to the project.

4.1.2.5 Air environment

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During construction phase the ambient air quality in and around the proposed project site will have marginal adverse impacts due to construction activities. Construction activities likesite preparation, approach roads, excavation, drilling, foundation, deployment of machinery, erection, transportation, dumping will cause dust and gaseous emissions. The pollutant released during the construction activities may cause immediate effect on the construction workers. **Table 4-1** gives the emissions from various construction equipments.

Table 4-1Trem and CEV Stage IV - V emission standards for Construction Vehicles

Engine Power	Date	CO	HC	NOx	PM	PN	Tost Cycle			
kW	Date		g/	/kWh		1/kWh	Test Cycle			
	Trem	Stage	IV and	l CEV	Stage IV					
$37 \le P < 56$	GEV 2021.04	5.0	4.	7*	0.025	-				
$56 \le P < 130$	CEV: 2021.04 Trem: 2023.01	5.0	0.19	0.4	0.025	-	NRSC and NRTC			
$130 \le P < 560$	110111. 2023.01	3.5	0.19	0.4	0.025	-				
Trem Stage V and CEV Stage V										
P < 8		8.0	7.5*		0.4	-	NRSC			
$8 \le P < 19$		6.6	7.	7.5*		-	NKSC			
$19 \le P < 37$		5.0	4.7*		0.015	1×10 ¹²				
$37 \le P < 56$	2024.04	5.0	4.	7*	0.015	1×10 ¹²	NRSC and NRTC			
$56 \le P < 130$		5.0	0.19	0.4	0.015	1×10 ¹²	NKSC and NKTC			
$130 \le P \le 560$		3.5	0.19	0.4	0.015	1×10 ¹²				
P ≥ 560		3.5	0.19	3.5	0.045	-	NRSC			
* NOx + HC										

(**Source**: Ministry of Road Transport and Highways, "Notification no. G.S.R. (201) (E) dated 05.03.2018 regarding Emission standards for CEV and Agricultural tractors," May 3, 2018)

Due to the short duration of the planned action, any impacts on Ambient Air Quality during construction activities are expected to be short term.

4.1.2.6 Noise Environment

Foundation work will involve land excavation, affecting environment by noise. Structural work, deployment of machinery, approach of road construction and erection of roads will result in noise and vehicular traffic. Material handling and transportation would also lead to significant noise pollution. Continuous exposure of workers to high sound levels may result in annoyance, fatigue. This negative impact will be short-term (limited to the duration of the road construction works) and is not considered to be a significant threat to the health or wellbeing of humans.

4.1.2.7 Water Environment

Construction phase requires water for various processing such as material preparation in equipment's. Change in quality of water isan important concern associated with the project particularly during the construction phase. Earth works, crushing of stones, cutting and modification of the terrain, alteration of drainage systems and soil erosion are the major factors that affect the water quality during construction phase.

During rainy season, the runoff water joining the water coursesinnearby areas of the development sites will add to debris and soil particles to enhance the level of suspended solids in the water bodies. This will adversely affect the fishes and other aquatic life forms apart from the human beings who are dependent on the surface water for their daily use.

Following are the most susceptible locations for contamination of water during construction:

- Surface and ground water resources close to construction material storage yard, concrete mixer plants and maintenance sites of construction vehicles;
- Leakage of lubricant or spill may cause water pollution of surface and ground water body.
- Impact due to accidental spills or due to bad construction practice, will be short term and low in magnitude and confined to the construction period only.
- Due to manpower, sewage will be generated which will be treated in pacakage STP.

4.1.2.8 Biological Environment

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Dust from the construction activities will affect the plant and animal respiration activity. Construction activities change the natural environment. But it also creates a built environment for the surrounding. Emissions such as PM_{10} , $PM_{2.5}$, NO_X , SO_X from D.G sets and other vehicles may also cause respiration problem for the surrounding organisms. The extent of the pollution will be about 2km from the project area.

Possible Accidents during Construction Phase

Possible accidents that are expected during construction phase are

- > Falls
- > Electrocution
- Struckbyobjects
- > Fire&explosions
- > Machineryaccidents

4.1.2.9 Socio Economic Environment

Positive Impacts

Income to the local material suppliers

This project will promote the procurement of equipment's and machineries for various activities of construction phase. Procurement of material from local suppliers will promote the growth of the economy of area.

Employment Opportunities

Proposed project will create employment opportunities to the local people living near the Project Site. It is estimated that 30people will be required for construction phase. These levels of short-term employment opportunities would have a positive impact on the local economy.

Negative Impacts

OHS Risk to Construction Workers

During construction phase of the proposed project the employeesare subject to Health and Safety Risks.

4.1.3 Environmental Impacts during Operational Phase

From an environmental perspective, this phase is of paramount significance due to its potential to invoke long-term impacts. Both positive and negative impacts may be expected in the surrounding environment due to various activities associated with the operations of the proposed project.

The impacts on various environmental attributed as detailed below:

- Air Quality
- Noise quality
- Water Resources and Water Quality
- Soil Quality, landscape and land use
- Ecology/Biodiversity
- Socio-economics

4.1.3.1 Air Environment

Base line data reveals that ambient air quality in the study area for the Parameters PM, SO2, NOx and CO are well within the permissible Limits as prescribed by the National Ambient Air Quality Standards (NAAQS) for Industrial Area, Residential, Rural & Other areas.

4.1.3.1.1 Meteorological Data

The meteorological data for a 3 month, i.e. from 01/03/2024 to 31/05/2024 was considered for the study. Data included for AERMET were daily wind speed, wind direction, temperature, relative



humidity, air pressure, precipitation, and solar radiation recorded during the period. AERMET reformats meteorological data so that it can be used as input for AERMOD model. Meteorology considered for modelling is shown below.

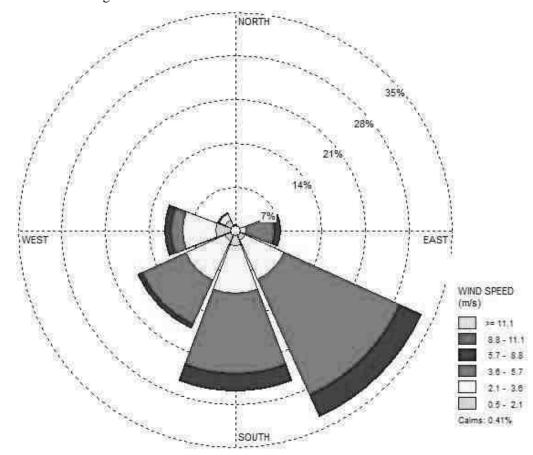


Figure 4-1 Wind rose diagram considered for Study period from March to May 2024

4.1.3.1.2 **AERMET Process**

For the 3 phase AERMET processing of the meteorological data, specifications of the land use in the area are required to determine the terrain roughness for modeling. The land use was characterized for in and around the site. The surface characteristics for the site and surroundings were selected and used to calculate the albedo, Bowen ratio and surface roughness parameter.

The meteorological data were processed in the AERMET software to generate wind flow pattern & to generate surface meteorological data and profile meteorological data in a prescribed format that can be fed to AERMOD for modeling.

4.1.3.1.3 AERMOD Process

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AERMOD Software Version 8.0.5 was used for air dispersion modelling and is applicable to a wide range of buoyant or neutrally buoyant emissions up to a range of 50 km. In addition to more straight forward cases, AERMOD is also suitable for complex terrain and urban dispersion scenarios.

AERMOD is a steady-state plume model. In the stable boundary layer (SBL), it assumes the concentration distribution to be Gaussian in both the vertical and horizontal. In the convective

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 $\frac{H/01/2024/CON/065}{RP003-R2}$

boundary layer (CBL), the horizontal distribution is also assumed to be Gaussian, but the vertical distribution is described with a bi-Gaussian probability density function (pdf). This behaviour of the concentration distributions in the CBL was demonstrated by Willis and Deardorff (1981) and Briggs (1993). Additionally, in the CBL, AERMOD treats "plume lofting," whereby a portion of plume mass, released from a buoyant source, rises to and remains near the top of the boundary layer before becoming mixed into the CBL. AERMOD also tracks any plume mass that penetrates into the elevated stable layer, and then allows it to re-enter the boundary layer when and if appropriate. For sources in both the CBL and the SBL, AERMOD treats the enhancement of lateral dispersion resulting from plume meander. Maximum incremental value for PM, SO2, NOx and CO has been represented as pictorial concentration contours and as tabular concentration values in following sections:

Proposed Manufacturing of Monoclonal	Antibodies and	l Formulation	Facility
Draft ElAreport			

H/01/2024/CON/065 RP003 – R2

1. Point Source

Table 4-2 Emission from the proposed project -Stack Emission

					S	Stack Detail	s		Emis	sions		
S. NO.	Source	Fuel Type	Fuel Quantity (KL / Day)	No. of Stack	Height (m)	Temp (°C)	Dia (m)	Exit Velocity (m/s)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
1	DG-600 KVA*	HSD	2.00	1	30	200	0.2	9.5	7.43E-03	6.93E-03	1.05E-01	2.26E-02
2	DG-600 KVA*	HSD	2.88		30	200	0.2	9.5	7.43E-03	6.93E-03	1.05E-01	2.26E-02
3	Boiler 1.5 TPH	HSD	2.509	1	30	210	0.3	10	3.41E-03	4.70E-04	6.62E-02	1.66E-02
	Total										2.76E-01	6.17E-02

Note: *In ToR application, DG sets capacity - 2x350 kVA.

Source:

1. Emission reference: AP-42: Compilation of Air Emissions Factors - DG.

2. National Pollutant Inventory: Emission estimation technique manual-Combustion in boilers



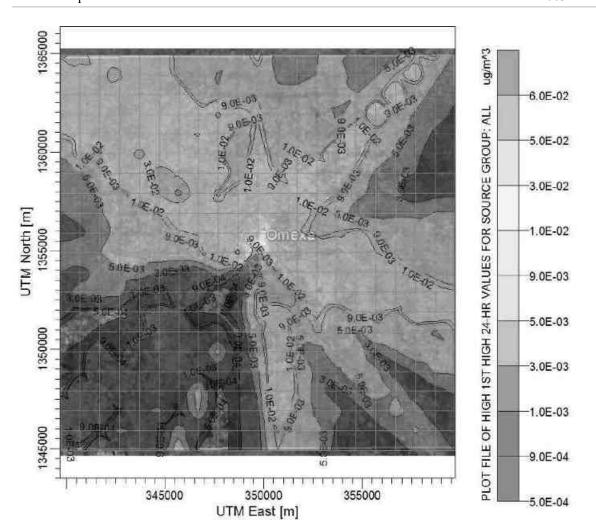


Figure 4-2Predicted 24-Hrs' GLC's of PM within 10 km Radius of the Study Area
Table 4-3Estimated Top 10 Highest Concentrations of PM Obtained through Modeling

	UTM coor	dinates (m)		Distance	Direction	
S. No	E	N	Conc. (μg/m³)	from Centre of Project Site (~Km)	from Centre of Project Site	
1.	345692	1357907	0.05684	5.00	WNW	
2.	344692	1358907	0.03688	6.40	WNW	
3.	343692	1359907	0.03435	7.81	WNW	
4.	348692	1354907	0.03342	1.00	W	
5.	344692	1357907	0.03339	5.83	WNW	
6.	347692	1361907	0.03334	7.28	NNW	
7.	346692	1360907	0.03129	6.70	NNW	
8.	350692	1354907	0.02923	1	E	
9.	345692	1358907	0.02899	5.65	NW	
10.	350692	1355907	0.02691	1.41	NE	

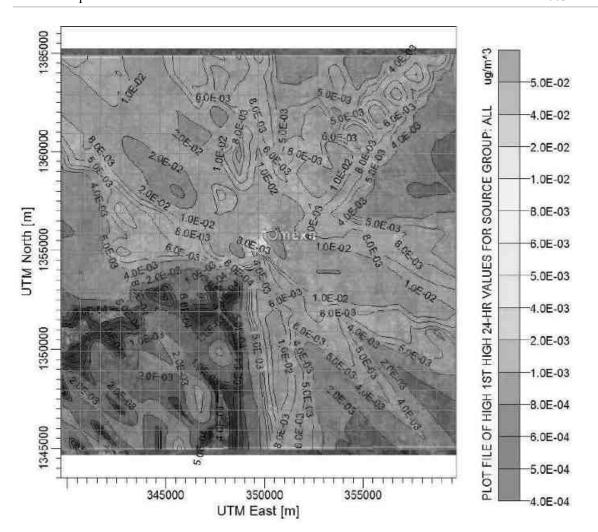


Figure 4-3Predicted 24-Hrs' GLC's of SO₂ within 10 km Radius of the Study Area

Table 4-4Estimated Top 10 Highest Concentrations of Sulphur Di Oxide Obtained through

Modeling

S.	UTM coor	dinates (m)	Conc.	Distance from Centre of	Direction from Centre	
No	E N		$(\mu g/m^3)$	Project Site (~Km)	of Project Site	
1.	345692	1357907	0.04864	5.00	WNW	
2.	344692	1358907	0.03155	6.40	WNW	
3.	347692	1361907	0.02945	7.28	NNW	
4.	343692	1359907	0.02913	7.81	WNW	
5.	344692	1357907	0.02777	5.83	WNW	
6.	348692	1354907	0.02677	1.00	W	
7.	346692	1360907	0.02651	6.70	NNW	
8.	345692	1358907	0.02399	5.65	NW	
9.	350692	1354907	0.02305 1		E	
10.	350692	1355907	0.02121	1.41	NE	

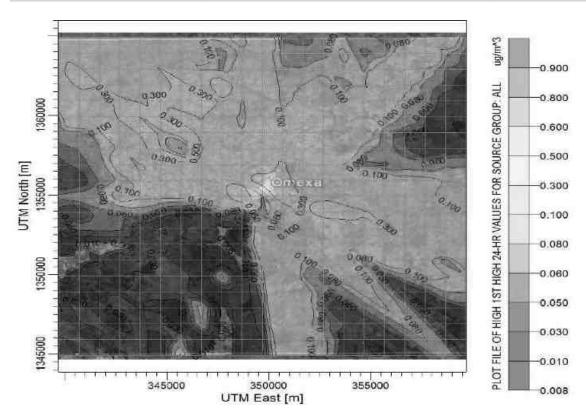


Figure 4-4Predicted 24-Hrs' GLC's of NO_x within 10 km Radius of the Study Area Table 4-5Estimated Top 10 Highest Concentrations of Oxides of Nitrogen Obtained through Modeling

	UTM coo	rdinates (m)		Distance from	Direction from
S. No	E	N	Conc. (μg/m³)	Centre of Project Site (~Km)	Centre of Project Site
1.	345692	1357907	0.83231	5.00	WNW
2.	344692	1358907	0.54017	6.40	WNW
3.	343692	1359907	0.50479	7.81	WNW
4.	348692	1354907	0.50152	1.00	W
5.	344692	1357907	0.49434	5.83	WNW
6.	347692	1361907	0.48204	7.28	NNW
7.	346692	1360907	0.46	6.70	NNW
8.	350692	1354907	0.44104	1	E
9.	345692	1358907	0.43001	5.65	NW
10.	350692	1355907	0.40613	1.41	NE

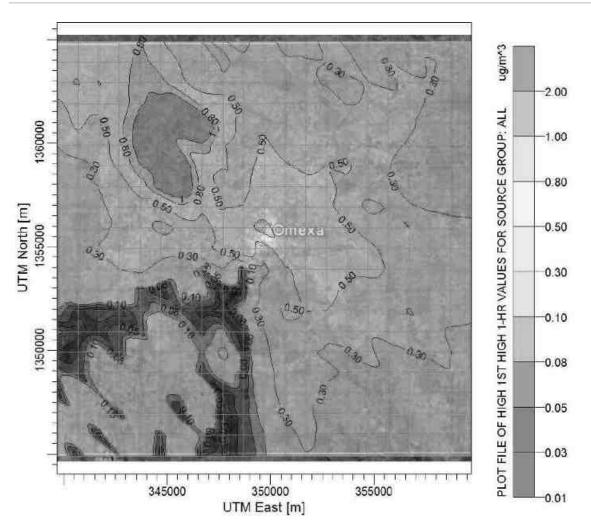


Figure 4-5Predicted 1-Hrs' GLC's of CO within 10 km Radius of the Study Area Table 4-6Estimated Top 10 Highest Concentrations of CO Obtained through Modeling

	UTM coor	dinates (m)		Distance from	Direction from
S. No	E	N	Conc. (μg/m³)	Centre of Project Site (~Km)	Centre of Project Site
1.	346692	1360907	1.4975	6.70	NNW
2.	345692	1357907	1.39965	5.00	WNW
3.	344692	1359907	1.39338	5.83	NNW
4.	345692	1358907	1.30665	5.65	NW
5.	344692	1360907	1.29465	7.78	NNW
6.	345692	1360907	1.23489	7.20	NNW
7.	344692	1358907	1.19009	6.40	WNW
8.	344692	1357907	1.18188	5.83	WNW
9.	343692	1359907	1.17981	7.81	WNW
10.	345692	1361907	1.15941	8.06	NNW

Conclusion

Maximum pollutant concentrations of PM, SO₂, NO_xobserved due to proposed for an 24hr-average period have been studied and CO observed due to proposed for an 1hr-average period have been studied. The total increase in concentrations above baseline status to estimate the percentage increase and summarized in **Table 4-7**.

Table 4-7Total maximum GLCs from the Stack Emissions

Pollutant	Max. Base line Conc. (μg/m³)	Estimated Incremental Conc. (µg/m³)	Total Conc. (μg/m³)	NAAQ standard (μg/m³)
PM	59.48	0.056	59.536	100
SO_2	12.46	0.048	12.508	80
NO _x	25.92	0.832	26.752	80
CO	720	1.497	721.497	4000

2. Line Source Emission:

Table 4-8Proposed project Transportations Emission

S.No	Type of Vehicle	No. of Vehicle	Emissions (g/s)			
5.110	Type of Vehicle	No. of venicle	PM	NO_x	CO	
1	2w	20	3.13E-05	6.25E-04	3.47E-03	
2	4w	4	5.00E-05	1.39E-03	8.22E-03	
3	Bus	2	6.94E-06	3.19E-04	2.78E-03	
4	Truck	1	3.47E-06 1.60E-04 1.39E-		1.39E-03	
Total		9.17E-05	2.49E-03	1.59E-02		

Source: Indian Emission Regulations by the Automotive Research Association of India.

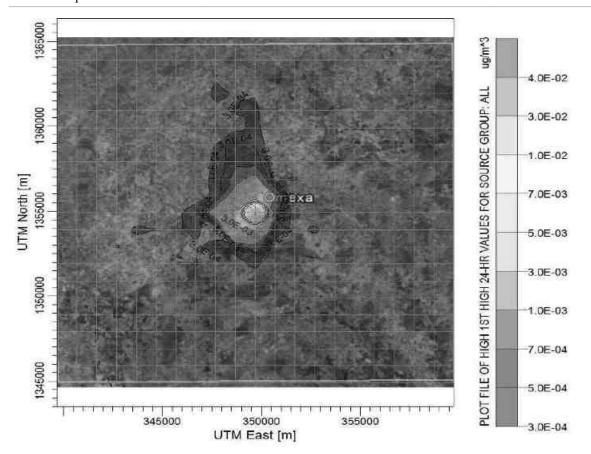


Figure 4-6 Predicted 24-Hrs' GLC's of PM within 10 km Radius of the Study Area

Table 4-9 Estimated Top 10 Highest Concentrations of Particulate Matter PM obtained through Modeling

- C	UTM coor	dinates (m)		Distance	Direction	
S. No	E	N	Conc. (μg/m³)	from Centre of Project Site (~Km)	from Centre of Project Site	
1.	349692	1354907	0.03227	Project Site	Project Site	
2.	348692	1354907	0.00337	1.00	W	
3.	349692	1353907	0.00298	1.00	S	
4.	348692	1353907	0.00288	1.41	SW	
5.	349692	1355907	0.0018	1.00	N	
6.	347692	1354907	0.00142	2.00	W	
7.	348692	1355907	0.00137	1.41	NW	
8.	349692	1356907	0.00119	2.00	N	
9.	350692	1355907	0.00111	1.41	NE	
10.	349692	1352907	0.00095	2.00	S	

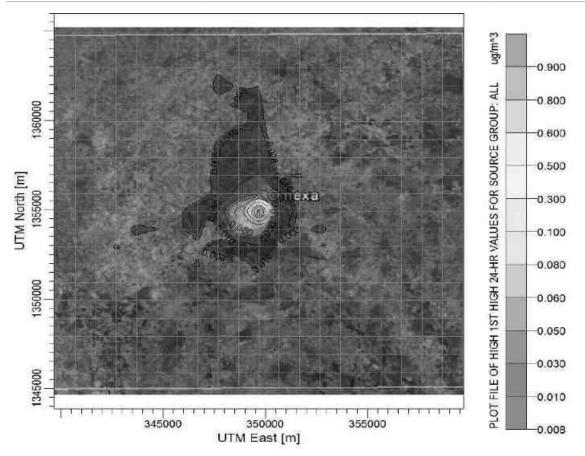


Figure 4-7 Predicted 24-Hrs' GLC's of NOx within 10 km Radius of the Study Area

Table 4-10 Estimated Top 10 Highest Concentrations of Oxides of Nitrogen Obtained through

Modeling

	UTM coo	ordinates (m)	Conc.	Distance from Centre of	Direction from
S. No	E	N	$(\mu g/m^3)$	Project Site (~Km)	Centre of Project Site
1.	349692	1354907	0.87709	Project Site	Project Site
2.	348692	1354907	0.09148	1.00	W
3.	349692	1353907	0.08097	1.00	S
4.	348692	1353907	0.07821	1.41	SW
5.	349692	1355907	0.04891	1.00	N
6.	347692	1354907	0.03868	2.00	W
7.	348692	1355907	0.03719	1.41	NW
8.	349692	1356907	0.03221	2.00	N
9.	350692	1355907	0.0302	1.41	NE
10.	349692	1352907	0.02586	2.00	S

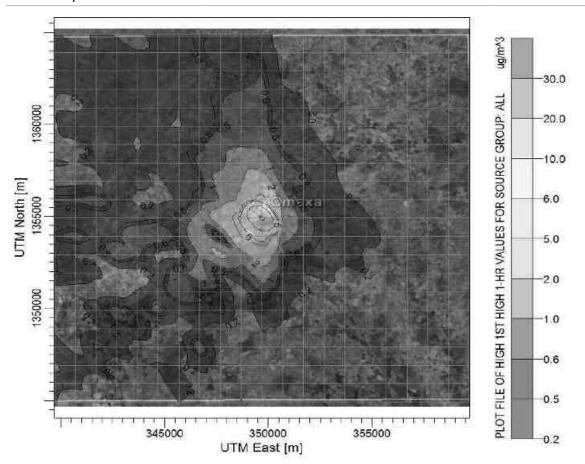


Figure 4-8 Predicted 1-Hrs' GLC's of CO within 10 km Radius of the Study Area
Table 4-11 Estimated Top 10 Highest Concentrations of CO Obtained through Modeling

~	UTM coor	dinates (m)	Conc.	Distance from Centre of	Direction from
S. No	E	N	$(\mu g/m^3)$	Project Site (~Km)	Centre of Project Site
1.	349692	1354907	22.16318	Project Site	Project Site
2.	349692	1353907	7.37441	1.00	S
3.	348692	1354907	6.49518	1.00	W
4.	349692	1355907	5.92599	1.00	N
5.	348692	1353907	5.02495	1.41	SW
6.	349692	1352907	3.26087	2.00	S
7.	347692	1354907	3.18965	2.00	W
8.	349692	1356907	3.09479	2.00	N
9.	347692	1352907	2.42241	2.82	SW
10.	348692	1355907	2.23555	1.41	NW

Conclusion

Maximum pollutant concentrations of PM and NOx observed due to proposed for an 24hr-average period have been studied. The total increase in concentrations above baseline status to estimate the percentage increase and summarized in **Table 4-12**.

Table 4-12 Total Maximum GLCs from the Transportation Emissions

	Max. Base line Conc.	Estimated		NAAQ
Pollutant	$(\mu g/m^3)$	Incremental	Total Conc. (μg/m³)	standard
	(μg/m)	Conc. (µg/m³)		$(\mu g/m^3)$
PM	59.48	0.03	59.51	100
NO _x	25.92	0.87	26.79	80
СО	720	22.16	742.16	4000

3. Cumulative:

Table 4-13Proposed and project Stack & Transportations Emission (Cumulative))

					Stack Details				Emissions			
S.No	Source	Fuel Type	Fuel Quantity (KL / Day)	No. of Stack	Height (m)	Temp (°C)	Dia (m)	Exit Velocity (m/s)	PM (g/s)	SO ₂ (g/s)	NO _x (g/s)	CO (g/s)
1	DG-600 KVA*	HSD	2.88	1	30	200	0.2	9.5	7.43E-03	6.93E-03	1.05E-01	2.26E-02
2	DG-600 KVA*	HSD	2.88	1	30	200	0.2	9.5	7.43E-03	6.93E-03	1.05E-01	2.26E-02
3	Boiler 1.5 TPH	HSD	2.509	1	30	210	0.3	10	3.41E-03	4.70E-04	6.62E-02	1.66E-02
	Turning											

Transportations

			Emissions			
S.No	Type of Vehicle	No. of Vehicle	(g/s) (g/s)			CO (g/s)
1	2w	20	3.13E-05	-	6.25E-04	3.47E-03
2	4w	4	5.00E-05	-	1.39E-03	8.22E-03
3	Bus	2	6.94E-06	-	3.19E-04	2.78E-03
4	Truck	1	3.47E-06	-	1.60E-04	1.39E-03
	Total			1.43E-02	2.78E-01	7.76E-02

Note: *In ToR application, DG sets capacity - 2x350 kVA.

1. Emission reference: AP-42: Compilation of Air Emissions Factors - DG.

2. National Pollutant Inventory: Emission estimation technique manual-Combustion in boilers.

3. Indian Emission Regulations by the Automotive Research Association of India.



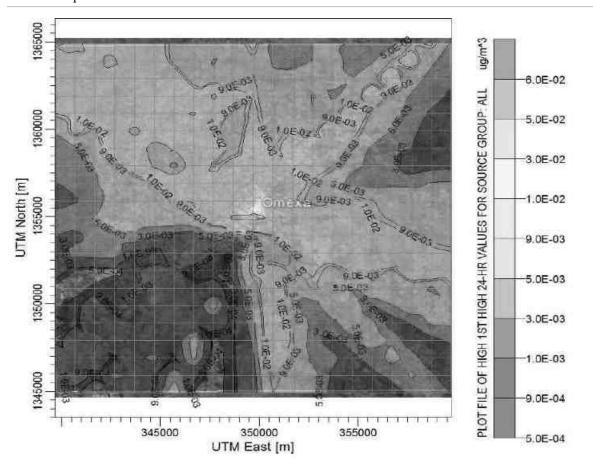


Figure 4-9 Predicted 24-Hrs' GLC's of PM within 10 km Radius of the Study Area
Table 4-14 Estimated Top 10 Highest Concentrations of PM Obtained through Modeling

S. No	UTM coor	rdinates (m) N	Conc. (μg/m³)	Distance from Centre of Project Site (~Km)	Direction from Centre of Project Site		
1.	345692	1357907	0.05701	5.00	WNW		
2.	344692	1358907	0.03704	6.40	WNW		
3.	343692	1359907	0.03441	7.81	WNW		
4.	347692	1361907	0.03373	7.28	NNW		
5.	348692	1354907	0.03365	1.00	W		
6.	344692	1357907	0.03345	5.83	WNW		
7.	349692	1354907	0.0323	Project Site	Project Site		
8.	346692	1360907	0.0314	6.70	NNW		
9.	350692	1354907	0.02939	1	E		
10.	345692	1358907	0.02908	5.65	NW		

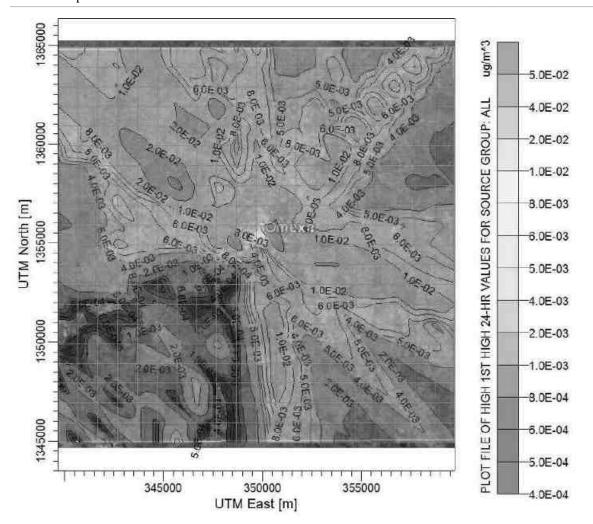


Figure 4-10 Predicted 24-Hrs' GLC's of SO2 within 10 km Radius of the Study Area

Table 4-15 Estimated Top 10 Highest Concentrations of Sulphur Di Oxide Obtained through

Modeling

~	UTM coordinates (m)		Conc.	Distance from Centre	Direction from Centre
S. No	E	N	$(\mu g/m^3)$	of Project Site (~Km)	of Project Site
1.	345692	1357907	0.04864	5.00	WNW
2.	344692	1358907	0.03155	6.40	WNW
3.	347692	1361907	0.02945	7.28	NNW
4.	343692	1359907	0.02913	7.81	WNW
5.	344692	1357907	0.02777	5.83	WNW
6.	348692	1354907	0.02677	1.00	W
7.	346692	1360907	0.02651	6.70	NNW
8.	345692	1358907	0.02399	5.65	NW
9.	350692	1354907	0.02305	1	E
10.	350692	1355907	0.02121	1.41	NE

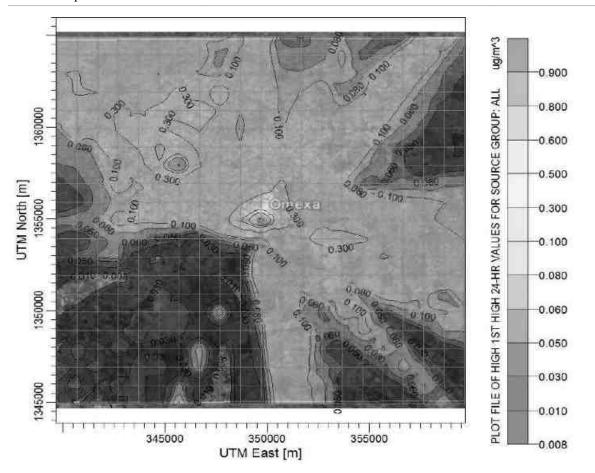


Figure 4-11 Predicted 24-Hrs' GLC's of NOx within 10 km Radius of the Study Area

Table 4-16 Estimated Top 10 Highest Concentrations of Oxides of Nitrogen Obtained through

Modeling

	UTM coor	dinates (m)	_	Distance from	Direction from
S. No	E	N	Conc. (μg/m³)	Centre of Project Site (~Km)	Centre of Project Site
1.	349692	1354907	0.87748	Project Site	Project Site
2.	345692	1357907	0.83703	5.00	WNW
3.	344692	1358907	0.54437	6.40	WNW
4.	348692	1354907	0.50789	1.00	W
5.	343692	1359907	0.50647	7.81	WNW
6.	344692	1357907	0.49588	5.83	WNW
7.	347692	1361907	0.49263	7.28	NNW
8.	346692	1360907	0.463	6.70	NNW
9.	350692	1354907	0.44541	1	E
10.	345692	1358907	0.43251	5.65	NW

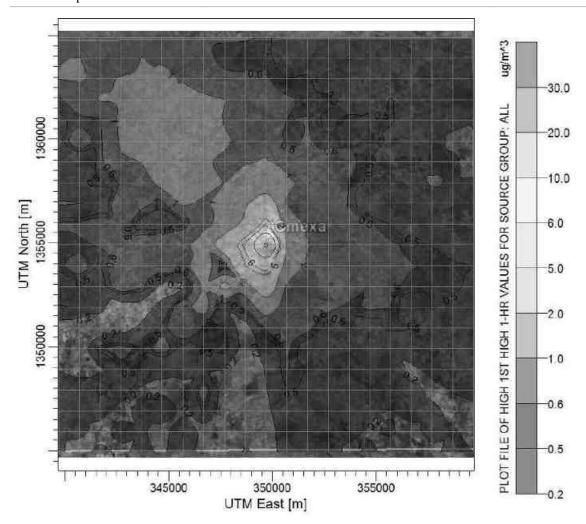


Figure 4-12 Predicted 1-Hrs' GLC's of COwithin 10 km Radius of the Study Area

Table 4-17 Estimated Top 10 Highest Concentrations of COObtained through Modeling

	UTM coordinates (m)			Distance from	Direction	
S. No	E	N	Conc. (μg/m³)	Centre of Project Site (~Km)	from Centre of Project Site	
1.	349692	1354907	22.16318	Project Site	Project Site	
2.	349692	1353907	7.37441	1.00	S	
3.	348692	1354907	6.49518	1.00	W	
4.	349692	1355907	5.92599	1.00	N	
5.	348692	1353907	5.02495	1.41	SW	
6.	349692	1352907	3.26087	2.00	S	
7.	347692	1354907	3.18965	2.00	W	
8.	349692	1356907	3.09479	2.00	N	
9.	347692	1352907	2.42241	2.82	SW	
10.	348692	1355907	2.23555	1.41	NW	

Conclusion

Maximum pollutant concentrations of PM, SO₂, NO_x observed due to proposed for an 24hr-average period have been studied and CO observed due to proposed for an 1hr-average period have been studied. The total increase in concentrations above baseline status to estimate the percentage increase and summarized in**Table 4-18**.

Table 4-18 Total Maximum GLCs from the Stack Emissions & Transportations Emissions

Pollutant	Max. Base line Conc.	Estimated Incremental	Total Conc. (μg/m³)	NAAQ standard
	$(\mu g/m^3)$	Conc. (µg/m³)	,	$(\mu g/m^3)$
PM10	59.48	0.05	59.53	100
SO2	12.46	0.04	12.5	80
NO _x	25.92	0.87	26.79	80
СО	720	22.16	742.16	4000

4.1.3.2 Impacts due to Traffic and Transportation

Project site is located near to the TANSIDCO Park Road which is connected to NH77 (Tindivanam – Krishnagiri Highway). The Google image of road connectivity for the project site is given in **Figure 4-13**. The vehicular movement for the proposed project is given in **Table 4-19**.

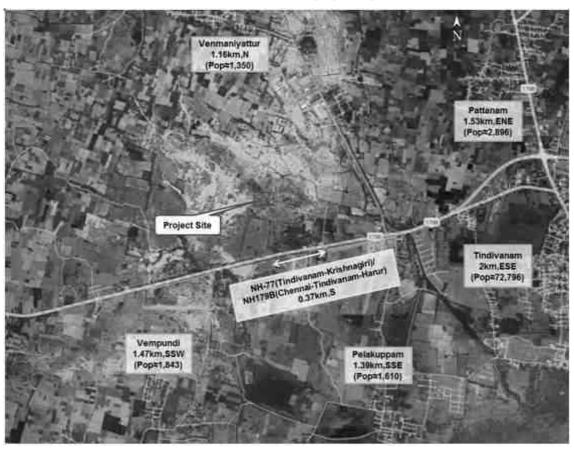


Figure 4-13 Google image of road connectivity to the project site

Table 4-19 Existing and Proposed Vehicular movement in NH-77 per hour

S. No	Type of Vehicles	Existing vehicles	Existing PCU	Proposed vehicles	Proposed PCU	Total vehicles after project implementat ion	PCU Factors IRC (SP41)	Total PCU after project implementat ion
1	2wheelers	350	263	20	15	370	0.75	278
2	3Wheeler	42	84	0	0	42	2	84
3	Cars	442	442	4	4	446	1	446
4	Truck / Lorry/ Bus	90	333	3	11.1	93	3.7	344
5	Agri tractor	8	32	0	0	8	4	32
6	Light commercial	45	90	0	0	45	2	90
	Total	977	1244	27	30.1	1004	-	1274

Based on the traffic for the proposed project, the expected LOS due to the project is given in **Table 4-20**.

Table 4-20 Traffic Volume after Implementation of the Project

For the Road	Volume of Traffic	Volume (V)	Road Capacity (C)	V/C Ratio	LOS Category*	Traffic Classification
Existing	977	1244	15000	0.08	"A"	Free Flow Traffic
After implementation	1004	1274	15000	0.085	"A"	Free Flow Traffic

*LOS (Level of Service) categories are A-Free Flow, B- Stable Traffic Flow, C- Restricted Flow, D-

High Density Flow, E- Unstable flow, F- Forced or breakdown flow

Table 4-21 Categorisation of traffic

Table 4-21 Categorisation of traine					
V/C	LOS	Classification			
< 0.35	A	Free flow Traffic			
0.35-0.55	В	Stable flow Traffic			
0.55-0.77	С	Restricted flow			
0.77-0.92	D	High Density flow			
0.92-1.0	Е	Unstable Flow			
>1.0	F	Forced Traffic flow			

Due to propose project there will be slight increment in the vehicle movement but the level of service (LOS) anticipated will be **Free Flow**.

^{*}LOS (Level of Service) categories are

4.1.3.3 Noise Environment

The impacts of the proposed project on the noise levels of the surrounding areas were assessed. All equipments in the plant is designed/operated to have a noise level not exceeding 85 to 90 dB(A) as per the requirement of Occupational Health and Safety Administration Standard (OHSAS). In addition, since most of the noise generating equipment would be in closed structures, the noise transmitted outside would be still lower.

4.1.3.4 Impact

Noise generation sources during operation phase are classified into two categories:

- Stationary sources due to operation of heavy-duty machinery at the project site like Air Compressors, DG sets, Pumps and ID fans etc.
- Mobile sources corresponding to mainly vehicular traffic for staff mobilization, materials, material transportation, liquid fuel transportation to project site, etc.

The impact of vibrations beyond the site would be negligible during normal operation phase. However, the impacts on workers engaged in the plant area would be considerable due to occupational exposure. The fixed major equipment/units such as air compressors, pumps, DG sets and ID fans etc., also generates vibrations during operational phase and may cause exposures to the workers/operators engaged at these units.

4.1.3.5 Noise modelling

Software – CUSTIC 3.2 English

Ambient Data:

Terrain:

- 1. Temperature 25 °C
- 2. Relative Humidity 70%

Source of Noise Modelling:

For modelling purpose two cases was assumed,

- Case 1- Equipment activity is considered (Point Source)
- Case 2- Truck activity is considered (Line Source)

Table 4-22 Source of Noise Modelling - Equipment Activity (Case-1)

S.no	Equipment	Noise Level	Unit dB(A)
1	DG Set	81	dB(A)
2	Boiler	91	dB(A)

Table 4-23 Source of Noise Modelling – Loading & Unloading Activity (Case-2)

	Sl. No	For Production Activity	Noise Level	Unit
ĺ	1	Vehicles	90	dB(A)

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Source: https://www.fhwa.dot.gov/Environment/noise/construction_noise/handbook/handbook09.cf
m

Receptor: Noise contours are generated based on receptors at 1.5m height above ground & Grid size -200.

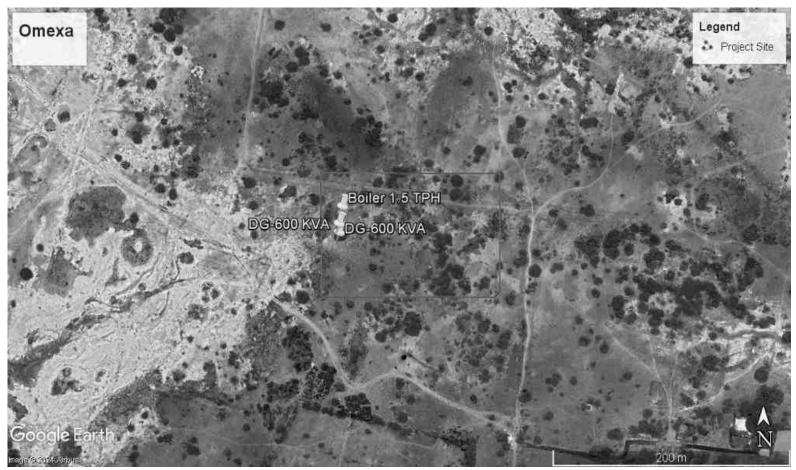


Figure 4-14 Base Map



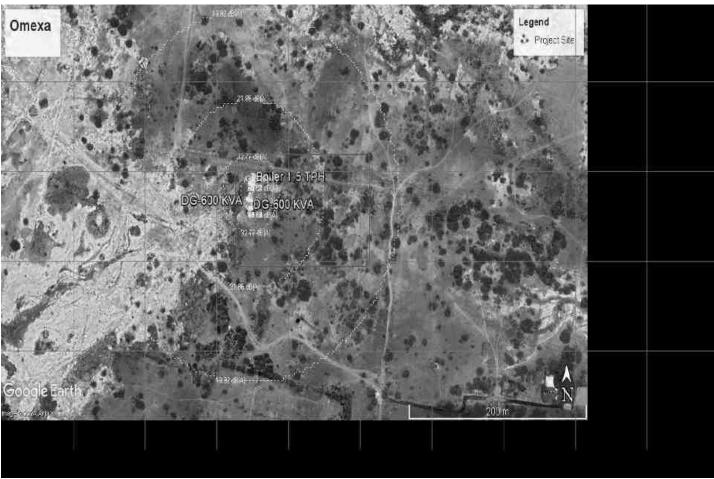


Figure 4-15 Equipment activity



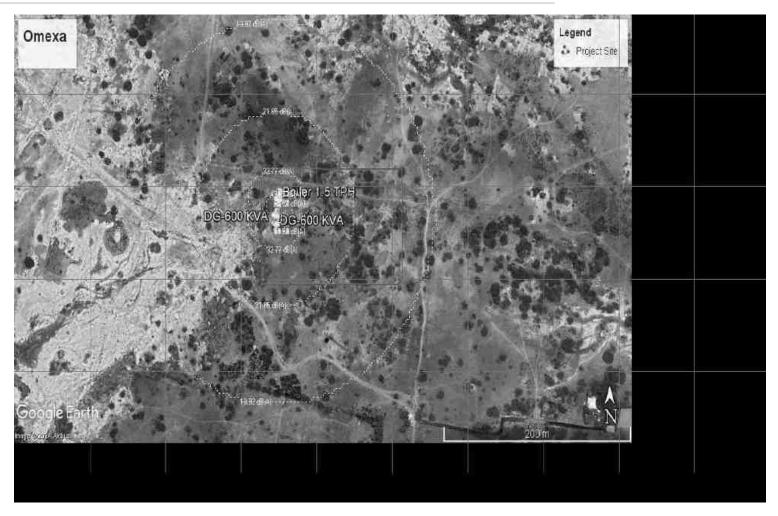


Figure 4-16 Noise Contour map for Loading & Unloading (Truck) Activity



Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility	H/01/2024/CON/065
Draft ElAreport	RP003 – R2

Summary:

The Noise level ranges within the limit for the proposed Equipment & Loading & Unloading (Truck) activity. The noise range for within site and within 0.5km radius is given below.

Table 4-24 Summary of noise modelling

Activities	Near Project Boundary dB (A)	At 0.5Km radius from the Project Site dB (A)	Noise Standard (Industrial - Day) dB (A)
Equipment Activity	21.85	10.92	75
Loading & Unloading(Truck) activity	65.23	52.19	75



4.1.3.6 Water Environment

Total water requirement for the proposed unit is 132.4 KLD. Fresh water requirements (70.1KLD) will be met from TANSIDCO. Recycled water (62 KLD) will be used for cooling tower make up and Boiler and Greenbelt development.

a)Impact due to Waste Water Generation

The source of wastewater generation from the project is as follows:

- Pre treatment System, RO Electrode ionization
- Water for injectabe, Pure Stream generation
- Lab, Boiler and cooling water blow down
- Process Cleaning
- Sewage

The untreated wastewater if discharged into nearby surface water may affect the surface water and/or if disposed off on land without treatment may pollute the ground and surface water.

4.1.3.7 Land Environment

Present land use for industrial prurpose only, since the proposed project is located at TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State

a) Impact due to discharges on Land

Discharge of untreated sewage, effluent and solid waste will have adverse impact on the land. Poor garbage management would lead to unsanitary conditions including fly infestation and odors as well as unsightly conditions. Spillage of waste oil from the D.G sets and boilers may also have an impact on soil quality.

4.1.3.8 Biological Environment

There are no National Parks/ Wildlife sanctuaries within 15 km radius from the site.

The impact on terrestrial ecology will be due to emission of gaseous pollutants like PM, NOX, SO2. The gaseous pollutants at higher doses are injurious to vegetation. The release of effluent and sewage, dumping of solid and hazardous waste will also affect the ecology of the region.

4.1.3.9 Socio-Economic Environment

Various modes of indirect employment i.e. increased business opportunities will reflect in the improved quality of life of the people in the study area.

Thus, it can be said that the proposed project will have significant beneficial impact on the socio economic scenario in the study area.

4.1.4 Occupational Health and Safety

All safety and health codes prescribed by the Department of Factories and Boilers will be strictly implemented. All appropriate fire protection and safety measures will be provided for the staff. Personal protective equipment's will be provided for all working employees in the industry. Health records will be maintained regularly by the industries. Other safety aspects to be followed by member industries are:

- Occupational Health Surveillance shall be undertaken as regular exercise for all the employees
 especially for those engaged in handling hazardous substances.
- The medical records of each employee shall be maintained separately by the member industries. Pre-employment medical examination shall be conducted.
- All workers shall be medically tested once in a year and at the end of his term of employment.
- Noise levels at the critical areas will be monitored regularly and the workers at high noise generating areas will undergo audiometric tests once in six months.
- Various types of fire extinguishers (Foam type, water type) will be provided inside the factory premises.
- Proper earthing will be done for all the electrical equipments.
- Training will be provided to all the employees on safety and health aspects.
- Pre-employment and routine periodical medical examinations for all the employees shall be undertaken on regular basis.
- Maintaining Good Management Practices (GMP) and providing Personnel protective equipments to the all employees.

4.2 Measures for minimizing and / or offsetting adverse impacts identified

4.2.1 Mitigation Measures during Construction Phase

Mitigation is the implementation of measures designed to reduce the undesirable effects of a proposed project on the environment. As companies and individuals, we have an important role to play in protecting the environment, which is very sensitive to change and once damaged can take along time to recover.

The mitigation measures on Air, Noise, Water, Soil and Ecology of the surrounding environment due to the activities carried out during the construction phase are discussed below:

4.2.1.1 Loss of Vegetation

The numbers and types of vegetation to be introduced during the landscaping exercise are expected to be greater and more diverse and will be pleasing aesthetically.

4.2.1.2 Drainage Pattern

- Proper storm water drainage system is proposed for the project so that the runoff during monsoon is not concentrated. The storm water drainage system will be connected to rainwater harvesting pits.
- Rainwater harvesting prevents the flooding of low-lying areas in the project premises. Rain
 Water Harvesting system is proposed throughout the industry and the excess rain water will
 be diverted to the nearby water body within the site after proper treatment.

4.2.1.3 Material Transportation

- All the materials will be covered during transportation to the site to prevent spillage and dusting.
- Trucks used for transportation of materials will be fitted with tail gates that close properly and with tarpaulins to cover the materials.
- The cleanup of spilled earth and construction material on the main roads will be the responsibility of the contractor and will be done in a timely manner (say within 4-6 hours) so that there is no inconvenience or endanger to other road users.
- There will be no congestion of vehicles within or outside the site.

4.2.1.4 Ambient Air Quality

4.2.1.4.1 Mitigation Measures for Air Pollution

Site clearance, excavation and earthmoving

The working area by uprooting of shrubs or vegetation will be sprayed with water for dust suppression immediately before, during and immediately after the operation so as to reduce dust emissions.

Access road

Every main haul road will be paved with concrete, bituminous materials and kept clean by spraying water so as to reduce dust emissions.

Construction equipments

- All machineries to be used for construction purpose will be of highest standard of reputed make and compliance of noise pollution control norms by these equipments will be emphasized by company.
- Acoustic laggings and silencers will be used in equipments wherever possible.
- Feasibility of putting up acoustic enclosure / temporary barrier around areas with high noise levels will also be explored.
- Equipments will be periodically checked for pollutant emissions against stipulated norms

Use of vehicle

Any vehicle leaving a construction site carrying a load of dusty materials, will be covered
entirely by clean impervious sheet.

Stock Piles

- All loose material either stocked or transported will be provided with suitable covering such as tarpaulin, etc.
- Water sprinkling will be done at the location where dust generation is anticipated.

DG Set

• D.G. set will be placed in an acoustic enclosure.

4.2.1.4.2 Mitigation Measures for Materials Storage

- Low beams will be placed around the piles and/or tarpaulin will be used to cover open piles of stored materials to prevent them from being washed away during rain.
- Safe storage areas will be identified and retaining structures will be constructed prior to the arrival of material.
- Fuels will be properly stored in appropriate containers and these will be safely locked away.
 Conspicuous warning signs (e.g. 'No Smoking') will be posted around hazardous waste storage and handling facilities

4.2.1.5 Noise Environment

- Construction activities will be restricted to normal working hours.
- Workers operating at high noise areas will be provided with ear muffs and ear plugs.
- Construction activities will be restricted to the day time and no construction will be practiced during night.

4.2.1.6 Water Environment

- Excavation will be avoided during monsoon season.
- Sewage will be treated through packaged STP during construction phase and treated sewage will be used for green belt development during construction phase.
- To prevent surface and ground water contamination by oil/grease, leak proof containers will be used for storage and transportation of oil/grease.

4.2.1.7 Biological Environment

- The dust emissions will be suppressed by spraying water.
- Emissions from D.G sets and vehicles will be minimized by proper maintenance and by avoiding use of adulterant fuels and will be maintained within the standard limits prescribed by competent authority
- Emission from process will be sent to scrubber, after scrubbing it will be sent to stack with adequate height.

4.2.1.8 Construction Waste Disposal

A site waste management plan will be prepared by the contractor prior to commencement of
construction activities. This will include the designation of appropriate waste storage areas,
collection and removal schedule, identification of approved disposal site, and a system for

- supervision and monitoring. Preparation and implementation of the plan must be made the responsibility of the building contractor with the system being monitored independently.
- Most of the construction materials like soil, bricks, concrete will be reused in backfilling, road construction, sub-grade reparation works. Metals, wood scraps & bitumen junks will be recycled either within site or outside with help of the local authority. The measures like reusing materials on-site and /or donating /selling salvaged items reduces waste, virgin material use and disposal cost.
- Vegetation and combustible waste will not be burnt at site.
- Reusable inorganic waste (e.g. excavated sand) will be stockpiled away from drainage features and used for filling where necessary.

4.2.1.9 Land Environment

- Topsoil (soil on the top 15 cm patch) will be preserved separately in a stack covered by tarpaulin. Efforts will be made to reinstate the soil for backfilling purposes. Topsoil will be reused for horticultural areas.
- The spillage of oil from the machinery or cement residue from concrete mixer plants will be properly collected and disposed off.

4.2.1.10 Measures to Minimize Accidents

- Providing Personnel Protective gears like hardhats, eye protection, hearing protection and harnesses. Slip-resistant boots, heavy duty gloves and masks to the construction workers.
- Enforcing regular breaks to improve safety.
- Wires and high voltage areas should be marked and the electricity should be deactivated when it is not in use.
- Substitution of explosive materials as far as possible, good ground exploration and trained workers reduce the likelihood of explosions.
- Proper planning and supervision of the work, and effective inspection, maintenance and repair arrangements will reduce the risk of accidents due to machinery.

4.2.1.11 Health & Safety Measures during Construction Phase

- Construction related activities will be confined only to project site area, hence no health
 related impact are envisaged within the project influenced area during the construction stage
 and will be limited to occupant levels.
- At the project site much direct exposure to dust generation and high noise generation sources likely to cause occupant health related impact such as asthma, bronchitis and Noise Induced Hearing Loss (NIHL) etc. on the construction workers
- Periodic monitoring of health of construction phase workers will be carried out.

4.2.2 Mitigation measures during operation phase

4.2.2.1 Air Environment

- Stack height of 30 m is proposed for boiler.
- Stack height of 30 m is proposed for DG.
- There are no process emissions from the proposed manufacturing facility.
- Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.
- Ambient air quality monitoring will be carried out regularly at selected locations in order to
 check and compare the predicted concentrations with the measured concentrations. NAAQS
 exceedance if any may be checked thoroughly and adequacy/Performance of Air Pollution
 Control measures shall be reviewed.
- Adequate Greenbelt width will be provided.

4.2.2.2 Noise Environment

- The major noise generating equipment like Compressors, DG sets, Boiler Feed water pumps
 etc. will be enclosed in an acoustic enclosure designed for an insertion loss of 25 dB (A) and
 silencers to other equipment etc.
- Major noise generating equipment will be designed with 85 dB (A) ensuring cumulative noise at 1.0 m remains at 85 dB (A).
- The occupational noise exposure to the workers in the form of eight hourly times weighted average will be maintained well within the prescribed Occupational Safety and Health Administration (OSHA) standard limits.
- Acoustic silencers will be provided in equipment wherever necessary.
- Acoustic design with sound proof glass panelling will be provided for critical operator cabins control rooms of individual modules as well as central control facilities.
- Use of personal protective equipments/devices such as ear-muffs, ear plugs etc. will be strictly enforced for the workers engaged in high noise areas.
- 33.08% greenbelt will be developed within the industry.

Ambient noise levels will be monitored at regular intervals during operational phase of the project. Workplace monitoring will also be carried out at regular intervals to ensure that noise levels are well within the standards prescribed by the Factories Act.

4.2.2.3 Water Environment

Various mitigation measures are proposed to minimize the impact on the water environment due to the wastewater/runoff generation during the operation phase of the project.

- Treatment of sewage and effluent to ensure Zero Liquid Discharge and reusing treated effluent for utilities and treated sewage for gren belt development.
- Institutional arrangement for monitoring of treated sewageand treated effluent quality.

A.Sewage & effluent Treatment Plant

Construction Phase: Total Sewage generation will be 1.22 KLD. It will be treated through mobile Sewage Treatment Plant of 3 KLD and treated sewage will be reused for Green belt development within the plant.

Operation Phase: Total waste water generated will be segregated into Sewage and industrial effluent. Sewage generated of approx. 4.6 KLD will be treated through dedicated STP (6 KLD). Effluent generated from the Process, utilities & Pretreatment followed by RO systems. Effluent will be treated in proposed ETP capacity of 70 KLD and followed by RO and MEE, MEE concentrate will be sent to ATFD and Salt will be disposed to TSDF. RO permeate and MEE condensate will be reused for utilities and greenbelt. RO reject will be sent to Multiple Effect Evaporator. Salts generated from ATFD will be disposed to nearby TSDF. No disposal of wastewater outside and Zero Liquid Discharge (ZLD) concepts will be implemented

Details of STP and ETP with process flow diagram are given in Section 2.7.5 of chapter-2.

4.2.2.4 Land Environment

- Treated sewage from STP will be used for green belt development within the industry.
- ETP with ZLD scheme is proposed to treat the effluent and recycle for utilities.
- Municipal solid wastes will be segregated and organic waste will be disposed through TANSIDCO bins and inorganic waste will be send to TNPCB Authorized Recyclers.
- Hazardous wastes generated will be disposed as per Hazardous waste (Management, Handling and Transboundary movement) amendment Rules 2016.
- Good housekeeping and best practices of waste handling will be adopted to eliminate/minimize the risks of soil contamination.

4.5.4 Plastic waste management

According to the Tamil Nadu Government Order (Ms) No.84 Environment and Forests (EC.2) department dated 25.06.2018 regarding ban on one time use and throw away plastics irrespective of thickness with effect from 01.01.2019 under Environment (Protection) Act, 1986. Omexa will follow the mitigation/action plan given below:

Action Plan:

Omexa will complythe plastic waste with the following measures:

- Not to use/manufacture 'Single Use Plastic' within the premises.
- To support and promote use of eco alternatives.
- Create plastic free industrial campuses & canteens.
- To support the District Administration with CSR funds to stop plastic pollution.

Omexa will strict the use of plastic item except the few plastics used for the following purpose:-

- b) The plastic bags which constitute of form an integral part of packaging in which goods are sealed prior to use at manufacturing/processing units.
- c) Carry bags made from compostable plastics bearing a label "compostable" and conforming to the Indian Standard: IS or ISO 17088:2008 titled as specifications for "compostable plastics".

4.2.2.5 Biological Environment

- DGs will be provided with stack height of 30 m AGL.
- Boilers will be connected with stack height of 30 m AGL.
- STP is proposed for treating the sewage generated and treated sewage will be used for green belt development within the industry.
- Zero Liquid Discharge (ZLD) scheme is proposed to treat the effluent and recycle for utilities.
 Hence there will be no discharge of treated/ untreated wastewater outside the project premises.
- Municipal solid wastes will be segregated and organic waste will be disposed through TANSIDCO bins.
- Hazardous wastes generated will be disposed as per Hazardous waste (Management, Handling and Transboundary movement) amendment Rules 2016.
- Green belt of 5011.40 Sq.m which is 33.08 % is proposed for the project. Green belt will help in improving the asthetics of the site.

4.2.2.6 Greenbelt Development

The total land area is 15147.40 Sq.m (3.743 Acres). Greenbelt area is 5011.40 Sq.m (33.08%). The purpose of developing the greenbelt in and around the project site is for:

- Preventing land degradation and erosion of topsoil due to activities during construction phase.
- Containment and abatement of pollution in the industrial environment, capturing
 of fugitive emissions if any and thereby improving the quality of the surrounding
 environment.
- Substantially reducing the adverse environmental impacts due to the proposed industrial activity.
- Serving as a barrier for attenuating the intensity of noise generated.
- Enhancing the biodiversity index of the region.
- Adding aesthetic value to the project area.
- Maintaining the ecological equilibrium of the area.

The following general guidelines and measures will be adopted:

• The plantation of trees will be initiated during construction stage so that substantial growth may be achieved when the project is completed. The greenbelt

development programme will be drawn to conform to natural climatic conditions and adaptability of the species.

- Species involved in green belt development will be indigenous, fast growing and eco-friendly.
- Proper drainage system and proper plantation techniques will be adopted.
- Plantation will be properly maintained and protected by fencing from grazing and felling.

The plantations would consist of a mixture of carefully chosen locally available species of trees, shrubs and herbs, preferably evergreen and resistant to pollution.

Around 1503 numbers of tree (2mx2m spacing for each tress) will be planted (by considering 80% survival rate) in that around 50 trees was already planted. List of green belt species proposed is given in Table 4-25.

Table 4-25Tentative Proposed green belt Species

S.No	Scientific Name	Common Name	No of Trees	Yearwise
1	Pongamia pinnata	Pungai	300	1 st Year
2	Thespesia populnea	Poovarasu	300	2 nd Year
3	Albizis lebback	Vaagai	150	2 Year
4	Cassia fistula	Sarakondai	150	3 rd Year
5	Lagestroemia Speciosa	Poo marudhu	150	3 Year
6	Pterocarpus Marsupium	Vengai	150	
7	Aegle Marmelos	Vilvam	150	4 th Year
8	Madhuca longifolia	Iluppai	153	
	Total		1503	

(Note: The plant species proposed are based on the guidelines for developing green belt by CPCB-March 2000)

Photos of tree planting within the site are given in Figure 4-17. Layout plan showing green belt area is given in Figure 4-18 and Annexure-6.



Figure 4-17 Photo of tree planting within the site

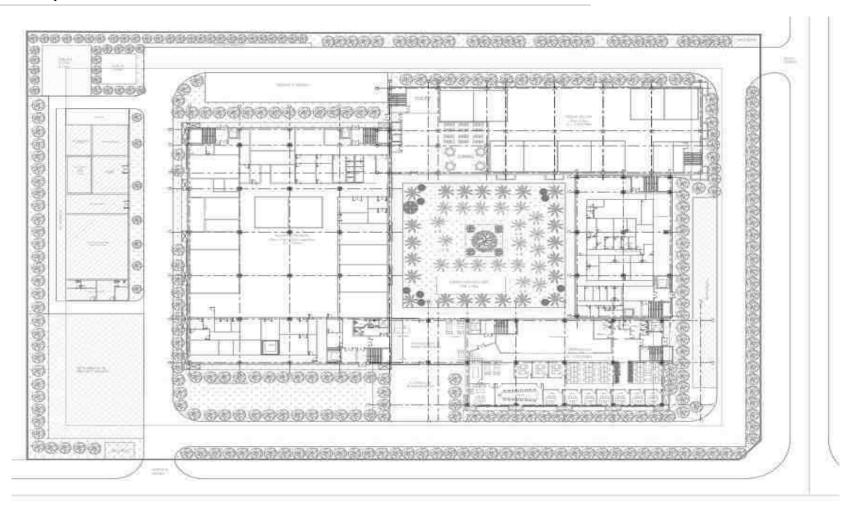


Figure 4-18 Greenbelt layout plan

4.3 Assessment of significance of impacts (Criteria for determining significance, Assigning significance)

4.3.1 Impact Assessment by Matrix Method

Water, Air and Land are the most vulnerable environmental attributes in serving the proposed industrial activities. Solid waste is another significant environmental issue from the proposed member industries. More discharges, discards and disposals can be listed to have significant impact on water, air and land environment.

A number of techniques are available for the assessment of impacts. Each of these techniques has their own advantages and disadvantages. The selection of any of these techniques for any particular project depends largely upon the choice of judgment of the analysis. The technique chosen should be comprehensive, easy to understand, systematic and flexible. Considering these criteria, for this project, the matrix method was used, with an impact scale of -4 to +4.

Impact identification and assessment of the site can be assessed by the matrix method, popularly known as Leopold matrix method, which is a universal tool for the EIA studies. The matrix used for the EIA consists of project activities on the x-axis and the environmental components likely to be affected by these activities on the y-axis. Each cell of the matrix represents a subjective evaluation of the impact of the particular components, in terms of magnitude importance. A blank cell indicates no impact of the activity on the component. The magnitude (m) is represented by a number from 1-4 where,

- 1= Minimal
- 2= Appreciable
- 3= Significant
- 4= Severe

A positive sign indicates a beneficial impact and the negative sign indicates an adverse impact. The impact classification is given below:

Table 4-26Overall impact classification

S.No	Project impact scale	Magnitude of impact
1	-100 to -75	Severely adverse
2	7-75 to -50	Significantly adverse
3	-50 to -25	Appreciably adverse
4	-25 to 0	Low Adverse Impact
5	0 to 25	Minimally beneficial
6	25 to 50	Appreciably beneficial
7	50 to 75	Significantly beneficial
8	75 to 100	Highly beneficial



Impact Scenarios

Impact score for the project was calculated for two scenarios using the matrix method described above. Matrices were prepared to represent each of these scenarios namely

- Project without EMP
- Project with EMP

Table 4-27Impact scoring system

Impact Matrix								
Insignificant impact	Minor impact	Moderate impact	Major impact					
(+/-1)	(+/-2)	(+/-3)	(+/-4)					
Temporary and very	Minor and short term	Moderate and medium	Significant long term					
short term		term						

Project without EMP

In this scenario, the proposed project is considered without proposing Environmental Management plan. The magnitude of the environmental components likely to be affected with the values for importance is tabulated in **Table 4-28**.



Table 4-28 Project scenario without EMP

					Operatio	n phase				
S.No	Environmental components likely to be affected		Transportation of men & materials	Emissions from Manufacturing process	Water requirement	Waste disposal (solid & liquid)	Chemical / solvent storage	Storage, handling and transporation of final poducts	Impact Score	Remarks
1	A in quality	Magnitude	-3	-3	-1	-2	-2	-2	-40	Appreciabily adverse
1	Air quality	Importance	3	4	3	2	3	3	-40	Appreciating adverse
2	Noise	Magnitude	-3	-3	-1	0	0	-2	-27	Appreciabily adverse
2	Noise	Importance	3	3	3	2	0	3	-27	Appreciabily adverse
3	Surface water quality	Magnitude	-1	-1	-3	-4	-2	-2	-35	Appreciabily adverse
3	Surface water quanty	Importance	1	1	3	4	2	2		Appreciabily adverse
4	Ground water quality	Magnitude	0	1	-1	-4	-1	-1	-18	Low adverse impact
-	Ground water quanty	Importance	0	3	2	4	1	2	-10	
5	Soil quality	Magnitude	-2	-2	0	-4	-2	-1	-29	Appreciabily adverse
	Son quanty	Importance	2	2	0	4	2	1	-29	Appreciaony adverse
6	Flora & fauna	Magnitude	0	-2	-1	-4	-1	-1	-23	Low adverse impact
0	1 Tota & Tauria	Importance	0	2	1	4	1	1	-23	Low adverse impact
7	Land use pattern	Magnitude	0	0	0	-1	0	0	-1	Low adverse impact
'	Land use pattern	Importance	0	0	0	1	0	0	-1	Low adverse impact
8	Socio economics	Magnitude	2	-2	-1	-3	-2	0	-14	Low adverse impact
0	Socio economies	Importance	2	2	1	3	2	0	-14	Low adverse impact

The overall impact was found to be -23.375 which is low adverseImpact

Project Scenario with EMP

In this scenario, the proposed development is considered with all the Environmental Management plans. The magnitude of the environmental components likely to be affected with the values for importance is tabulated in Table 4-29.

Table 4-29 Project scenario with EMP

						Operation phas	e				
S.No	Environmental comp affec		Transportation of men & materials	Emissions from Manufacturing process	Water requirement	Waste disposal (solid & liquid)	Chemical / solvent storage	Storage , handling and transporation of final poducts	Impact on the components	Remarks	
1	Air quality	Magnitude	1	-1	0	1	-1	-1	-5	Low Adverse Impact	
1	An quanty	Importance	3	4	3	2	3	3] -3	Low reverse impact	
2	Noise	Magnitude	-1	-1	0	-1	-1	-1	-11	Low Adverse Impact	
2	INUISC	Importance	3	3	3	2	0	3	-11	Low Adverse impact	



2	Surface water quality	Magnitude	1	1	-1	1	1	1	7	Minimally beneficial
3	Surface water quality	Importance	1	1	3	4	2	2		
4	Ground water quality	Magnitude	1	1	-1	1	1	1	Q	Minimally beneficial
4	Ground water quanty	Importance	0	3	2	4	1	2	o	
5	Soil quality	Magnitude	1	1	1	1	1	1	11	Minimally beneficial
3	Soil quality	Importance	2	2	0	4	2	1	11	
6	Flora & fauna	Magnitude	1	1	1	1	1	1	0	Minimally beneficial
	Fiora & faulta	Importance	0	2	1	4	1	1	7	
7	Land use pattern	Magnitude	1	1	1	1	1	0	1	Minimally beneficial
/	Land use pattern	Importance	0	0	0	1	0	0	1	
8	Socio economics	Magnitude	3	-1	-1	1	-1	0	4	Minimally beneficial
8	Socio economics	Importance	2	2	1	3	2	0		

The impact was found to be 24 which is Minimally beneficial.



4.4 Decommissioning Stage

Since it is a Greenfield project, decommissioning stage is not envisaged.

4.5 Irreversible and Irretrievable commitments of environmental components

Irreversible commitments of resources are those which cause either direct or indirect use of natural resources such that the resources cannot be restored or returned to their original condition.

An irreversible or irretrievable commitment of environmental components refers to impacts due to proposed project activities on various environmental components that cannot be recovered or reversed

Material and energy resources committed for the unit would include construction materials (e.g., steel, concrete) and fuels (e.g., HSD). All energy used during construction and operation would be irreversible and irretrievable

For proposed project, construction activity will be carried out. Due to construction activity, there shall be loss of existing plants and soil characteristics. Care shall be taken that new construction will take where no plants exist or if required for that area then same plants will be replanted at another suitable area. Before construction, top soil consist of plant will be stored at identified place and same will be utilized as a top layer at another plantation area. This will result in loss of habitat for some time till construction over.

There is no ground water extraction for the proposed project. So there is no an irreversible and irretrievable commitment.

During transportation & utility operation, fossil fuels like Diesel will be consumed which is irretrievable but can be minimized by adopting sophisticated technology.



CHAPTER – 5 ANALYSIS OF ALTERNATIVES

5 ANALYSIS OF ALTERNATIVES

5.1 Justification for Project Site Selection

Project site is located at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. Site has been selected due to the following advantages:

- 1. It is allocated within Notified TANSIDCO Industrial Park.
- 2. Proximity to roads (~0.37 km, S), railways (~4.31 Km, ESE).
- 3. Sufficient land is available within the TANSIDCO.
- 4. 100% assurance of water & power supply by TANSIDCO.

The following table provides the site selection criteria for the project.

Table 5-1Environment analysis for alternate sites for proposed project

S. No	Environmental Attributes	TANSIDCO Industrial park	Alternate Site
1	Land Availability	Limited	
2	Road Access	Available	1
3	Soil Conditions	Sandy Clay loam	
4	Ecological Sensitivity	Nil	
5	Land use classification	Industrial Zone	Not Envisaged
6	Interference with fresh water sources	Nil	
7	R& R Requirements	Nil	
8	Project Timeline	Optimum	
9	Economics	Less/More	

The following table the arbitrary value of importance for site selection.

Table 5-2Site Selection Criteria- Arbitrary Value of Importance

S. No.	Selection Criteria	Value of Importance
1	Land Availability	200
2	Road Access	100
3	Soil Conditions	100
4	Ecological Sensitivity	200
5	Land use classification	100
6	Interference with fresh water sources	100
7	R& R Requirements	100
8	Project Timeline	50
9	Economics	50
	Net Score	1000

Table 5-3Site selection based on arbitrary value

S.		Value of	TANGINGO I I 4 1 1	Alternate
No	Selection Criteria	Importance	TANSIDCO Industrial park	Site
1	Land Availability	200	200	
2	Road Access	100	100	
3	Soil Conditions	100	50	
4	Ecological Sensitivity	200	150	
5	Land use classification	100	100	Not
6	Interference with fresh water	100	50	Envisaged
	sources			
7	R& R Requirements	100	100	
8	Project Timeline	50	50	
9	Economics	50	50	
	Net Score	1000	850	0
	Choice Ranking		I	

Site with a score of 850 is selected for development of the facility.

5.2 Site Connectivity

The project site is located at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State and the connectivity is given in **Table5-4**.

Table 5-4 Connectivity of the Site

Naamby Highyyaya	NH-77 (Tindivanam-Krishnagiri)/ NH179B (Chennai-Tindivanam-							
Nearby Highways	Harur)~0.37 km (S)							
Nearest railway	Normal Dellarge Challery Timberson (121 law (ECF)							
Station	Nearest Railway Station - Tindivanam ~4.31 km (ESE)							
Nearby Airports	Puducherry Airport ~37.48 km (SSE)							
Nearest Town	Tindivanam(Pop~72,796) ~2 km (ESE)							

Connectivity to the project site and availability of all the required infrastructures, in the TANSIDCO industrial area and the location being an industrial area are the major advantages for the project.

5.3 Fuel Alternatives

HSD will be used as fuel for Utility. Alternate fuel for the Boiler may be PNG at present it is not available there. If we get ahead in time, we will use PNG.

5.4 Water Supply Alternatives

The entire water requirement is to be met by TANSIDCO. So, any alternative source of water is not considered.

5.5 Technology Alternatives

For the proposed products, currently we are implementing the Single Use technology, which will reduce the 70% of water consumption compared to the other Stainless steel technology; unit will adopt the latest and best technology available so far in the market. Moreover, the unit is very concerned and conscious about the product quality and equally about the environmental protection and resource conservation. The company will upgrade the technology as per requirement from time to time with the best as per the requirement.

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CHAPTER – 6 ENVIRONMENTAL MONITORING PROGRAM

6 ENVIRONMENTAL MONITORING PROGRAM

6.1 Introduction

The primary aim of environmental monitoring program is to formulate a systematic, site-specific plan for monitoring the environmental parameters within the impact area, during and after commissioning of the project, which would aid in assessing the effectiveness of mitigation and environmental protection measures implemented for the proposed project based on the existing environmental scenario and probable environmental impacts appraisal.

The plan framed for the intended facility will describe:

- The details of the proposed mitigation measures taken for safeguarding the environment at the project site as well as in the vicinity of the industrial site.
- Details of management plans (Greenbelt development plan, Solid waste management plan etc)
- Post project environmental monitoring programme to be undertaken after commissioning of the project.
- The associated cost components of the pollution control systems installed at the site.

For each of the environmental attributes, the monitoring plan specifies the parameters to be monitored, location of monitoring sites, frequency and duration of monitoring and it also denotes the applicable standards, implementation and supervising responsibilities.

6.1.1 Objectives

- Ensure day to day operational activities will beconducted in a manner in compliance with the applicable regulatory approvals including legislation and industry standards.
- Evaluate the adequacy of mitigation and pollution control measures implemented for reducing
 the adverse impacts caused during the construction and operation stage and suggest additional
 mitigation measures, if appropriate, in the light of the results.
- Define a detailed framework to monitor and document for achieving full compliance with statutory requirements.
- Encourage good environmental management practices through planning, commitment and continuous improvement.
- Develop clearly defined environmental monitoring program designed to assess the nature and extent of environmental impacts of the proposed operations and progressively refine such programs against the targets
- Define roles and responsibilities of site personnel and ensure that all people onsite are fully informed of their responsibilities and accountabilities with regard to the environment.

- To comply with all regulations stipulated by the Central Pollution Control Board (CPCB)/
 State Pollution Control Board (SPCB) related to air emission and liquid effluent discharge as
 per air and water pollution control act/ laws.
- To handle hazardous wastes as per the Hazardous Waste (Management & Handling) Rules
 1989and Hazardous and Other Wastes (Management and Transboundary Movement) Rules,
 2016 and subsequent amendments.
- Review, improve and update environmental management procedures and standards.
- Establish response procedures for actual/potential environmental impacts including community complaints and ensure corrective action is taken.
- Perspective budgeting and allocation of funds for environmental management expenditure,
 Continuous development and search for innovative technologies for a cleaner and better environment.

6.2 Environmental Monitoring Programme

It is imperative that the Project Authorities set up regular monitoring stations to assess the quality of environment during construction phase and after commissioning of the project. An environmental monitoring programme is important as it provides useful information and helps to:

Verify the predictions on environmental impacts presented in this study assist in detecting the development of any unwanted environmental situation, and thus, provides opportunities for adopting appropriate control measures, and identify the effectiveness of mitigative measures suggested in the EMP.

6.2.1 Environmental Monitoring Program – Construction Phase

During construction to assess the environmental parameters, monitoring will be carried out which include Ambient Air Quality, noise, water and soil quality of site and surrounding areas. Monitoring programme including areas, number and location of monitoring stations, frequency of sampling and parameters to be covered is summarized in **Table 6-1**.

Table 6-1 Environmental Monitoring Programme- Construction Phase

S.No	Item	Parameters	Frequency
1	Ambient air quality	All the parameters as per NAAQ Standards	Once in three months
2	Noise level	Equivalent Noise levels	Once in three months
3	Ground water	Physical, chemical and bacteriological	Once in three months
4	Surface water	Physical, chemical and bacteriological	Once in three months
5	Soil	General parameters	Once in three months

6.2.2 Environmental Monitoring Program – Operation Phase

After commissioning of the project, post project monitoring of environmental parameters will be carried out at regular intervals. The monitoring programme in different areas of the environment has been based on the findings of the impact assessment studies. The post project monitoring programme including areas, number and location of monitoring stations, frequency of sampling and parameters to be covered is summarized in **Table 6-2**.

Table 6-2 Environmental Monitoring Programme - Opertion Phase

S.	Area of	Number of	Frequency of	
No			Sampling	Parameters to be Analyzed
1.	Micro Meteorology	One	Hourly and Daily basis.	Wind speed and direction, Temperature, Relative Humidity, Atmospheric pressure, Rainfall.
2.	Ambient Air Quality	2 Stations (one in up wind and one in down wind)	Once in a year as per CTO condition through NABL labs	All the 12 parameters as per NAAQ Standards and Hydrocarbons
3.	Noise	2 (one within plant premises and one outside plant premises)	Once in 6 months through NABL labs	Ambient Equivalent continuous Sound Pressure Levels (Leq) at day and Night time.
4.	Water	One surface and ground water sample near the site	Once in 6 months through NABL labs	All the parameters as per IS 10500:2012
5.	Soil	2 (one within plant premises and one outside plant premises)	Once in 6 months through NABL labs	Physicochemical properties, Nutrients and Heavy metals
	Liquid	Effluent inlet and outlet	Once in 6 months through NABL labs	pH, Temp, Conductivity, Oil and Grease, TSS, TDS, BOD.
6.	Effluents	STP inlet and outlet	Once in 6 months through NABL labs	pH, TSS, BOD & COD
7.	Boiler & DG set	Stack of Boiler & DG sets	Once in 6 months through NABL labs	PM, SO ₂ , NO _x & CO

6.2.3 Submission of Compliance Reports

As a part of environmental monitoring programme, following compliance report will be submitted to TNPCB and Regional Office of MoEF&CC.

 Half yearly compliance reports of Environmental Clearance terms and conditions on 1stJune and 1stDecember every calendar year

- Environmental statement (Form-V) for the financial year ending March 31 to TNPCB on or before September 30 every year.
- Format for maintaining records of hazardous waste in Form-3 as per Hazardous and other Wastes (Management and Handling and Transboundary movement) Rules, 2008.
- Safety data sheet for hazardous chemicals will be maintained as per schedule-9 of MSIHC rules, 1989 (amended 2000),
- Format for maintaining notification of major accident in schedule-6 as per MISHC rules, 1989 (amended 2000).

6.2.4 Emergency Procedures

On-site Mock Drills Requirements

On-site mock drills are very important as it helps employees to be aware of the safety procedures and how to react during the time of crisis. Conducting mock drills at regular intervals will enhances preparedness and checks the viability of environmental/disaster management plan. Mock drills are essential for the following reasons:

- Helps in revising/improving the environmental/disaster management plan
- Helps to evaluate whether the responsible officials are trained efficiently for the unforeseen event
- Helps in evaluating whether the emergency equipment are being maintained at premises

To ensure efficient environmental/disaster management, EHS department/EMP cell shall conduct periodic on-site mock drills in case of occurrence of the following activities:

- Fire, Natural calamities (cyclones, floods, earthquakes)
- Power break down
- Bomb threats; War alerts/terrorist attacks

Mock drills should also involve fire department, police, municipal authorities, hospitals and other department/agencies that are mandated to provide emergency support. Documenting the outcome of mock drills is an important aspect as this helps in enchancing the proposed plans more efficiently. In all safety programmes the right personnel need to be employed and this is of utmost importance.

6.2.5 Budget for Environmental Monitoring

Quarterly environmental monitoring for the project will be outsourced to NABL accredited laboratories. Budget for Environmental monitoring is given in **Tables 6-3** & **Table 6-4**.

Table 6-3 Budget for Environmental monitoring – construction phase

S. No	Area of Monitoring	Number of Sampling Stations	Frequency of Sampling	Rate per sample (INR)	Total cost / year (INR)
1	Ambient Air Quality	Three stations (one at site, one in	Quarterly	2,500	30,000

S. No	Area of Monitoring	Number of Sampling Stations	Frequency of Sampling	Rate per sample (INR)	Total cost / year (INR)
		upwind direction and one in down wind direction)			
2	Noise	Three locations at site in different places	Quarterly	500	6,000
3	Water	Two number of surface and ground water samples near the site.	Quarterly	2,500	40,000
4	Soil	Three locations within the site	Quarterly	3,000	36,000
		Total	8,500	112,000	

Table 6-4 Budget for Environmental monitoring – Operation phase

S. No.	Area of Monitoring	Number of Sampling Stations	Frequency of Sampling	Rate per sample (INR)	Total cost / year (INR)
1	Meteorology	Onsite Meteorological station	Hourly on daily basis	3000	36000
2	Ambient Air Quality	2 Stations (one in up wind and one in down wind)	Half yearly	12000	48000
3	Stacks of DGs& Boiler	2 stacks (2 DGs)& 1 Stack (Boiler)		4000	24000
4	Noise	2 (one within plant premises and one outside plant premises)	Half yearly	200	2400
5	Wet scrubbers	1 No	Half yearly	8000	16000
6	Water	One surface and ground water sample near the site	Half yearly	2000	8000
7	STP	Inlet and outlet	Half yearly	4000	16000
8	ETP	Inlet and outlet	Half yearly	12000	48000
9	Soil	2 (one within plant premises and one outside plant premises)	Half yearly	12000	48000
		Total		57,200	2,46,400

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7 ADDITIONAL STUDIES

7.1 Public Hearing

As per issued ToR vide File No:10894, dated: 29.06.2024. Draft EIA report has been prepared and submitted for Public Hearing (PH). After completion of Public Hearing, the Final EIA report along with action plan for commitment by the proponent will be submitted to TNSEIAA for further appraisal of the project and obtaining Environmental Clearance.

7.2 Rehabilitation and Resettlement

There is no R & R Since the site is coming with TANSIDCO Industrial Park premises.

7.3 Risk Assessment

7.3.1 Introduction

Risk assessment is an indispensable part of Process Safety Management (PSM). PSM must be invariably invoked when involved in handling, using, storing, moving, or manufacturing of highly hazardous chemicals. The M/s.Omexa Formulary Pvt Ltd is planning to manufacture of bulk drugs & intermediates & formulation products, handles some solvents which pose health and flammability hazard. Thus, the risk associated with production facility was assessed and to be elaborated in this report. The Risk Assessment study has been performed as dictated by the IS15656:2006 "HAZARD IDENTIFICATION AND RISK ANALYSIS - CODE OF PRACTICE" to give crucial insights on the hazards involved in the facility line of production.

Based on the available studies & plant layout, the potential scenarios which can cause significant consequences like Dispersion of Vapour cloud, fire and explosion scenarios were identified.

- The purpose of the study includes the following:
- > To identify those hazards that pose health and flammability risks as per NFPA rating.
- > To eliminate or reduce to as Low as Reasonably Practicable (ALARP) the risk to human health, risk of injury, risk of damage to plant, equipment and environment, business interruption or loss etc.
- > To Suggest On-site Mitigation Measures.

7.3.2 Scope of the Study

Hazard Identification and Risk Analysis including identification, screening of scenarios, consequence analysis of the various risk scenarios, recommendation and preparation of reports and relevant drawing showing damage and risk contours.

The scope of the study mainly involves:

- > Identifications of Hazards
- > Consequence modeling of:

- ✓ Dispersion of Vapour cloud
- ✓ Flash fire
- ✓ Pool fire
- ✓ Jet fire
- ➤ Impact limits identifications
- > Contour mapping of the risk on the layouts.
- Mitigating measures for handling and storage to reduce impacts & prevent incidents.

7.3.3 Risk Assessment Methodology

7.3.3.1 Identification of Hazards & Release Scenarios

A technique commonly used to generate an incident list is to consider potential leaks and ruptures of all process pipelines and vessels/tanks. The following data were collected to envisage scenarios:

- > Type of chemicals/ Solvents used.
- Capacity of the Solvent storage and process.
- Atmospheric conditions viz. Temperature, Humidity and Wind direction

7.3.3.2 Selection

The goal of selection is to limit the total number of incident outcome cases to be studied to a manageable size. The purpose of incident outcome selection is to develop a set of incident outcomes that must be studied for each incident included in the finalized incident study list. Each incident needs to be considered separately. Using the list of incident outcomes, the risk analyst needs to determine which may result from each incident. While the analyst can decide whether an incident involving the loss of a process chemical to the atmosphere needs to be examined using dispersion analysis because of potential toxic gas effects, what happens if the same material is immediately ignited on release.

7.3.3.3 Characterizing the Failures

Accidental release of flammable or toxic vapours can result in severe consequences. Delayed ignition of flammable vapours can result in blast overpressures covering Large areas. This may lead to extensive loss of life and property. Toxic clouds may cover yet Larger distances due to the lower threshold values in relation to those in case of explosive clouds (the lower explosive limits). In contrast, fires have localized consequences. Fires can be put out or contained in most cases; there are few mitigating actions one can take once a vapour cloud gets released. Major accident hazards arise, therefore, consequent upon the release of flammable or toxic vapours or BLEVE in case of pressurized liquefied gases. In an industry, main hazard arises due to storage and handling of hazardous chemicals. To formulate a structured approach to identification of hazards and understanding of contributory factors is essential.

7.3.3.4 Inventory

Inventory Analysis is commonly used in understanding the relative hazards and short listing of release scenarios. Inventory plays an important role in regard to the potential hazard. A practice commonly used to generate an incident list is to consider potential leaks and major releases from fractures of pipelines and vessels containing sizable inventories.

The potential vapour release (source strength) depends upon the quantity of liquid release, the properties of the materials and the operating conditions (pressure, temperature). If all these influencing parameters are combined into a matrix and vapour source strength computed for each release case, a ranking should become a credible exercise.

7.3.3.5 Loss of Containment

Liquid Release may be instantaneous. Failure of a vessel leading to an instantaneous outflow assumes the sudden appearance of such a major crack that practically all of the contents above the crack shall be released in a very short time. The more likely event is the case of liquid release from a hole in a pipe connected to the vessel. The flow rate will depend on the size of the hole as well as on the pressure head in the line, prior to the accident. Such pressure is basically dependent on the pressure in the vessel. The vaporization of released liquid depends on the Vapour pressure and weather conditions. Such consideration and others have been kept in mind both during the initial listing as well as during the shortlisting procedure. Initial listing of all significant inventories in the process plants was carried out. This ensured no emission through inadvertence.

7.3.3.6 Factors Considered for Identification of Hazards

In any installation, main hazard arises due to loss of containment during handling of flammable and toxic chemicals. The Chemicals are classified according to the properties and hazard class given by National Fire Protection Association (NFPA) is responsible for 380 codes and standards that are designed to minimize the risk and effects of fire by establishing criteria for building, processing, design, service and installation.

NFPA classification (**Table 7-1**) for Health, Flammability & Reactivity of a chemical is on a scale from 0-4 least to worst. As per the NFPA Rating on the scale from 0-4 the chemicals having 3&4 are considered are highly hazardous and considered for analysis.

Table7-1- NFPA Classification

Rating	Health	Fire
0	No hazard	will not burn
1	Can cause significant irritation	must be preheated before ignition occur
2	Can cause temporary incapacitation or residual injury	must be heated or high ambient temperature to burn
3	Can cause serious or permanent injury	can be ignited under almost all ambient
4	Can be lethal	will vaporize and readily burn at normal temperature

NFPA provides standard for the chemicals to reduce the risk of fire and other hazards. The chemicals handled by the facility, that pose health and fire hazards as identified by their NFPA ratings, are mentioned in **Table 7-2**.

Table7-2-NFPA Ratings

	Raw Materials/	D :: 1(0C)	Flash		NFI	PARating
S. No	Products	Boiling Point(°C)	point(°C)	Health	Fire	Reactivity
1	Sodium Hydroxide	>130	-	3	0	1
2	Ethanol	78.3	14	0	3	0
3	Hydrochloric acid	50.5	-	3	0	0

7.3.3.7 Types of Outcome Events

In this section of the report we describe the probabilities associated with the sequence of occurrences which must take place for the incident scenarios to produce hazardous effects and the modeling of their effects.

Considering the present case, the outcomes expected are

- ➤ Jet fire
- > Flash Fire
- Vapour Cloud
- ➤ Pool Fire

a) Jet Fire

Jet fire occurs when a pressurized release (of a flammable gas or vapour) is ignited by any source. They tend to be localized in effect and are mainly of concern in establishing the potential for domino effects and employee safety zones rather than for community risks.

b)Flash Fire

A flash fire is the non-explosive combustion of a vapour cloud resulting from a release of flammable material into the open air, which after mixing with air, ignites. A flash fire results from the ignition of a released flammable cloud in which there is essentially no increase in combustion rate. The ignition source could be electric spark, a hot surface, and friction between moving parts of a machine or an open fire. Part of the reason for flash fires is that, flammable fuels have a vapour temperature, which is less than the ambient Temperature. Hence, as a result of a spill, they are dispersed initially by the negative buoyancy of cold vapours and subsequently by the atmospheric turbulence. After the release and dispersion of the flammable fuel the resulting vapour cloud is ignited and when the fuel vapour is not mixed with sufficient air prior to ignition, it results in diffusion fire burning. Therefore, the rate at

which the fuel vapour and air are mixed together during combustion determines the rate of burning in the flash fire.

The main dangers of flash fires are radiation and direct flame contact. The size of the flammable cloud determines the area of possible direct flame contact effects. Radiation effects on a target depend on several factors including its distance from the flames, flame height, flame emissive power, local atmospheric transitivity and cloud size.

c) Vapour Cloud

Vapour cloud is the result of flammable materials in the atmosphere, a subsequent dispersion phase, and after some delay an ignition of the vapour cloud. Turbulence is the governing factor in blast generation, which could intensify combustion to the level that will result in an explosion. Obstacles in the path of vapour cloud or when the cloud finds a confined area, as under the bullets, often create turbulence. Insignificant level of confinement will result in a flash fire. The vapour cloud will result in over pressures. It may be noted that vapour cloud has been responsible for very serious accidents involving severe property damage and loss of lives.

d)Pool Fire

This represents a situation when flammable liquid spillage forms a pool over a liquid or solid surface and gets ignited. Flammable liquids can be involved in pool fires where they are stored and transported in bulk quantities. Early pool fire was caused when the steady state is reached between the outflow of flammable material from the container and complete combustion of the flammable material when the ignition source is available. Late pool fires are associated with the difference between the release of material and the complete combustion of the material simultaneously. Late pool fires are common when Large quantity of flammable material is released within short time.

e)Heat Radiation

The effect of fire on a human being is in the form of burns. There are three categories of burn such as first degree, second degree and third degree burns. The consequences caused by exposure to heat radiation are a function of:

The radiation energy onto the human body [kW/m²];

- ➤ The exposure duration [sec];
- The protection of the skin tissue (clothed or naked body).

The limits for 1% of the exposed people to be killed due to heat radiation, and for second-degree burns are given in **Table 7-3**

Table 7-3 Damages To Human Life Due To Heat Radiation

Exposure Duration (sec)	Radiation energy (1% lethality, kW/m²)	Radiation energy for 2nd degree burns, kW/m ²	Radiation energy for first degree burns, kW/m ²
10	21.2	16	12.5
30	9.3	7	4

Table 7-4 Effects Due To Incident Radiation Intensity

Radiation Intensity (kW/m²)	TYPE OF DAMAGE
0.7	Equivalent to Solar Radiation
1.6	No discomfort for long exposure
4	Sufficient to cause pain within 20 sec. Blistering of skin (first degree burns are likely)
9.5	Pain threshold reached after 8 sec. second degree burns after 20 sec.
12.5	Minimum energy required for piloted ignition of wood, melting plastic tubing's etc.
37.5	Heavy Damage to process equipment

7.3.3.8 Type of Damage

The actual results would be less severe due to the various assumptions made in the models arising out of the flame geometry, emissivity, angle of incidence, view factor and others. The radiation output of the flame would be dependent upon the fire size, extent of mixing with air and the flame temperature. Some fraction of the radiation is absorbed by carbon dioxide and water vapour in the intervening atmosphere. Finally, the incident flux at an observer location would depend upon the radiation view factor, which is a function of the distance from the flame surface, the observer's orientation and the flame geometry.

a) Consequence analysis

Table 7-5 Consequence analysis table

	Table 7-5 Consequence analysis table													
s	СНЕ	SCENAR IO		VAPOUR CLOUD DISPERSION		JET FIRE		LATE POOL FIRE			FLASH FIRE			
N o	MIC ALS		WEATHER	UFL	LFL	1/2 LFL	4 KW /m2	12.5 KW/ m2	37.5 KW /m2	4 KW/ m2	12.5 KW/m 2	37.5 KW/ m2	LFL	1/2 LFL
		Catastro phic rupture	Category 1.5/F	5.368	5.369	5.369	NA	NA	NA	71.17	85.63	52.54	5.369	5.369
			Category 5/D	4.735	4.735	4.735	NA	NA	NA	71.2	91.17	53.49	4.735	4.735
1	HSD		Category 1.5/D	5.401	5.447	5.45	NA	NA	NA	71.2	85.55	52.47	5.447	5.45
1	HSB	Small Leak	Category 1.5/F	NA	NA	NA	NA	NA	NA	7.424	24.02	14.83	NA	NA
			Category 5/D	NA	NA	NA	NA	NA	NA	7.415	25.66	17.65	NA	NA
			Category 1.5/D	NA	NA	NA	NA	NA	NA	7.427	24.08	14.89	NA	NA

Medium	Category 1.5/F	NA	NA	NA	NA	NA	NA	14.85	33.05	19.07	NA	NA
Leak	Category 5/D	NA	NA	NA	NA	NA	NA	14.83	34.9	22.07	NA	NA
	Category 1.5/D	NA	NA	NA	NA	NA	NA	14.86	33.07	19.1	NA	NA
Large	Category 1.5/F	NA	NA	NA	NA	NA	NA	22.28	39.22	22.83	NA	NA
Leak	Category 5/D	NA	NA	NA	NA	NA	NA	22.26	41.39	23.5	NA	NA
	Category 1.5/D	NA	NA	NA	NA	NA	NA	22.27	39.23	22.85	NA	NA

b) Summary and conclusions

Summary - vapour cloud dispersion - worst case scenario

For HSD, LFL Fraction received at maximum distance due to Vapour CloudDispersion in Catastrophic Rupture scenario is 5.45 m at 1.5m/s wind speed andstabilityclassesD. The contours of vapour cloud dispersion slightly exceeds the site boundary.

Summary - late pool fire - worst case scenario

For HSD, Radiation profile (12.5 kW/m²) received at maximum distance due to Late PoolFire in Catastrophic Rupture scenario is 91.17 m at 5m/s wind speedandstability classes D. The contours for late pool fire exceeds the site boundary.

Summary - flash fire - worst case scenario

For HSD, Radiation profile LFL fraction received at maximum distance due to Flash Fire in Catastrophic Rupture scenario is 5.45 m at 1.5m/s wind speed and stability classes D. The contours fall inside the site boundary.

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c)Contours for all worst case scenarios

a) Contours for vapour cloud dispersion

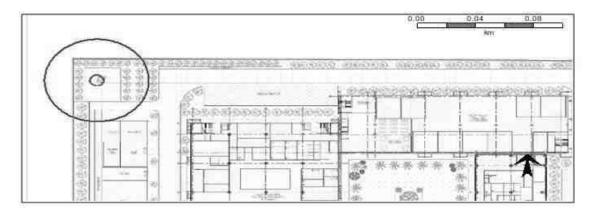


Figure 7-1 HSD-catastrophic rupture-vapour cloud dispersion- project layout

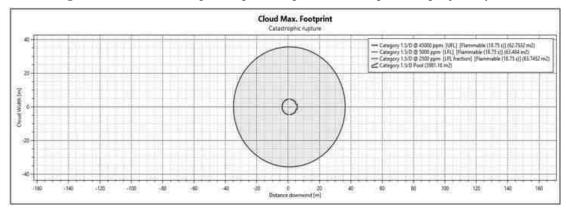


Figure 7-2HSD -catastrophic rupture-vapour cloud dispersion- graphical representation

b) Contours for late pool fire

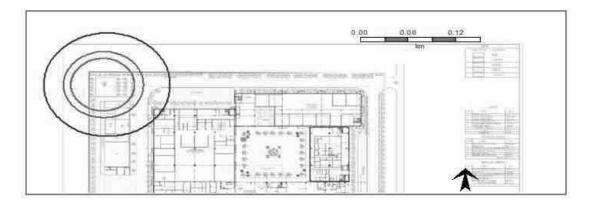


Figure 7-3HSD -catastrophic rupture-late pool fire - Project layout

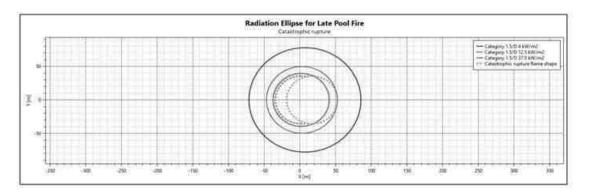


Figure 7-4HSD -catastrophic rupture-late pool fire - graphical representation

c) Contours for flash fire

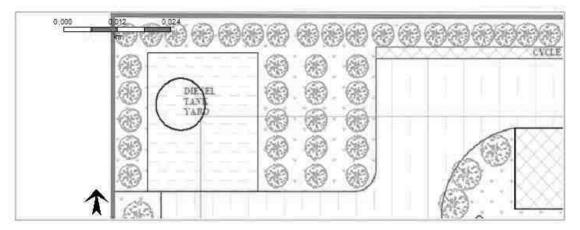


Figure 7-5 HSD -catastrophic rupture-flash fire - project layout

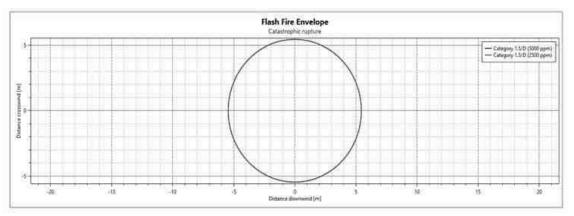


Figure 7-6 HSD -catastrophic rupture- flash fire - graphical representation

7.3.3.9 Mitigation measures and Recommendations for improving safety

The following measures be considered for enhancing the safety standards at site:

- Install advanced HVAC systems to control vapour concentrations and maintain air quality, especially in indoor processing and storage areas. Ensure regular maintenance and monitoring of these systems to prevent buildup of explosive or harmful atmospheres.
- Use explosion-proof equipment and electrical systems in areas where flammable solvents or chemicals are stored and processed. Regularly inspect and maintain these systems to ensure compliance with safety standards.
- Store all chemicals in tightly sealed containers or tanks made of non-reactive materials such as stainless steel or high-grade glass. Implement secondary containment measures to prevent leaks and spills.
- Keep storage areas well-ventilated, cool, and away from sources of ignition, heat, or incompatible substances.

- Establish designated storage areas with clear signage, access restrictions, and spill containment measures. Use color-coded labels and safety symbols to enhance visibility and awareness.
- Segregate the chemicals from incompatible substances such as oxidizing agents, strong acids, and alkalis to prevent accidental reactions or releases.
- Develop and implement comprehensive emergency response plans for spills, leaks, or releases of chemicals. Conduct regular drills and simulations to ensure staff are familiar with emergency procedures.
- Provide ongoing training to employees on emergency procedures, evacuation routes, and first aid measures. Include training on the specific hazards associated with monoclonal antibody production.
- Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation of ethanol, such as PESO, MSIHC Rule 1989, OSHA's Process Safety Management Standard and EPA guidelines etc.
- Train personnel on safe handling practices, including proper storage, transfer, and use of hazardous chemicals. Use Standard Operating Procedures (SOPs) and ensure they are easily accessible to all employees.
- Implement continuous training and retraining programs for operators. Conduct regular mock drills based on identified scenarios to ensure preparedness for emergencies.
- Enforce a strict work permit system for all maintenance and operational activities. Ensure permits are not bypassed and are reviewed and approved by safety officers.
- Strictly prohibit smoking and carrying smoking accessories in all areas of the facility. Implement clear signage and regular inspections to enforce this rule.
- Safety Procedures and Do's and Don'ts should be prepared and displayed in handling, processing and storage area.
- The Plant commissioning has an important role to ensure long term safety. Proper cleaning and flushing of the system should be ensured in storage area and fire hydrant system to avoid possible hold up of welding slag's, bolts, nuts etc., which could hamper smooth operation.
- The Environment Management Team to be trained on industrial hygiene and sampling/ testing techniques.
- Keep the storage of critical chemicals to a minimum necessary for smooth plant operation. Implement a just-in-time inventory system to reduce on-site quantities.
- Even though most of the chemicals are stored in drums/barrels, the storage area will be kept
 effective to contain the material within and to clear the area immediately in case of any spillage in
 a safer way.
- The firefighting equipment will be kept ready and tested periodically to confirm their efficiency.
- Minimum 10% of employees, in each shift, to be trained to do the needful during emergencies.

- It is suggested to consider fire detectors (with alarm/beacon) in such areas for earliest detection and response by the operator in the control room and those in the field.
- Ensure active fire protection measures as per requirement mentioned under applicable standards/guidelines.
- Automatic shutdown system shall be installed and other instrumentation system like SCADA shall be installed.
- All the project premises shall be monitored by surveillance cameras.
- Proper checking of contract people for Smoking or Inflammable materials to be ensured at entry
 gates to avoid presence of any unidentified source of ignition in the plant.

7.3.4 Biological risk assessment

The use of animal cell cultures has become very beneficial for diverse applications in biotechnology. Animal cell cultures become an indispensable tool to produce a variety of products, including biopharmaceuticals, monoclonal antibodies and products for gene therapy. The use of animal cell cultures constitutes also adequate test systems for studying biochemical pathways, virus production, pathological mechanisms or intra- and intercellular responses.

Along with the increasing importance of the contained use of animal cell cultures, biosafety concerns have pointed to the risks with respect to human health and environmental considerations. A maximal reduction of these risks necessitates a thorough biosafety risk assessment, taking account of the type of manipulation and the biological hazards inherent to the use of cell cultures.

7.3.4.1 Hazards of biological contamination of biopharmaceuticals

Biological contamination of biopharmaceuticals may perhaps cause product spoilage. It may result in product metabolization by micro-organisms and therefore, lead to a decrease in biopharmaceutical potency. The product spoilage may also provide a potential health hazard to patients and lead to outbreaks of infections that may cause additional compliances. In addition, microbial-derived agents secreted in products such as endotoxins can be hazardous to a patient's health.

The biological contaminants are

- Bacteria and Fungi
- Endotoxins
- Viruses
- Mycoplasma
- Cross-contamination

The table below summarises the occupational health & safety hazards, risks associated and corresponding mitigation measures in brief.

Table 7-6 Occupational health & safety hazards, risks and mitigationMeasures

	Tuble 7 6 Geoupational nearth & safety nazaras, risks and integration/reasures					
Sl. No.	Activity	Hazards	Risks	Mitigation Measures		
1	Raw Material Handling	Chemical spills	Environmental contamination, worker exposure	Use of proper storage containers, spill containment systems, and spill response protocols		
2	Cell Culture and Fermentation	Exposure to biological agents	Infections, allergic reactions	Use of biosafety cabinets, personal protective equipment (PPE), and regular health monitoring		
3	Purification Processes	Chemical exposure	Toxicity, respiratory issues	Adequate ventilation, use of PPE, regular safety training, and proper handling procedures		
4	Filtration and Concentration	High- pressure equipment	Equipment failure, injury to workers	Regular maintenance, pressure relief systems, and training on safe operation of equipment		
5	Formulation	Exposure to hazardous chemicals	Skin and eye irritation, respiratory issues	Proper ventilation, use of PPE and adherence to safety data sheets (SDS)		
6	Filling and Packaging	Exposure to preservatives and solvents	Skin sensitization, respiratory issues	Closed systems, proper ventilation and use of PPEs		
7	Storage and Transportation	Temperature fluctuations, chemical leaks	Product degradation, environmental contamination	Controlled storage conditions, temperature monitoring, and leak detection systems		

7.3.4.2 Biosafety Recommendations and Containment Measures

The implementation of an appropriate containment level includes the following general and more specific work practices and containment measures.

- Respect good microbiological practices, especially those that are aimed at avoiding accidental contamination.
- Avoid opening of culture vessels or contact with culture fluid through a defective culture vessel, stopper or poor technique because of the ever present likelihood of contamination with airborne pathogens.
- Treat each new culture that is manipulated for the first time in the laboratory facility as potentially infectious.
- Clean up any culture fluid spills immediately with a validated disinfectant.
- Work with one cell line at a time and disinfect the work surfaces between two handlings involving cell lines.
- Aliquot growth medium so that the same vessel is not used for more than one cell line.
- Avoid pouring actions, which are a potential source of cross-contamination.

- Proceed to an adequate use of the biosafety cabinet, this is turn on for a period before and
 after use, thoroughly disinfect biosafety cabinet surfaces after each work session and do not
 clutter the biosafety cabinet with materials.
- Restrict the use of antibiotics in growth media.
- Quarantine new cell cultures to a dedicated biosafety cabinet or separate laboratory until the culture has been shown negative in appropriate tests.
- Carry out a quality control of cells demonstrating the absence of likely contaminating pathogens on a regular basis or whenever necessary.
- Handle cell cultures from undefined sources as risk group agents. If there is a reasonable likelihood of adventitious agents of higher risk class, the cell line should be handled under appropriate containment level until tests have proven safety.

a) Personal Protective Equipment

- Coveralls and gowns
- Head covering
- Gloves
- Protective eyewear
- Respiratory protective equipment
- Shoe covers

7.4 Disaster Management Plan:

7.4.1 Objectives

- To establish a method of systematic, safe and orderly evacuation in the least possible time, to a safe area or by the nearest safe means of way out.
- Control the accidents.
- Rapid control and containment of hazardous situation.
- Rescue and treatment of casualties.
- Safeguard people (both at site and neighborhood).
- Minimize damage to property and environment.
- ➤ Identify casualties, notify their relatives and render necessary help to them.
- > Proper training of the concerned person.
- > Prevent recurrence.
- ➤ Be capable of dealing with largest incident that can reasonably be foreseen.
- ➤ Have sufficient flexibility with a view to handling the emergency efficiently and avoiding unnecessary calling external agencies like fire brigade services.

7.4.1.1 Basic forms of emergency

- > Fire
- > Explosions
- > Toxic release
- Natural disaster (earthquake, flooding, tsunami etc.)

7.4.1.2 Action plan to various emergencies

1)Fire

In case of any fire incident the following steps are to be followed by the site occupants:

- > Be concerned about your own safety as well as that of others.
- ➤ Inform others by verbal signal: "FIRE, FIRE, FIRE".
- ➤ If the fire is controllable by nearby fire extinguishing equipment and you know firefighting, control the fire without undue personal risk.
- > Shut off the electrical supply quickly.
- ➤ Use fire hydrant system point located nearer to the affected area.
- ➤ If you can't extinguish it alone, activate the fire alarm/MCP and get help.
- ➤ Inform to Safety and security team-nearest helpdesk
- ➤ Inform to manager and site controller
- Make certain you know your escape route and assembly point/safe place.
- Do not panic.
- ➤ People not involved in firefighting operation directly, should quickly move through emergency exit routes & assemble at nearest emergency assembly point/safe place.
- For any other assistance Call emergency number.

2)Toxic release:

- Cover your nose with wet hand kerchief/ cloth and breathe through it.
- Come out in open, check the wind direction and move away quickly in perpendicular direction of wind. (crosswind direction).
- Immediately try to get to a higher elevation, if gas is heavier than air (like chlorine, as it settles in low lying area).
- Follow the instruction and reach safe shelter as instructed notified by Government Authority or Public authority.

3) Natural calamities

In case any natural disaster like earthquake the following procedure should be followed by the occupants:

a) When earthquake is felt:

➤ Take a safe position (e.g. Under the table, concrete wooden beam, concrete column, door bracket)

- > Do not use lift. Do not stand near doors, gate
- > If you are driving, or on road, go to open space
- > Keep away from walls, building, and electric pole/wires.
- ➤ Keep away from building, sheds, electric wires
- ➤ Keep cool & keep others cool.

b) After the earthquake:

- > There can be more such jerks immediately hence go to open space.
- ➤ Close connections of LPG, Electricity, water.
- > Do not smoke, ignite matchstick, or put on main switches.
- > Do not touch electric wires.
- > Drink clean water.
- > Do not go near partially collapsed buildings.
- > Keep roads clear for traffic.

c) In case of flood:

- ➤ Be ready to evacuate as directed by the Emergency Coordinator.
- ➤ Follow the recommended primary or secondary evacuation routes.
- > Climb to high ground and stay there.
- ➤ Avoid walking or driving through flood water.
- > Avoid walking or driving through flood water.
- > For further help, contact emergency.

d) Post cyclone measures:

- You should remain in the shelter until informed that you can return to your home.
- > You must get inoculated against diseases immediately.
- > Strictly avoid any loose and dangling wires from lamp posts.
- > If you have to drive, do drive carefully.
- > Clear debris from your premises immediately.
- ➤ Report the correct losses to appropriate authorities

4)Structural collapse

- > Raising the emergency signal.
- Evacuate the site immediately and assemble at Assembly point/safe place
- > Isolate & Barricade if necessary.
- ➤ Head count to be taken by the security or emergency response team.
- Rescue Operation to be carried out in case of missing personals.
- ➤ Hospitalize the victims in case of injury.

5) Medical emergency

▶ Provide information to Emergency Response Team immediately.

- > Provide the necessary first aid treatment.
- > In case of critical emergency, move injured person to hospital
- ➤ Local legal requirement to be carried out.
- > Information to be given to branch manager.

7.4.2 Types of emergency

7.4.2.1 On-site emergency

An accident/ incident that take place in a factory, with effects being confined to the factory premises, involving only the persons working in the factory and the property inside the factory is called On-site Emergency. It can further be classified as minor and major emergency based on severity of the incident.

a) Minor emergency (evacuation is not required)

In the case of minor emergency there is no need for an evacuation siren and the respective department personnel will handle the same with assistance of Safety Squad.

b) Major emergency (evacuation is required)

In case of major emergency, there must be an emergency siren and situation is tackled as per the plan.

7.4.2.2 Off-site emergency

If the accident is such that it affects inside the factory uncontrolled and it may spread outside the factory premises, it is called as Off-site Emergency. The detailed risk assessment report with Disaster management plan is prepared and attached as **Annexure -7.**

7.5 Social Impact Assessment and R&R Action Plans.

Not applicable, since no land acquisition involved.

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CHAPTER – 8 PROJECT BENEFITS

8 PROJECT BENEFITS

8.1 Improvements in the Physical Infrastructure

Establishment of new manufacturing facility is not only increases the market availability of bio based drugs but also reduces the imports in the country and also support the government by paying the taxes.

In addition to this, certain social contributions will help in economic growth of the area. Further the proposed project will result in improvement of infrastructure as well as up-liftment of social structure in the area. The people residing in the nearby areas will be benefited indirectly.

8.2 Improvement in the Social Infrastructure

- Further development of small and medium scale industries may be developed as consequence;
- Increased revenue to the state by way of taxes and duties;
- Overall Growth of the neighboring area viz.:
- Sustainable lively hood and strengthening of village Self Help Groups.

8.3 Employmentpotential-skilled; semi-skilledandunskilled

1. Construction Phase Benefits

a) Employment Opportunities

The major benefit due to the proposed project will be in the sphere of generating temporary employment for substantial number of personnel. Around 30 no. of persons would be required during the construction phase. Both skilled & un-skilled personnel's will be required during this phase of the activity.

2 Operational Phase Benefits

a) Employment Opportunities

During operation phase around 120 persons are expected to be employed at full capacity which includes permanent and contract workers.

8.4 Other tangible benefits

As mentioned above, the project will have employment & trade opportunities with the inception of the construction activities. Thus, these considerable employment & trade opportunities will eventually result in appreciable economic benefits to the local people & businesses/contractors.

8.4.1 Corporate Social Responsibility

The company is aware of the obligations towards the society and to fulfill the social obligations, company will employ semi-skilled and skilled labour from the nearby villages as much as possible and also try to generate maximum indirect employment in the nearby villages by appointing local contract workers.

Various CSR activity as per company policy will be initiated in the surrounding villages as per below categories

- Education
- Health
- Infrastructure development
- Sports and Cultural activity

8.4.2 Corporate Environmental responsibility (CER)

As per OM.F.No.22-65/2017-IA.III Dated: 1st May 2018, 2.0% of the total project cost (INR 1.9 crores) ie., will be used for CER activities. This will be used for nearest village water tank sustainability development and other environmental related activities in nearby villages as per the observation made in public hearing.

However, As per ToR Condition by SEAC, Suitable flora and fauna study will be conducted and details of same will be educated to students in nearby Govt. School as Part of CER activities. Budget of **INR 5.0 lakhs** will be allotted for Awarness Campus and distribution of Tree sapling and seed ball to students

Schools	Budget (INR. Lakhs)
Pattanam Panchayat Union Middle School:	
Awarness camp about local Flora and Fauna	1.0
 Distributing 50 Tree sapling and seed ball bags 	
Kollar Goverment Higher Secondary School:	
Awarness camp about local Flora and Fauna	2.0
 Distributing 100 Tree sapling and seed ball bags 	
Singanur Goverment ADW Higher Secondary School	
Awarness camp about local Flora and Fauna	2.0
 Distributing 100 Tree sapling and seed ball bags 	
Total	5.0

CHAPTER – 9 ENVIRONMENTAL COST BENEFIT ANALYSIS

9 ENVIRONMENTAL COST BENEFIT ANALYSIS

Not applicable, since the proposed site is located within TANSIDCO (part of SIPCOT which have a valid EC) and land was already under the procession of project proponent.

CHAPTER – 10 ENVIRONMENTAL MANAGEMENT PLAN

10 ENVIRONMENTAL MANAGEMENT PLAN

10.1 Description of the administrative aspects of ensuring that mitigative measures are implemented and their effective effectiveness monitored, after approval of the EIA

10.1.1 Introduction

This Environmental Management Plan (EMP) for M/s. Omexa Formulary Pvt Ltd identifies the principles, procedures and methods that will be used to control and minimize the environmental impacts of the proposed construction and operational activities associated with the project development. It is intended to ensure that commitments are made by proponent to minimize project related environmental and social impacts.

As part of the ongoing commitment to excel in environmental and social performance, proponent will ensure the following:

- i. Fulfill all environmental conditions associated with project approvals.
- ii. Develop, promote and foster a shared sense of responsibility for environmental and performance of the project.
- iii. Promote environmental awareness and understanding among employees and contractors through training, identification of roles and responsibilities towards environmental management.
- iv. Linking project performance to overall environmental performance.
- v. To monitor the environmental performance throughout the project and implement an adaptive management approach for continuous improvement and to meet the regulations.

10.1.2 Objectives of EMP

- To suggest the formation of a core group (Environment Management Cell) responsible for implementation of environmental control & protective measures as well as monitoring of such implementation.
- To ensure project components are compliant with all laws and approval conditions.
- Continue baseline monitoring.
- Facilitate a continual review of post construction and operation activities.
- To suggest preventive and mitigation measures to minimize the adverse impact and to maximize the beneficial impacts.
- Preparation of afforestation or Greenbelt Development scheme.
- Preparation of rain water harvesting scheme and energy conservation actions
- To prepare a capital cost estimate and annual recurring cost for Environmental Management Plan.
- To prepare a detailed action plan for implementation of mitigation measures.
- Measure the effectiveness and success of proposed mitigation measures.

10.1.3 EMP Roles and Responsibilities a) Environmental Management Cell (EMC)

- Each industry should identify within its setup a Department/Section/Cell with trained personnel to take up the model responsibility of environmental management as required for planning and implementation of the projects.
- Environmental Cell consisting of Managing Director and departmental heads will be created for efficient management of the environmental activities in the industry.
- The EMC will handle all issues related to different environmental attributes; it will be responsible for overall environmental and social management in project being undertaken.
- The EMC will be responsible for the technical planning, implementation and monitoring of all environmental mitigation and compensation measures.

The Organization and Environmental Management Cell (EMC) set-up by the company is given in Figure 10-1

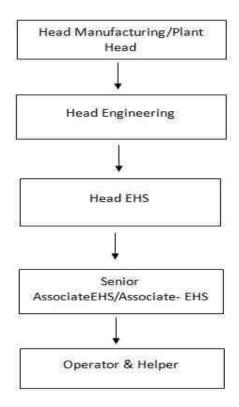


Figure 10-1Environment Management Cell Organogram

Table 10-1EMC Responsibility

Designation	Responsibilities
Manufacturing	Responsible for overall environmental management.
Head/ Plant Head	Regularly coordinate with EMC cell and monitor all the activities performed

	under EMC and give directions to succeeding component.				
	Managing all the activities performed under EMC.				
	Responsibility to various issues like accidents, incident takes place etc.				
	Ensure Prevention activities Evaluate any non-conformity stipulated by				
	different regulatory agencies.				
Head EHS	Work permit, Mock rill activity, Safety Inspection & audit work, daily record				
	keeping, EHS Incidents/ Accident investigation Employee observations/near				
	misses along with corrective action.				
	Follow up for routine cleaning & maintenance work for plant and EMS				
	systems.				
	Identify environmental aspects, normal, abnormal and emergency conditions				
	Ensure implementation of standard operating procedures as updated from time				
	to time.				
Sr. Associate/	Ensure and implement necessary corrective actions Establish procedures for				
Associate-EHS	reporting, document and record control				
	Establish and implement procedures for incident and near miss reporting,				
	investigation and root cause analysis and prescribe corrective action.				
	Observe regularity, discipline, working strength of operators and helpers/fitters				
	Routine cleaning & maintenance of plant and EMS systems.				
	Maintain minimum stock of required chemicals/materials, maintain hazardous				
Operator & Helper	waste storage area in good condition & Record of it, inform immediately				
	whenever any breakdown or incident takes place to Manager& start immediate				
	control measures.				

In addition to the above, company will prepare a suitable HSE policy to adhere with standard operating process in order to comply with the statue and bring into focus any infringement of any norms and directives with regards to the Health, Safety and Environment and to take further corrective actions.

b) Safety, Health and Environment policy

Omexa will adhere to the Safety, Health and Environment policy and place it at appropriate places in the factory premises and record



SAFETY, HEALTH & ENVIRONMENT POLICY

HEALTH AND SAFETY POLICY:

- Provided and maintain so far as is reasonably, practicable, plant, equipment, systems
 and working conditions which are safe and without risk to the health of all employees,
 visitors, contactors, and public and which avoid damage to property and adverse impact on
 the environment.
- Protect all employees from exposure to any substance or activity which may be hazardous to health by providing suitable control measures based on assessment of the risks and recommendations made through periodical safety audits.
- Provide information, instruction, training and supervision for all employees to enable them to carry out their duties and responsibilities in a safe and effective way.
- Develop and maintain appropriate emergency response procedures, contingency plans and resources, commensurate with the risks to business activities.
- Provide n effective occupational heath programme.
- Take full account of health, safety and loss prevention considerations in projects, planning and decision making.
- Treat local laws and regulations on health and safety as minimum standards to be improved upon wherever reasonably practicable.
- Actively encourage the involvement of employees in the promotion of health and safety.
- Encourage employees to accept individual responsibility for their own health and safety
 and for that their colleagues and to coordinate fully with company management in
 maintaining and improving health and safety standards.

For Omexa Formulary Pvt. Ltd.

E. Ramanathan Director

Kalyani tower, 174C 2nd Avenue, Ashok nagar Chennai - 600083 Contact No. +91 8428424699. E-mail - Contact @ Omexa.in

Figure 10-2Safety, Health & Environment Policy



ENVIRONMENT POLICY:

- · To take account of environmental consideration in planning and decision making.
- To monitor the impact of all the company activities upon the environment and to ensure that it is maintained.
- To pay special regards to the environment protection of the communities in which its operations are located.
- To conduct periodical audits to ensure implementations of the company's environmental policy.
- That environmental regulations laid down by the government and public authorities are treated as minimum standard to be improved upon wherever practicable.
- That the company works closely with appropriate authorities in seeking to improve its environmental performance.

-or Omexa Formulary Pvt. Ltd.

Kalyani tower, 174C 2nd Avenue, Ashok nagar Chennal - 600083 Contact No. +91 8428424699. E-mail - <u>Contact@Отека.in</u>

Figure 10-3Environmental Policy

10.1.4 EMP for Construction Phase

Environmental impacts during the construction phase can be attributed to the site preparation activity and the mobilization of workforce. The impacts of the construction phase on the environment would be basically of transient nature and are expected to wear out gradually on completion of the construction programme.

Inorder to mitigate such impacts and restrict them within tolerable levels, the following measures shall be adopted:

- 1. Proper and prior planning of approach and access roads, and appropriate sequencing and scheduling of all major construction activities.
- 2. Adoption of appropriate soil conservation programme and its timely implementation in the proposed project site.
- 3. Initiation of an appropriate landscape programme including plantation of trees and flowering plants in and around the project site particularly, at all available spaces which would serve the dual purpose of controlling fugitive dust and abatement of noise levels in addition to improving the aesthetics of the area.
- 4. Water sprinkling in the vulnerable areas to suppress the dust generated during excavation, levelling and other operations.
- 5. Use of properly tuned construction machinery & vehicles in good working condition with low noise & emission and engines turned off when not in use.
- 6. Control of quality of construction wastewater within the construction site through suitable drainage system with traps for arresting the sediment load and disposed into the main natural drainage system around the site.
- 7. Implementation of suitable disposal methods of sediment/ construction debris at designated places to avoid water logging at construction site.
- 8. Provision of protective gears such as ear mufflers etc. for construction personnel exposed to high noise levels and locating the temporary labour sheds for housing the construction labourers away from the construction site.

10.1.5 EMP for Operational Phase

1)Air quality

The major sources of emission are Boiler and D.G sets (in case of power failure). Stacks will be provided with adequate height. Development and maintenance of Green belt within the premises will attenuate the air pollutants. Regular monitoring of Stack and ambient air quality will be carried out.

Following measures can be adopted to mitigate the impacts of pollutants on the ambient air quality:

- Stack height of 30 m is proposed for boiler.
- o 30m stack height will be provided for DG
- There are no process emissions from the proposed manufacturing facility.

- o Wet scrubber with stack height of 3.0m (AGL) is proposed for QC Lab vent.
- Ambient air quality monitoring will be carried out regularly at selected locations in order to check and compare the predicted concentrations with the measured concentrations. Adequacy/Performance of Air Pollution Control measures shall be reviewed.
- Water sprinkling shall be carried out on road surfaces at the project site.
- o Adequate Green belt area will be provided.
- Vehicular speed will be limited to 20km/hr on areas of unconsolidated or unsealed soil associated with the immediate site work.

2) Noise Environment

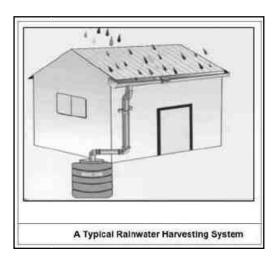
- > The major source of noise pollution in the industry is Boiler, DG sets, air compressors. Preventive measures are taken to reduce the noise generated during operation phase.
- > The DG set room, will be isolated from the outside environment and proper acoustic arrangements are provided to control the noise.
- > Use of well-maintained machinery and vehicles could considerably help in this matter.
- ➤ Vehicles and operational equipment with internal combustion engines will be provided with proper silencers and mufflers in order to reduce noise levels.
- > To prevent the hearing damage to workers, they will be provided with ear plugs and muffs and job rotation will also be practiced.
- > Plantation and landscaping will be designed to ensure that there is a green belt all around the project area so that further noise attenuation is achieved.
- Maintenance of proper green belt will also help in attenuating noise pollution.
- ➤ All efforts will be made to maintain the noise level within the proposed premises around 50 dB (A) in day time & 40 dB (A) during nigh time.

3) Water and wastewater management

- ➤ Effluent 59.5 KLD will be treated in ETP of 70 KLD and treated effluent will be resued for utilities and greenbelt.
- > Sewage will be routed to PSTP of 6 KLD Capacity and treated sewage will be reused for flushing and Greenbelt.
- > Measures are implemented to prevent seepage of liquid material into ground water.

Rainwater Harvesting: Rainwater harvesting is an important component of area wise resource use and environmental management. The total amount/quantity of water i.e., received in the form of rainfall over an area is called the rain water endowment of that area, out of which the amount of water that can be effectively harvested is called the rain water harvesting potential. The collection efficiency

accounts for the fact that all the rain water falling over an area cannot be effectively harvested due to losses on account of evaporation, spillage or run off etc.,



Rainwater Harvesting will be implemented at project site to conserve rainwater. Roof top area, greenbelt/ green area, road/paved area and open areas proposed in the project site are considered for rainwater which can be harvested. The approximate quantities of rainwater that can be harvested at project site issummarized below

The equation used for run off estimation is based on CPCB guidelines on 'Concepts and Practices for Rain water Harvesting'- Oct 2001.

Table 10-2Rainwater harvesting calculation

Description	Area (m²)	Run off Coefficient	Intensity of rainfall-I (m/day)	Total Discharge- Q(m3/day)
Ground coverage (plinth)	6472	0.8	0.073	377.96
Greenbelt	5011.4	0.2	0.073	73.17
Open Space	144	0.7	0.073	7.36
Road & Parking	3520	0.7	0.073	179.87
Total	15,147.40	0.00	0.00	638.36

Formula:

Discharge, Q= CIA (m³/day)

Where,

Q= Discharge (in m^3/day)

C=Coefficient of Runoff

I= Intensity of rainfall (in mm/day) (Max Flood in 12.11.2022- 73.79 mm as per IMD Villupuram)

A= Area (in Sq.m)

Runoff calculation:

- ightharpoonup Total runoff Load = 638.36 m³/day
- \triangleright Total runoff load per hour =638.36/24 = 26.60 m3/hr.

- ➤ RWH pits of 1.5m dia and 4.0 m depth, capacity of each pits= 3.53 m3 and we considered 50% percolation so the capacity of RWH pit is 1.77 m3.
- No. of RWH pits proposed = 26.60/3.53 = 15.02 Say 15 Nos.

15 no. of rainwater harvesting pits are proposed Storm water will be collected in RWH pits through storm water drains and only ecess storm water will be let into TANSIDCO Drain. Layout with storm water drain is attached as an **Annexure -8**.

Cost Estimation for Rainwater harvesting:

Description	Nos	Amount (INR. Lakhs)
Rain water harvesting pits (in Cu.m)	15	10
Storm water drain (in R.m)	-	16
Total	-	26.0

4) Solid and Hazardous waste management

a) Solid waste management

The source of municipal solid waste in the industry will be from the domestic use. Solid wastes generated will be stored and disposed to municipal authority.

Details of municipal solid waste generation and its disposal method are explained in **Section 2.7.6** of **Chapter-2.**

b) Hazardous waste

Hazardous waste would be generated mainly from the maintenance activites, handling of chemicals. These wastes would be stored in the hazardous waste storage area in double lined polythene bags before dispatch to the TSDF. Hazardous waste materials are being properly disposed as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 1989 and subsequent amendment in 2016.

Details of Hazardous waste generation and its disposal method are explained in **Section 2.7.7** of **Chapter-2.**

5)Land Environment

Following measures are proposed to mitigate negative impact during operational phase of the project on the land environment.

- Air emissions are effectively controlled by use of stacks and therefore deposition of air pollutants in and around the premises and surrounding area is not envisaged.
- Disposal of solid waste is carried out through authorized vendor.
- No effluent is discharged directly on land without treatment; impact on the land environment is not envisaged.

- Hazardous materials are prohibited to be drained or dumped in the premises. Accidental spills shall be cleaned, reported and monitored.
- Thus, no impact on land is envisaged due to discharge of gaseous emission, solid waste or liquid effluent from the proposed project.

6)Biological Environment

The proposed project activity does not require tree cutting or removal. Also, the study zone does not have any ecologically sensitive location and hence, the plant activities are not expected to have any impact on ecology and biodiversity. Air emissions, liquid effluent disposal and solid waste generation are likely to have some impacts on terrestrial ecosystems. However, there will be no net increase in air pollution. Solid wastes will be collected and disposed of properly. Hence, negligible impact on ecology is expected. Greenbelt development is proposed to conserve and maintain the environment.

7)Socio-economic environment

The proponent is committed to the socio – economic upliftment of the people in region and has actively involved in formulating and implementing proactive measures as part of the corporate social responsibility. Moreover, various modes of indirect employment i.e., transportation, increased business opportunities to shopkeepers, small scale business entrepreneurs etc. will lead to development of the area.

8) Solar power:

- > We are proposed to install Solar panel on roof top and obtain 100 KVA through Solar energy.
- Remaining 775 kVA will be sourced from renewable green energy vendors who are authorized by from TNEB and Agreement will be made them after all statutory Approvals.

Layout plan of the project site showing the solar panel for 100 KVA is attached as an Annexure-3.

10.1.6 SafetyManagement Systems

1)Fire Hydrant System

Fire hydrant will be placed across the plant & required firefighting equipments like extinguishers, Fire safety alarms, fire buckets etc will be provided where ever required. Trained people will be allotted to mitigate the fire during emergency and regular mock drills will be conducted to enrich the knowledge of the people.

Table 10-3List of safety Equipments Proposed

S. No.	Safety And Fire Fighting Equipments Description	Qty	Capacity
1.	Underground static water tank	1 No	300 KL
	Fire water pumps (as per NBC guidelines and Tamil Nadu Fire and Rescue services guideline)	1 No	130 Cum/Hr
3.	Jockey pumps	1No's	40 Cum/Hr

	Note:	
	Delugevalves, Manual Call Points, Hand Siren, Gas	Will be provided as
4	Monitoring System, Foam trolley, Fire Hydrant Lines, MVW	
	Sprinkler etc.,	design

Table 10-4Extinguishing Media for Different Fires

S. No	Class of fire	Suitable Fire Extinguisher
1	Class A: Organic Material i.e., wood, papers, rubber & plastics.	DCP, Mechanical Foam
2	Class B: Flammable Liquid and Flammable Gases i.e., Petroleum Products, Paints, Chemicals etc.	Mechanical Foam,CO ₂ and DCP
3	Class C: Electrical	DCP and CO ₂
4	Class D: Flammable Metals i.e., Lithium, Sodium, and Potassium etc.	Special DCP, Sand

Table 10-5List of Fire Extinguishing proposed for the project site with count

S. No.	Type of Fire Extinguishers	Capacity	Unit	Quantity
1	CO_2	4.5	Kg	10
2	DCP	9.0	Kg	50
3	Foam	50.0	Litres	10

Preliminary Layout plan showing the location of fire hydrant is attached as Annexure-13.

2) Emergency Equipments and PPEs

The unit will have total 3 number of Emergency cupboards, in that one at Production Block, Storage area and another at Utility Area / Boiler Room. Each Emergency Cupboard will have the following items;

- Self Contained Breathing Apparatus (SCBA)
- Nose Mask
- Helmet-Provided to individuals
- Ear Plug
- Safety Glass -10 & Face Shield to individuals
- Gum boot to individuals
- Safety Belt in safety department
- Manila Rope/Life Safety Rope
- Fire Axe
- Fire Proximity Suit
- Safety Ladder
- Emergency Flame proof Torches

• Hand gloves

Operation of SCBA (Self Contained Breathing Apparatus) Procedure for wearing Equipment:

- Extend shoulder straps and waist belt on the equipment.
- Fasten the buckle and then pull the ends of waist belt away from buckle until secure and comfortable on the hip. Tuck ends in belt loops.
- Pull down the shoulder straps until the equipment is secure and comfortable. Tucks trap ends under waist belt.
- Extend face piece head harness straps, leaving centers traps in position. Put neck strap over neck.
- Before opening the cylinder valve press reset button.
- Open the cylinder valve fully to pressurize the system and check the pressure gauge & carry out pressure leak test.

Procedure for wearing Face piece

- Fit harness over head. Pull it back until the head-strap fits smoothly.
- Adjust mask until it fits properly
- Tighten the neck-straps and temple-straps evenly and tighten the front-strap as necessary.
- Breathe normally through vent system. During venting observe the gauge-waist alarm. The alarm should blow at cylinder pressure of 55bar ±5bar.

SCBA - Face piece

- Remove the equipment in a safe and hazard free area.
- Unbuckle the waist belt, lift shoulder-strap buckles to loosen and remove the equipment.
- Close the cylinder valve and keep in the box, cylinder valve should be in upward direction.
- After using the equipment, in form to safety department for inspection/checking.

Fire Axe

A fire axe is a type of axe which has been designed specifically for the use of fire-fighters, and it includes several features which makes it ideally suitable to mitigate emergency services.

Helmet

A helmet with face shield is a form of protective gear worn on head to protect head and face from hazards such as flying objects and chemical splashes or potentially in factious fluid.

Fire Suit

Fire suit is a protective clothing designed to protect a fire fighter from high temperatures, especially near fires of extreme temperature.

Manila rope

Manila rope is very durable, salt water and damage resistant, flexible fiber which shall be used to access at height/Confined space during emergency.

Safety torch

Compact and simple to use, this torch is designed for use in emergency situations or wherever the need arises for a handheld safety torch.

10.1.7 Spill Emergency Mitigation Procedure

- > Spill kit is kept in all emergency cupboards.
- > Once the spill is observed, spill kit shall be collected from the nearest area/emergency cupboard installed and neutralizing agent (if required) based on the nature of the spill. In case if the spill is not controlled, immediately declare the emergency as per emergency response procedure.
- ➤ While handling the spill, use most appropriate PPE's like chemical suit, acid/ alkali proof hand gloves, face shield, safety goggles, gum boots or even respiratory masks with suitable cartridges.
- > Once the spill is controlled using sorbent pad/boom collect in a double polythene bag and secure with the plastic ties. Dispose it as per applicable disposal procedure.
- > Report the incident of spill to EHS department through online incident reporting system.
- > Once in a month, the items of the spill kit shall be inspected and recorded by EHS representatives of the individual area.

10.1.8 Eye wash and Safety Shower

The unit will have total 2 Nos. of Eyewash and Safety showers, one in Production Block and another in Warehouse.

10.1.9 Wind Sock

Wind sock will be placed above the Production block which can be seen from any point in the plant premises.

10.1.10 Occupational Health Centre (OHC)

Omexa will have agreement signed with nearby hospital for their valuable service during emergency along with 24/7 ambulance facility. Unit will provided Occupational Health Centre within their premises with facilities like bed and O₂ Generator. Cost estimation for OHC is given in below:

Table 10-6Cost Estimation for OHC

S. No.	Description	Capital cost (in lakhs)	Recurring cost / Month (in lakhs)
1	OHC Expenses	1.5	0.2
	Total	1.5	0.2

Occupational Health Center is located at the main gate and working the entire 24 hrs. Agreement with doctor based on the need base visit the company during general shift. Every shift having first -aid trained person available.

10.1.11 First Aid Boxes

A first aid kit is a collection of supplies and equipment for use in giving first aid. First Aid boxes will be kept available in Security Room, production block and at OHC. First Aid items will be issued to injure only by authorized persons.

Following are the contents of First Aid Box,

- a. Dettol Antiseptic solution
- b. Ciplox Eye Drops
- c. Soframycin Skin ointment
- d. Silverex Burn ointment
- e. Betadine Microbicidal solution
- f. Iodex Pain reliever
- g. Sterilized Cotton Wool
- h. Surgical Paper Tape
- i. Small Sterilized Dressings
- j. Medium Sterilized Dressings
- k. Roller Bandage 5 cm wide
- 1. Roller Bandage 10cm wide
- m. Band Aid
- n. Crocin / Paracetamol Tablet

Along with the above safety systems, company also ensured the below safety features to ensure Zero Accident.

- 1. No ignitable zones are declared and marked so.
- 2. Work permit system with strict compliance.
- 3. Dedicated chemical storage area with good ventilation and exhaust system and all chemical are stored as per compatibility.
- 4. Dyke walls provided for the day storage chemical tanks.
- 5. All reactors provided with safety valves followed by rupture discs and relief valve outlets are extended.
- 6. Calibration is ensured for the gauges of pressure, temperature and vacuum.
- 7. All reactors will be hydro tested and certified by the competent person once in a year.
- 8. Body earthing provided to all equipments involved in the process, electrical earthing, static earting and instrument earthing provided wherever required.

The tentative Emergency Organization Chart will be prepared and followed.

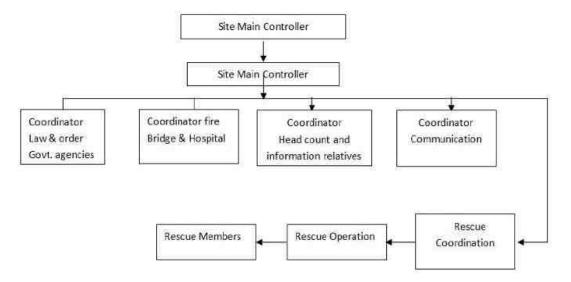


Figure 10-4Emergency Organization Chart

10.1.12 Occupational Health and Safety program

M/s.Omexa provides a safe and healthy work environment to its employees by conducting annual medical check-ups for all the employees. The main objectives are:

- Maintenance and promotion of worker's health and working capacity.
- ➤ Improvement of working environment by following well-being program for its employees.
- Monitor the workplace to maintain industrial hygiene practices.
- > Development of work culture in a direction which will support health and safety at work and thereby promoting positive social climate for smooth operation that will enhance productivity.
- > Employees undergo annual health check-up.
- > All personnel are provided with personal protective equipments individually as required.

Operational phase

General functions of the safety committee will be;

- Conduct routine workplace inspections.
- Provide Personal Protective Equipment.
- Develop and implement safe work procedures and rules.
- Provide on-going safety training & Enforce safety rules and appropriate discipline.
- Promote safety awareness and reduce the potential for injury/loss.
- Identify workplace hazards.
- Enforce of safety rules, measure safety performance & reduce frequency/severity of injuries.

10.1.13 Occupational Health Monitoring

Medical Surveillance Program: Medical surveillance program is essential to assess and monitor employees' health and fitness both prior to employment and during the course of work; to determine fitness for duty and to provide emergency and other treatment as needed. Effectiveness of a medical program depends on active involvement of employees. M/s. Omexa Formulary medical surveillance program having the following major elements;

- 1. Developing an OH-IH Medical Surveillance Program.
- 2. Periodic Medical Examinations
- 3. Determination of fitness for duty.
- 4. Communications.
- 5. Emergency medical treatment.
- 6. Medical records.

Periodic Medical Examinations - Periodic medical examination is the same as the pre-employment screening and may be modified according to current conditions, such as changes in the employee's symptoms, site hazards or exposures.

Comparison of sequential medical reports with baseline data is essential to determine biologic trends that may mark early signs of adverse health effects, and thereby facilitate appropriate protective measures. The frequency and content of examinations are normally one year. Apart from this for workers working in hazardous area, medical examination is conducted by the Doctor Authorized by the Factory Inspectorate.

10.1.14 Cost Estimate for Environment Management Plan (EMP)

The cost estimate for Environment Management Plan is provided in **Table 10-7**

Table 10-7 Tentative Estimated budget for EMP (Capital and Recurring cost)

S. No	Particulars	Capital Investment (Rs in lakhs) Proposed	Recurring Cost per Annum (Rs in Lakhs)		
Environ	nment Management Plan				
Water I	Pollution Control				
1	ЕТР	350	20		
2	MEE/ATFD and RO				
3	STP	8.5	2		
Air Pol	lution Control				
4	DG & Boiler Stack/ Wet scrubber	60	3		
Environmental Monitoring					
5	Environmental Monitoring by third party	0	4.4		

Solid V	Waste Management		
6	Solid Waste Management	2	3
Green	belt		
7	Greenbelt Development	7	2
Hazar	dous Waste Management		
8	Hazardous Waste Management	2	5
Storm	Water and Rain water harvesting manag	gement	
9	Storm Water and Rain water harvesting management	26	2.6
10	OHC Expenses	1.5	0.2
	Total	456.0	42.2

CHAPTER-11 SUMMARY & CONCLUSION

11 SUMMARY & CONCLUSION

11.1 Overall justification for implementation of the project

M/s. Omexa Formulary Private Limited has proposed a new unit for manufacturing of Monoclonal antibodies with Capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Nos/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State.

The marginal impacts that might be caused by the proposed activity will be mitigated by the pollution control and environmental management measures.

In a true and a larger sense, in view of the considerable benefits from the project with no major impacts, the proposed project is said to be more beneficial to the nation.

The EMP implemented for the construction and operation stages of the project will include:

- Air Pollution control and management
- Noise Control and Management
- Solid and Hazardous Waste Management
- Sewage treatment and Management
- Effluent treatment and Management

In order to effectively implement the EMP, an environmental management system will be formulated.

11.2 Explanation on how adverse effects will be mitigated

The baseline study carried out for the study area indicates that all the physical, chemical and biological characteristics of the environmental attributes in the surrounding area are well within the permissible limits.

Based on this environmental assessment, the possible impacts during both pre-project and post-project phase are anticipated and the necessary adequate control measures are formulated to meet the statutory compliances.

Follwing mitigation measures are proposed for the project:

- Water environment Fresh water will be sourced from TANSIDCO.
- Sewage will be treated through 6 KLD PSTP and treated water will be reused in flushing and Greenbelt.
- Effluent will be treated through 70 KLD ETP followed by RO, MEE and ATFD.
 Treated effluent will be reused in utilities and process.
- Storm water will be collected in RWH pits through storm water drains and only excess storm water will be let into nearby water bodies after filteration.

- Adequate stacks and scrubbers will be provided as per TNPCB Norms
- Solid and Hazardous waste: Organic waste will be disposed through TANSIDCO Bins.
 Inorganic waste will be disposed to TNPCB authorized recyclers/vendors
- Hazardous waste will be disposed to TNPCB authorized TSDF/recyclers as applicable by individual industries.
- Noise: 33.08 % green belt is proposed for the Industrial Area. Unit will provide acoustic enclosures for their D.G.sets, Boiler etc.
- Environmental Monitoring: Unit will be conducting periodical monitoring of AAQ, noise, water, soil and traffic, to ensure the parameters are within the prescribed limits.
- Environmental Management Cell is available to take care of the mitigation measures proposed for the project.

With very minimal negative impacts, the project positively leads to commercial business opportunities, employment opportunities, increased revenue and infrastructural development.

Thus, this project may kindly be granted Environmental Clearance.

CHAPTER 12 DISCLOSURE OF CONSULTANTS

12 DISCLOSURE OF CONSULTANT

In order to assess the potential environmental impacts due to the new manufacturing facility at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. M/s. Omexa Formulary Private Limited has engaged M/s. Hubert Enviro Care Systems (P) Limited, Chennai to undertake EIA study. The nature of consultancy service rendered covers terrestrial environmental assessment.

12.1 BriefResume and nature of Hubert Enviro Care Systems (P) Ltd.

HECS is a total Environmental management company which provides Environmental consultancy services, Analytical testing services, turnkey solutions and Operation-Maintenance services for water and wastewater facilities.

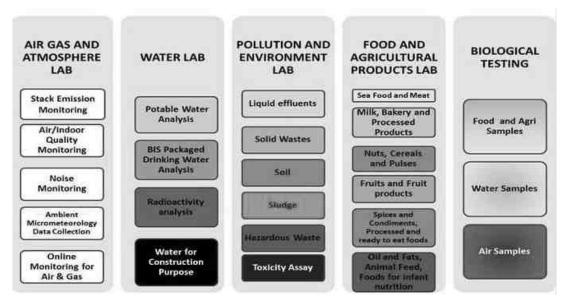
The company provides solutions to several industries like Refineries, Thermal Power Plant, Pharma, R&D Facilities, Electroplating and Manufacturing, IT Parks, Residential Complexes, Mines, Dairies, Food Processing, Textile mills, Breweries, etc.

The company is specialized in executing projects right from concept development, supply, erection, commissioning and operation on turnkey basis. HECS has successfully executed more than 300 environmental engineering projects for various industrial sectors both in India and overseas

Consultancy Profile:

- ♣ An approved consultant for carryout EIA studies across India
- → India's leading multidisciplinary Environmental Consultancy organization
- → HECS- Consultancy division comprises of technical skilled and competent Team of 40 people. The team consists of Three Doctorates & about thirty postgraduates
- HECS has industry specific prominent expert to provide solutions & recommendations
- ♣ Serving client more than 25 years & pan India presence in the following sectors:
 - o Environmental Clearance
 - o Coastal Regulation Zone
 - Risk Assessment, DMP, HAZOP studies
 - Feasibility/ treatability studies
 - Due diligence studies
 - Ground water Clearance
 - o DISH, PESO and other statutory approvals
 - o Consent to Establish, Consent to Operate
 - Hazardous waste, bio- medical waste authorization

- o Other environmental approvals
- Has an in-house laboratory wherein the following activities are being carried out:



12.1.1 QCI - NABET Accreditation

Consultancy	Hubert Enviro Care Systems (P) Ltd., Chennai
NABET Certificate No	NABET/EIA/24-27/RA0335, valid up to 31.03.2027
MoEF Reg. Lab	TC-12310 Dated: 25.09.2023 Valid Till 24.09.2025





National Accreditation Board for Education and Training

Certificate of Accreditation

Hubert Enviro Care Systems, Chennai

A-21, III Phase, Thiru Vi Ka Industrial Estate-600032

The organization is accredited as Category-A under the QCI-NABET Scheme for Accreditation of EIA Consultant Organization, Versian 3: for preparing EIA/EMP reports in the following Sectors-

S.No	Costor Description	Sector (as per)		Cat.
	Sector Description		MoEFCC	
1.	Mining of minerals including opencast / underground mining		1(a)()	A
2.	Offshore and onshore oil and gas exploration, development & production	2	1 (b)	A
3.	River Valley projects	3	1 (c)	A
4.	Thermal power plants	4	1 (d)	A
5.	Mineral beneficiation	7	Z (b).	, A
6.	Metallurgical industries (ferrous & non-ferrous)	8	3 (a)	A
7,	Cement plants	9	3 (b)	(8)
g.	Petroleum refining industry	10	4 (a)	(A)
9.	Pesticides industry and pesticide specific intermediates (excluding formulations)		5 (b)	:A
10.	Petro-chemical complexes		5 (c)	- A
11_	Petrochemical based processing		5 (0)	-:A
12.	Synthetic organic chemicals industry		5 (f)	A
33.	Industrial estates/ parks/ complexes/areas, export processing Zones (EPZs). Special Economic Zones (SEZs), Biotech Parks, Leather Complexes		7 (c)	A
14.	Bio-medical waste treatment facilities		7(d a)	В
15.	Ports, harbours, break waters and dredging		7 (n)	A
16.	Highways,		7 (1)	8
17.	Common Effluent Treatment Plants (CETPs)		7 (h)	B
18.	Common Municipal Solid Waste Management Facility (CMSWMF)		7 (0)	.0
19.	Building and construction projects		8 (a)	В
20.	Townships and Area development projects		8 (b)	В

Note: Names of approved EIA Coordinators and Functional Area Experts are mentioned in RAAC minutes dated May 31, 2024, posted on QCF-NABET website.

The Accreditation shall remain in force subject to continued compliance to the terms and conditions mentioned in QCI-NABET's letter of accreditation bearing no QCI/NABET/ENV/ACO/24/3292 dated June 25, 2024. The accreditation needs to be renewed before the expiry date by Hubert Enviro Care Systems, Chemical following due process of assessment.

Issue Date June 25, 2024

Valid up to March 31, 2027

Mr. Ajay Kumar Jha (Sr. Director, NABET)

Certificate No. NABET/EIA/24-27/RA 0335 Prof (Dr) Varinder S Kanwar (CEO- NABET)

For the updated List of Accredited E/A Consultant Organizations with approved Sectors please refer to QCI-NABET website

Annexure

For

"Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility"

At

Plot No. 27 & 28, TANSIDCO Industrial Park,

Village: Pellakuppam Taluk: Tindivanam District: Villupuram State: Tamil Nadu

By



M/S. OMEXA FORMULARY PVT LTD

Kalyani towers, 174c, 2nd Avenue, Ashok Nagar, Chennai-600083, Tamil Nadu.

[Project is termed under Schedule 5 (f)-Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates)shall be considered as a Category "B1" since located within TANSIDCO Industrial Park]

LIST OF ANNEXURE

Annexure-1a - Land allotment order given by TANSIDCO for the plot no: 27 (1.883 Acres) & plot no: 28 (1.863 Acres)

Annexure-1b- Environmental Clearance issued by TNSEIAA to SIPCOT for the development of IP over an extent of 291.60.5 Ha under Schedule 8(b) and Category B1

Annexure-1c- Office order between SIPCOT and TANSIDCO for the development of Industrial Park over an extent of 113.00 acres

Annexure-2 - Terms of Reference issued by SEIAA, Tamil Nadu

Annexure-3 - Layout plan of the project site showing the solar panel for 100 KVA

Annexure-4a-MSDS of Proposed Raw materials

Annexure-4b MSDS of Proposed products

Annexure-5a- Technical Specification of STP

Annexure-5b- Technical Specification of ETP (ZLD)

Annexure-6 - Layout plan showing green belt area along with GPS coordinates

Annexure-7 - Risk Assessment report including disaster management plan and Emergency evacuation plan

Annexure-8 –Layout plan showing the location of RWH pits and storm water drain

Annexure-9- Master layout plan

Annexure-10-Detailed Standard Operating Procedure (SOP) for the production process

Annexure-11- Acknowledgement copy for the submission of Request letter to DFO for the details of Reserve Forests, Protected Areas, Sanctuaries, Tiger reserve etc., up to a radius of 25 km from the proposed site

Annexure-12- Raw data of all AAQ measurement

Annexure-13 Layout plan showing the location of fire hydrant and Hose and Fire tank

Annexure-14 Sworn affidavit for no ligitation

Annexure-15 Layout plan showing the parking and traffic movement

Annexure-16 GFA for the proposed project

Annexure-17 Layout plan of TANSIDCO



TAMIL NADU SMALL INDUSTRIES DEVELOPMENT CORPORATION LIMITED(TANSIDCO)

Regd. Office: SIDCO Corporate Office Building, Thire-Vi-Ka Industrial Estate,

Guindy, Chennai - 600 032 CIN : U74999TN1970SGC005821

Phone: 2250 1461 / 2250 1422 / 2250 1210 Fax: 2250 0792 E-mail: ho.sidco@nic.m website : www.tansidco.tn.gov.in

Rc.No. 2029/EG2/2024-2

Date: 15-03-2024.

AMENDED ALLOTMENT ORDER FOR PLOT - OUTRIGHT SALE BASIS

To

By RPAD

Thiru Ekambaranathan Ramanathan, M/s. Omexa Formulary Private Limited, 1727B 2nd Street 14th Sector KK Nagar, Chennai 600 078 pincode:600078 Mobile No: 9940023926

Sub : TANSIDCO - Industrial Estate at Tindivanam Mega Pharma Cluster -

Allotment of Plot bearing No. 27, to M/s. Omexa Formulary Private Limited

on OUTRIGHT SALE BASIS - Provisional Allotment Orders - Issued.

Ref: 1.Allotment Order No. 2029/EG2/2024-58 dated 07.03.2024.

2. Your Email request letter dated 11-03-2024

1.

1.1 The plot no 45,46 with an total extent of 4.740 acres at Industrial Estate, Tindivanam Mega Pharma Cluster was allotted to M/s. Omexa Formulary Private Limited vide reference 1st cited. Based on the request of M/s. Omexa Formulary Private Limited, vide ref 2nd cited. The following Plot in TANSIDCO Industrial Estate at Tindivanam Mega Pharma Cluster is allotted to M/s. Omexa Formulary Private Limited on Outright Sale basis for setting up an Industry thereon for the line of activity of Biosimilar Manufacturing.

S.No.	Description	Particulars
a)	Plot No.	27(1.883),
b)	Total Extent of the Plot (in Sq.m)	7620.240
c)	Total Extent of the Plot (in Acres)	1.883

1.2 The Allotment Order is issued to the Private Limited Company consisting of the following Directors:

S.No.	Name	Shareholding (%)
1	Thiru.Ekambaranathan Ramanathan	1
2	Thiru.Ashu Singla	1
3	Ayur Inc	98
		100

2. Plot Cost and Terms of Payment:

- 2.1 The cost of the Plot is Rs. 20983300/- (Rupees Two Crore Nine Lakhs Eighty Three Thousand Three Hundred only) at the rate of Rs. 11143500/- per Acre which is inclusive of TANSIDCO's Administrative Charges.
- 2.2 TANSIDCO reserves the right to revise the Plot cost in the event of TANSIDCO having to pay additional cost to the Government for the land alienated or enhanced compensation to the land owners as awarded by the Hon'ble Court of law for the land acquired or in case of escalation in development cost or for any other reason and such revised amount shall be paid by the Allottee, without any demur.
- 2.3 The cost of the Plot shall be paid in the manner indicated below:
 - (i) The initial payment of 25% of the Plot cost amounting to Rs.5245900/- (Rupees Fifty Two Lakhs Fourty Five Thousand Nine Hundred Only) shall be paid within 2 months from the date of first Allotment Order i.e. on or before 06-05-2024 failing which the Allotment shall stand automatically cancelled and the Earnest Money Deposit (EMD) will be forfeited.
 - (ii) The balance payment of 75% of the Plot cost after adjusting the EMD (Rs.10000/-) amounting to Rs.15727400/- (Rupees One Crore Fifty Seven Lakhs Twenty Seven Thousand Four Hundred Only) shall be paid within 6 months from the date of first Allotment Order i.e. on or before 06-09-2024 failing which the Allotment shall stand automatically cancelled and the EMD will be forfeited. The initial payment will be refunded within a period of 30 days without interest.
 - (iii) All payments shall be made by means of the online payment through TANSIDCO website.

3. Handing over and taking possession of the Plot:

- 3.1 The possession of the Plot shall be handed over only after the payment of the entire Plot cost and execution of a Memorandum of Understanding (MoU) with the Branch Manager concerned in the prescribed Format. The Allottee shall take possession of the Plot in "as is where is condition".
- 3.2 The Plot would be deemed to have been cancelled automatically if
 - (i) The entire Plot cost is paid but the MoU is not executed by the Allottee within a period of 30 days from the date of payment of entire Plot cost.
 - (ii) The Plot is not taken possession within a period of 30 days from the date of execution of MoU.

In such circumstances, only Plot cost paid by the Allottee will be refunded without any interest after deducting the EMD and Administrative charges.

4. Utilization / Commencement of production:

- 4.1 The Plot shall be utilized only for the purpose for which it was allotted.
- 4.2 The construction of the industrial building on the Plot shall be commenced within 3 months from the date of taking possession of the Plot by obtaining the necessary Approvals from the Competent Authorities.
- 4.3 The Allottee shall submit the plan of action towards the utilization of the plot to TANSIDCO and TANSIDCO will monitor the work in progress as per the Plan of action at the intervals of three months time till the utilization of the Industrial plot.
- 4.4 The production shall be commenced within 24 months from the date of taking over the possession of the Plot.
- 4.5 The Allottee should obtain the requisite approval / license / permission of the Competent Authorities under the law for the time being in force relating to the proposed industry.
- 4.6 The building constructed in the Plot shall be in conformity with the by-laws of the local body / or Development Control Regulation (DCR), building regulations in force from time to time. Any building constructed on the Plot without obtaining the approval of the local authorities concerned or in violation of the terms and conditions of such approval shall be demolished if so directed by TANSIDCO or the Authorities concerned or will be demolished by TANSIDCO at the cost of the Allottee.
- 4.7 The Allottee should provide a culvert in front of the entrance of the Plot at his own cost without obstructing drainage so as to have a free flow of storm water.

- 4.8 If the production is not commenced by the Allottee within the stipulated time specified in Clause 4.4, an extension period of 12 months shall be given, subject to payment of 10% penalty on the prevailing cost of the Plot.
- 4.9 If the production is not commenced by the Alfottee within the extension period specified in Clause 4.8, a further extension period of 12 months shall be given, subject to payment of 20% penalty on the prevailing cost of the Plot. No further extension will be granted and action will be taken by TANSIDCO to cancel the Allotment Order.
- 4.10 The Allottee shall not dig any well/ bore well/ tube well within the Plot allotted except with the prior permission of TANSIDCO subject to the conditions as applicable.
- 4.11 The Allottee shall not draw water from bore wells / open wells / tube wells sunk in private lands adjacent to the Industrial Estate unauthorisedly trespassing the premises of the Industrial Estate. If any time, such trespass is found by TANSIDCO, the trespassed waterline shall be removed by TANSIDCO and the expenditure will be recovered from the Allottee.
- 4.12 Even though the Allottee obtained permission from TANSIDCO as in Clause 4.10, the Allottee shall not be allowed to sell the drawn water from the Industrial Plot allotted to them. The water drawn from the well/ bore well/ tube well within the Industrial Plot shall be utilized only for their industrial purpose in the allotted plot and not for any other purposes.

5. Change in Name / Line of Activity / Constitution / Ownership:

- 5.1 Change in the name of the Unit / LLP / Partnership firm / Company or Line of Activity in any manner whatsoever shall be made only with the prior approval of TANSIDCO in writing. Any application made by the Allottee for such approval will be considered by TANSIDCO subject to the terms and conditions and on payment of the fees prescribed by TANSIDCO from time to time.
- 5.2 (i) Change of constitution /Change in Constitution / Lease of allotted land / transfer of ownership of the allottee or legal statusof the Plot shall be permitted only after minimum 50% utilization of Plot area by the original Allottee for the purpose for which it was allotted and execution of Sale Deed on payment of the fees prescribed by TANSIDCO from time to time subject to the terms and conditions.
 - (ii) Change of constitution means any change of the constitution such as proprietorship firm into a partnership firm or LLP or company and vice versa.
 - (iii) Change in constitution of an Allottee means a change in the ownership pattern of the Allottee in such a way that the ownership of more than 50% of the Allottee(Unit / LLP / Partnership firm / Company) is acquired by a new party.

- 5.3 In case the Change of constitution / Change in constitution / lease of allotted land / transfer of allotted land / transfer of ownership of the allottee or legal status is necessitated before execution of Sale Deed due to exigencies like technical collaboration, demise of the Proprietor / Partners / Shareholders, the same shall be considered on merits of the case subject to collection of difference in Plot cost between the allotted cost and the prevailing cost.
- 5.4 Where the Change of constitution / Change in constitution/lease of allotted land / transfer of allotted land / transfer of ownership of the allottee or legal status is required among the family members before execution of Sale Deed due to demise of the Proprietor / Partners / Shareholders, and / or induction of new Partners / Shareholders from the blood relatives of the Proprietor / Partners / Shareholders, the samemay be permitted without collecting difference in Plot cost.

6. Mortgage of the Plot:

6.1 Creation of charge over the Plot to raise Term Loan or working capital or other financial assistance from any Banks/ Financial Institution / Non Banking Financial companies (NBFCs) for the proposed industry shall be made only after obtaining No Objection Certificates (NOC) from TANSIDCO. Such financial assistance shall be utilized only for the purpose of setting up / operation of the industry in the allotted Plot.

7. Surrender of the Plot:

7.1 As and when the Allottee decides that Plot or Part thereof is no longer required by the Allottee for the purposes for which it was allotted, the Allottee shall surrender the Plot or Part thereof to TANSIDCO so as to enable the utilization by allotting to needy entrepreneurs. However, TANSIDCO reserves the right to accept the part surrender of the Plot. On acceptance of the surrender, only proportionate Plot cost estimated on the basis of the Plot cost paid by the Allotteefor the surrendered extent will be refunded without any interest after deducting the EMD, Administrative charges and dues payable to TANSIDCO. No compensation will be paid for any structures created / development works undertaken in the Plot by the Allottee.

8. Cancellation of Allotment:

8.1 TANSIDCO reserves the right to serve 45 days show cause notice for cancellation of the Allotment, if it is found that the Allottee has not put to use the Plot for the purpose for which it was allotted and is in non-compliance of the terms and conditions of the Allotment Order including non-implementation of the project and / or having unutilized extent of the allotted Plot and/or non-payment of dues.

8.2 Unless it is rectified by the Allottee within a period of 45 days from the date of show cause notice, TANSIDCO reserves the right to cancel the Allotment and initiate proceedings for resumption of the Plot or Part thereof under the provisions of the Tamil Nadu Public Premises (Eviction of Unauthorized Occupants) Act, 1975 (Tamil Nadu Act 1 of 1976) or under any Statute for time being in force for eviction against the Allottee as well as for any other mode of recovery in force at that point of time as prescribed by law. In such circumstances, only Plot cost paid by the Allottee will be refunded without any interest after deducting the EMD, Administrative charges and dues payable to TANSIDCO.No compensation will be paid for any structures created / development works undertaken by the Allottee. Further, any damages payable to TANSIDCO under the provisions of the said Act will be recovered from the Allottee.

9. Payment of charges and taxes :

- 9.1 Subject to availability, TANSIDCO will provide water supply from common source on payment of the charges as fixed by TANSIDCO from time to time. Failure to pay the water charges will lead to disconnection of water supply without any prior intimation.
- 9.2 Maintenance expenditure incurred towards the common amenities/facilities such as roads, drainage, sewerage, street lights, avenue plants etc. shall be apportioned among the Allottees of the Industrial Estate. The Allottee shall pay the same without any demur within the prescribed time. TANSIDCO reserves the right to take any action as it may deem fit including disconnection of EB supply, water supply, other basic amenities and withholdingof No Objection Certificates (NOC) to recover the dues. Further necessary legal action will be initiated under the provisions of the Transfer of Property Act, 1882 (Act IV of 1882), Indian Contract Act, 1872 (Act IX of 1872), the Registration Act, 1908 (Act XVI of 1908) and the Specific Relief Act, 1963 (Act 47 of 1963) which constitute the Civil Code of India and govern the transfer of immovable property.
- 9.3 Property tax and other applicable taxes and charges payable now or hereafter become payable in respect of the Plot shall be paid by the Allottee to the Concerned Authorities.

10. Execution of Sale Deed:

- 10.1 Sale Deed in respect of the Plot will be executed in the name of the Unit / LLP / Partnership firm / Company subject to fulfilling the following conditions:
 - (i) Commencement of production certified by the concerned Branch Manager.
 - (ii) Utilization of atleast 50% of the allotted extent certified by the concerned Branch Manager.
 - (iii) Payment of all dues including water charges, maintenance charges etc.

- (iv) Submission of copy of Statutory Approvals / Permissions / No Objection Certificates (NOC) relevant to the proposed industry.
- (v) Uploading the geotagged photo with time stamp.
- 10.2 The Allottee shall produce the following documents to TANSIDCO for the execution of Sale Deed in respect of the Plot allotted to them subject to the applicability of the concern Unit / LLP / Partnership firm / Company:
 - (i) Copy of EB receipt (proof of electricity consumption).
 - (ii) Copy of Udyam Registration certificate.
 - (iii) List of machineries erected.
 - (iv) Copy of Demand order/Job order.
 - (v) Copy of Purchase invoice of raw material.
 - (vi) Copy of sale invoice where the sale have been made.
 - (vii) Copy of GST registration.
 - (viii) Any other evidential documents as may be demanded by TANSIDCO in support of commencement of production.

11. General Conditions:

- 11.1 The Allottee shall keep TANSIDCO indemnified against any and all claims for damages which may be caused to any adjoining buildings or other premises as a consequence of the erection of the buildings and industrial installations by the Allottee. The Allottee shall also keep TANSIDCO indemnified against all payments whatsoever which, during the progress of work, may become payable or be demanded by the Local Authority in respect of the said works, or of anything done under the authority herein contained.
- 11.2 No temporary or semi-permanent structures shall be built on the Plot except during the period of construction.
- 11.3 TANSIDCO or persons authorized by TANSIDCO shall have the right to enter upon and inspect the Plot at any time without any prior notice.
- 11.4 TANSIDCO shall have the right of having access into and utilizing any portion of the Plot as required at all times for the limited purpose of laying pipelines, cables, underground drainage, channels, etc.

- 11.5 The Allottee shall not dump debris or any waste materials within the premises of the Industrial Estate.
- 11.6 TANSIDCO is not liable or under no obligation to provide electrical energy required for the industry and it is the responsibility of the Allottee to obtain the required power supply from the TNEB.
- 11.7 The Allottee shall not carry out any other activity like residential, commercial unless specifically permitted in the allotted Plot other than the industrial purposes which is prejudicial to the preservation of characteristics and homogeneity of the Industrial Estate or which is punishable under any law.
- 11.8 The Allottee may be allowed to set up a display center in the allotted Plot wherever necessary with a prior permission of TANSIDCO along with a condition to display the product which is manufactured in the industrial plot and not for any other product. No retail outlet will be permitted in the allotted plot. If it is found that he is using the display center//retail outletfor any other product other than the product manufactured in the industrial plot ,TANSIDCO will initiate necessary legal action for the same.
- 11.9 The Allottee is allowed to utilize only a maximum of 20% of the industrial plot area for the display center for which the Allottee must get No Objection Certificate (NOC) from the TANSIDCO for converting the portion of allotted Industrial Plot to Display center of their own product subject to collection of difference in prevailing plot cost for commercial purpose.
- 11.10 The Allottee shall comply with all conditions stipulated in the statutory approvals / clearances / No Objection Certificates (NOC) obtained from the Competent Authorities from time to time. In case of non-compliance, the same will be intimated to the Competent Authorities for remedial action.
- 11.11 Industrial effluent should not be let out into the sewer lines of the Industrial Estate. Separate effluent treatment plant (solid / liquid / gas) and equipment to prevent noise, vibrations and fire, health hazards, etc. shall be erected or installed at the industrial premises by the Allottee at his cost in accordance with the standards prescribed by the Tamil Nadu Pollution Control Board or other Authorities concerned and necessary clearance should be obtained from the said Board or other Authorities concerned before commencement of production and a copy thereof to be produced to TANSIDCO.
- 11.12 Any change in the address of the Registered Office or Administrative Office of the Allottee shall be informed to TANSIDCO failing which any communication, demand, notice intended and required to be served on the Allottee will be addressed to the last known address and the same shall be deemed to have been sufficiently served on the Allottee.
- 11.13 If TANSIDCO found that the allotment is obtained by the Allottee by misrepresentation or fraud, TANSIDCO shall be at liberty to immediately cancel the Allotment.

11.14 The Allottee shall not close, modify or alter the sewage / water lines inside the allotted plot without the permission of TANSIDCO and TANSIDCO shall be entitled to enter upon the Plot to carry out such repairs / modifications / alterations in sewage / water lines as the TANSIDCO may consider necessary.

11.15 On matters not specifically stipulated in this Order, TANSIDCO shall be entitled to give directions to the Allottee and the Allottee shall comply with such directions from time to time as per the existing guidelines of the government. Any default in carrying out such directions will be a breach of the

conditions of Allotment.

12 The Allottee irrevocably agrees that the appropriate judicial forums of Tamil Nadu shall have jurisdiction to hear, settle and/or determine any dispute, controversy or claim (including any non-contractual dispute, controversy or claim) arising out of or in connection with this allotment, including

any question regarding its existence, validity, formation or termination.

13 The Allottee shall furnish the name of the product, export details if any, annual turnover and GST

invoice copy to TANSIDCO on or before 1st June of every year.

14 The Allottee must forward the duly signed copy of the Allotment Order No. 2029/EG2/2024-2 dated 15-03-2024 by acknowledging the terms and conditions specified therein and by affixing the seal of the Unit / Partnership firm / LLP / Company to this Office as a token of having accepted the terms and conditions contained herein within 15 days from the date of this Allotment Order, failing which it will

be construed that the Allottee accepted the terms and conditions of the Allotment Order.

15 You are requested to make plot cost payment through the portal "www.tansidco.org/client" with your

Login Id and Password given below

Password: 9940023926

Login ID: tansidco2023974

Yours faithfully
For TANSIDCO LTD.,

Deputy General Wanger (Legal)

Copy to:

The Branch Manager,

TANSIDCO Branch Office.

Villupuram.



TAMIL NADU SMALL INDUSTRIES DEVELOPMENT CORPORATION LIMITED(TANSIDCO)

Regd. Office: SIDCO Corporate Office Building, Thiru-Vi-Ka Industrial Estate, Guindy, Chennai - 600 032 CIN: U74999TN1970SGC005821 TANSIDCO Maniforwary

Date: 01-09-2023.

By RPAD

Phone: 2250 1461 / 2250 1422 / 2250 1210 Fax: 2250 0792 E-mail: ho.sidco@nic.in website : www.tansidco.tn.gov.in

Rc.No. 9599/EG2/2023-I-13

ALLOTMENT ORDER FOR PLOT - OUTRIGHT SALE BASIS

To
Thiru Ekambaranathan Ramanathan,
M/s. Omexa Private Limited,
AP1727B, 102nd Street 14th Sector, K K Nagar
pincode:600078
Mobile No 9940023926

Sub: TANSIDCO – Industrial Estate at Tindivanam Mega Pharma Cluster – Allotment of Plot bearing No. 28, to M/s. Omexa Private Limited on OUTRIGHT SALE BASIS – Provisional Allotment Orders – Issued.

Ref: 1. Your Online Application No TANSIDCO/2023/205 dated 10-07-2023.

2. Screening Committee held on dated 16-08-2023.

1.

1.1 The following Plot in TANSIDCO Industrial Estate at Tindivanam Mega Pharma Cluster is allotted to M/s. Omexa Private Limited on Outright Sale basis for setting up an Industry thereon for the line of activity of Biosimilars.

S.No.	Description	Particulars
a)	Plot No.	28(1.860),
b)	Total Extent of the Plot (in Sq.m)	7527.160
c)	Total Extent of the Plot (in Acres)	1.860

1.2 The Allotment Order is issued to the Private Limited Company consisting of the following Directors:

S.No.	Name	Shareholding (%)
1	Thiru.Ekambaranathan Ramanathan	50
2	Thiru.Rajan Garg	50
		100

2. Plot Cost and Terms of Payment:

- 2.1 The cost of the Plot is **Rs.** 19593700/- [10534200 * 1.860 and rounded off to nearest 100/-] (Rupees One Crore Ninety Five Lakhs Ninety Three Thousand Seven Hundred only) at the rate of Rs. 10534200/- per Acre which is inclusive of land cost of Rs.8476200/- per acre and SPV contribution of Rs.2058000/- per acre towards the development of common facilities in Mega Pharma Park at Tindivanam.
- 2.2 The cost of the Plot shall be paid in the manner indicated below:
 - (i) The initial payment of 50% of the Plot cost amounting to Rs.9796900/- (Rupees Ninety Seven Lakhs Ninety Six Thousand Nine Hundred Only) shall be paid within 2 months from the date of Allotment Order i.e. on or before 31-10-2023 failing which the Allotment shall stand automatically cancelled and the Earnest Money Deposit (EMD) will be forfeited.
 - (ii) The balance payment of 50% of the Plot cost after adjusting the EMD (Rs.10000/-) amounting to Rs.9786800/- (Rupees Ninety Seven Lakhs Eighty Six Thousand Eight Hundred Only) shall be paid within 4 months from the date of Allotment Order i.e. on or before 31-12-2023 failing which the Allotment shall stand automatically cancelled and the EMD will be forfeited. The initial payment will be refunded within a period of 30 days without interest.
 - (iii) All payments shall be made by means of online payment through TANSIDCO website.

3. Handing over and taking possession of the Plot:

- 3.1 The possession of the Plot shall be handed over only after the payment of the entire Plot cost and execution of a Memorandum of Understanding (MoU) with the Branch Manager concerned in the prescribed Format. The Allottee shall take possession of the Plot in "as is where is condition".
- 3.2 The Plot would be deemed to have been cancelled automatically if
 - (i) The entire Plot cost is paid but the MoU is not executed by the Allottee within a period of 30 days from the date of payment of entire Plot cost.
 - (ii) The Plot is not taken possession within a period of 30 days from the date of execution of MoU.

In such circumstances, only Plot cost paid by the Allottee will be refunded without any interest after deducting the EMD and Administrative charges.

4. Utilization / Commencement of production :

- 4.1 The Plot shall be utilized only for the purpose for which it was allotted.
- 4.2 The construction of the industrial building on the Plot shall be commenced within 3 months from the date of taking possession of the Plot by obtaining the necessary Approvals from the Competent Authorities.
- 4.3 The Allottee shall submit the plan of action towards the utilization of the plot to TANSIDCO and TANSIDCO will monitor the work in progress as per the Plan of action at the intervals of three months time till the utilization of the Industrial plot.
- 4.4 The production shall be commenced within 24 months from the date of taking over the possession of the Plot.
- 4.5 The Allottee should obtain the requisite approval / license / permission of the Competent Authorities under the law for the time being in force relating to the proposed industry.
- 4.6 The building constructed in the Plot shall be in conformity with the by-laws of the local body / or Development Control Regulation (DCR), building regulations in force from time to time. Any building constructed on the Plot without obtaining the approval of the local authorities concerned or in violation of the terms and conditions of such approval shall be demolished if so directed by TANSIDCO or the Authorities concerned or will be demolished by TANSIDCO at the cost of the Allottee.
- 4.7 The Allottee should provide a culvert in front of the entrance of the Plot at his own cost without obstructing drainage so as to have a free flow of storm water.

- 4.8 If the production is not commenced by the Allottee within the stipulated time specified in Clause 4.4, an extension period of 12 months shall be given, subject to payment of 10% penalty on the prevailing cost of the Plot.
- 4.9 If the production is not commenced by the Allottee within the extension period specified in Clause 4.8, a further extension period of 12 months shall be given, subject to payment of 20% penalty on the prevailing cost of the Plot. No further extension will be granted and action will be taken by TANSIDCO to cancel the Allotment Order.
- 4.10 The Allottee shall not dig any well/ bore well/ tube well within the Plot allotted except with the prior permission of TANSIDCO subject to the conditions as applicable.
- 4.11 The Allottee shall not draw water from bore wells / open wells / tube wells sunk in private lands adjacent to the Industrial Estate unauthorisedly trespassing the premises of the Industrial Estate. If any time, such trespass is found by TANSIDCO, the trespassed waterline shall be removed by TANSIDCO and the expenditure will be recovered from the Allottee.
- 4.12 Even though the Allottee obtained permission from TANSIDCO as in Clause 4.10, the Allottee shall not be allowed to sell the drawn water from the Industrial Plot allotted to them. The water drawn from the well/ bore well/ tube well within the Industrial Plot shall be utilized only for their industrial purpose in the allotted plot and not for any other purposes.

5. Change in Name / Line of Activity / Constitution / Ownership :

- 5.1 Change in the name of the Unit / LLP / Partnership firm / Company or Line of Activity in any manner whatsoever shall be made only with the prior approval of TANSIDCO in writing. Any application made by the Allottee for such approval will be considered by TANSIDCO subject to the terms and conditions and on payment of the fees prescribed by TANSIDCO from time to time.
- 5.2 (i) Change of constitution /Change in Constitution / Lease of allotted land / transfer of ownership of the allottee or legal statusof the Plot shall be permitted only after minimum 50% utilization of Plot area by the original Allottee for the purpose for which it was allotted and execution of Sale Deed on payment of the fees prescribed by TANSIDCO from time to time subject to the terms and conditions.
 - (ii) Change of constitution means any change of the constitution such as proprietorship firm into a partnership firm or LLP or company and vice versa.
 - (iii) Change in constitution of an Allottee means a change in the ownership pattern of the Allottee in such a way that the ownership of more than 50% of the Allottee(Unit / LLP / Partnership firm / Company) is acquired by a new party.

- 5.3 In case the Change of constitution / Change in constitution / lease of allotted land / transfer of allotted land / transfer of ownership of the allottee or legal status is necessitated before execution of Sale Deed due to exigencies like technical collaboration, demise of the Proprietor / Partners / Shareholders, the same shall be considered on merits of the case subject to collection of difference in Plot cost between the allotted cost and the prevailing cost.
- 5.4 Where the Change of constitution / Change in constitution/lease of allotted land / transfer of allotted land / transfer of ownership of the allottee or legal status is required among the family members before execution of Sale Deed due to demise of the Proprietor / Partners / Shareholders, and / or induction of new Partners / Shareholders from the blood relatives of the Proprietor / Partners / Shareholders, the samemay be permitted without collecting difference in Plot cost.

6. Mortgage of the Plot:

6.1 Creation of charge over the Plot to raise Term Loan or working capital or other financial assistance from any Banks/ Financial Institution / Non Banking Financial companies (NBFCs) for the proposed industry shall be made only after obtaining No Objection Certificates (NOC) from TANSIDCO. Such financial assistance shall be utilized only for the purpose of setting up / operation of the industry in the allotted Plot.

7. Surrender of the Plot:

7.1 As and when the Allottee decides that Plot or Part thereof is no longer required by the Allottee for the purposes for which it was allotted, the Allottee shall surrender the Plot or Part thereof to TANSIDCO so as to enable the utilization by allotting to needy entrepreneurs. However, TANSIDCO reserves the right to accept the part surrender of the Plot. On acceptance of the surrender, only proportionate Plot cost estimated on the basis of the Plot cost paid by the Allotteefor the surrendered extent will be refunded without any interest after deducting the EMD, Administrative charges and dues payable to TANSIDCO. No compensation will be paid for any structures created / development works undertaken in the Plot by the Allottee.

8. Cancellation of Allotment:

8.1 TANSIDCO reserves the right to serve 45 days show cause notice for cancellation of the Allotment, if it is found that the Allottee has not put to use the Plot for the purpose for which it was allotted and is in non-compliance of the terms and conditions of the Allotment Order including non-implementation of the project and / or having unutilized extent of the allotted Plot and/or non-payment of dues.

8.2 Unless it is rectified by the Allottee within a period of 45 days from the date of show cause notice, TANSIDCO reserves the right to cancel the Allotment and initiate proceedings for resumption of the Plot or Part thereof under the provisions of the Tamil Nadu Public Premises (Eviction of Unauthorized Occupants) Act, 1975 (Tamil Nadu Act 1 of 1976) or under any Statute for time being in force for eviction against the Allottee as well as for any other mode of recovery in force at that point of time as prescribed by law. In such circumstances, only Plot cost paid by the Allottee will be refunded without any interest after deducting the EMD, Administrative charges and dues payable to TANSIDCO.No compensation will be paid for any structures created / development works undertaken by the Allottee. Further, any damages payable to TANSIDCO under the provisions of the said Act will be recovered from the Allottee.

9. Payment of charges and taxes:

- 9.1 Subject to availability, TANSIDCO will provide water supply from common source on payment of the charges as fixed by TANSIDCO from time to time. Failure to pay the water charges will lead to disconnection of water supply without any prior intimation.
- 9.2 Maintenance expenditure incurred towards the common amenities/facilities such as roads, drainage, sewerage, street lights, avenue plants etc. shall be apportioned among the Allottees of the Industrial Estate. The Allottee shall pay the same without any demur within the prescribed time. TANSIDCO reserves the right to take any action as it may deem fit including disconnection of EB supply, water supply, other basic amenities and withholdingof No Objection Certificates (NOC) to recover the dues. Further necessary legal action will be initiated under the provisions of the Transfer of Property Act, 1882 (Act IV of 1882), Indian Contract Act, 1872 (Act IX of 1872), the Registration Act, 1908 (Act XVI of 1908) and the Specific Relief Act, 1963 (Act 47 of 1963) which constitute the Civil Code of India and govern the transfer of immovable property.
- 9.3 Property tax and other applicable taxes and charges payable now or hereafter become payable in respect of the Plot shall be paid by the Allottee to the Concerned Authorities.

10. Execution of Sale Deed:

- 10.1 Sale Deed in respect of the Plot will be executed in the name of the Unit / LLP / Partnership firm / Company subject to fulfilling the following conditions:
 - (i) Commencement of production certified by the concerned Branch Manager.
 - (ii) Utilization of atleast 50% of the allotted extent certified by the concerned Branch Manager.
 - (iii) Payment of all dues including water charges, maintenance charges etc.

- (iv) Submission of copy of Statutory Approvals / Permissions / No Objection Certificates (NOC) relevant to the proposed industry.
- (v) Uploading the geotagged photo with time stamp.
- 10.2 The Allottee shall produce the following documents to TANSIDCO for the execution of Sale Deed in respect of the Plot allotted to them subject to the applicability of the concern Unit / LLP / Partnership firm / Company:
 - (i) Copy of EB receipt (proof of electricity consumption).
 - (ii) Copy of Udyam Registration certificate.
 - (iii) List of machineries erected.
 - (iv) Copy of Demand order/Job order.
 - (v) Copy of Purchase invoice of raw material.
 - (vi) Copy of sale invoice where the sale have been made.
 - (vii) Copy of GST registration.
 - (viii) Any other evidential documents as may be demanded by TANSIDCO in support of commencement of production.

11. General Conditions:

- 11.1 The Allottee shall keep TANSIDCO indemnified against any and all claims for damages which may be caused to any adjoining buildings or other premises as a consequence of the erection of the buildings and industrial installations by the Allottee. The Allottee shall also keep TANSIDCO indemnified against all payments whatsoever which, during the progress of work, may become payable or be demanded by the Local Authority in respect of the said works, or of anything done under the authority herein contained.
- 11.2 No temporary or semi-permanent structures shall be built on the Plot except during the period of construction.
- 11.3 TANSIDCO or persons authorized by TANSIDCO shall have the right to enter upon and inspect the Plot at any time without any prior notice.
- 11.4 TANSIDCO shall have the right of having access into and utilizing any portion of the Plot as required at all times for the limited purpose of laying pipelines, cables, underground drainage, channels, etc.
- 11.5 The Allottee shall not dump debris or any waste materials within the premises of the Industrial Estate.

- 11.6 TANSIDCO is not liable or under no obligation to provide electrical energy required for the industry and it is the responsibility of the Allottee to obtain the required power supply from the TNEB.
- 11.7 The Allottee shall not carry out any other activity like residential, commercial unless specifically permitted in the allotted Plot other than the industrial purposes which is prejudicial to the preservation of characteristics and homogeneity of the Industrial Estate or which is punishable under any law.
- 11.8 The Allottee may be allowed to set up a display center in the allotted Plot wherever necessary with a prior permission of TANSIDCO along with a condition to display the product which is manufactured in the industrial plot and not for any other product. No retail outlet will be permitted in the allotted plot. If it is found that he is using the display center//retail outletfor any other product other than the product manufactured in the industrial plot ,TANSIDCO will initiate necessary legal action for the same.
- 11.9 The Allottee is allowed to utilize only a maximum of 20% of the Industrial plot area for the display center for which the Allottee must get No Objection Certificate (NOC) from the TANSIDCO for converting the portion of allotted Industrial Plot to Display center of their own product subject to collection of difference in prevailing plot cost for commercial purpose.
- 11.10 The Allottee shall comply with all conditions stipulated in the statutory approvals / clearances / No Objection Certificates (NOC) obtained from the Competent Authorities from time to time. In case of non-compliance, the same will be intimated to the Competent Authorities for remedial action.
- 11.11 Industrial effluent should not be let out into the sewer lines of the Industrial Estate. Separate effluent treatment plant (solid / liquid / gas) and equipment to prevent noise, vibrations and fire, health hazards, etc. shall be erected or installed at the industrial premises by the Allottee at his cost in accordance with the standards prescribed by the Tamil Nadu Pollution Control Board or other Authorities concerned and necessary clearance should be obtained from the said Board or other Authorities concerned before commencement of production and a copy thereof to be produced to TANSIDCO.
- 11.12 Any change in the address of the Registered Office or Administrative Office of the Allottee shall be informed to TANSIDCO failing which any communication, demand, notice intended and required to be served on the Allottee will be addressed to the last known address and the same shall be deemed to have been sufficiently served on the Allottee.
- 11.13 If TANSIDCO found that the allotment is obtained by the Allottee by misrepresentation or fraud, TANSIDCO shall be at liberty to immediately cancel the Allotment.
- 11.14 The Allottee shall not close, modify or alter the sewage / water lines inside the allotted plot without the permission of TANSIDCO and TANSIDCO shall be entitled to enter upon the Plot to carry out such repairs / modifications / alterations in sewage/water lines as the TANSIDCO may consider necessary.

- 11.15 On matters not specifically stipulated in this Order, TANSIDCO shall be entitled to give directions to the Allottee and the Allottee shall comply with such directions from time to time as per the existing guidelines of the government. Any default in carrying out such directions will be a breach of the conditions of Allotment.
 - 12. The Allottee irrevocably agrees that the appropriate judicial forums of Tamil Nadu shall have jurisdiction to hear, settle and/or determine any dispute, controversy or claim (including any non-contractual dispute, controversy or claim) arising out of or in connection with this allotment, including any question regarding its existence, validity, formation or termination.
 - 13. The Allottee shall furnish the name of the product, export details if any, annual turnover and GST invoice copy to TANSIDCO on or before 1st June of every year.
 - 14. The Allottee must forward the duly signed copy of the Allotment Order No.Rc.No. 9599/EG2/2023-I-13 dated 01-09-2023 by acknowledging the terms and conditions specified therein and by affixing the seal of the Unit / Partnership firm / LLP / Company to this Office as a token of having accepted the terms and conditions contained herein within 15 days from the date of this Allotment Order, failing which it will be construed that the Allottee accepted the terms and conditions of the Allotment Order.
 - 15. You are requested to make plot cost payment through the portal "www.tansidco.org/client" with your Login Id and Password given below

Login ID: tansidco2023205

Password: 9940023926

Yours faithfully For TANSIDCO LTD.,

General Manager

Copy to:

The Branch Manager, SIDCO Branch Office, Villupuram



Dr. JAYANTHI. M, I.F.S MEMBER SECRETARY

STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY – TAMIL NADU

3rd Floor, Panagal Maaligai, No.1 Jeenis Road, Saidapet, Chennai-15. Phone No.044-24359973 Fax No. 044-24359975

ENVIRONMENTAL CLEARANCE (EC)

Letter No. SEIAA-TN/F. 6497/EC/8(b)/681/2019 dated; 27.11.2019.

To

The Managing Director

M/s. State Industries Promotion Corporation of Tamil Nadu Limited.

19-A, Rukmani Lakshmipathy Road

Post Box No.7223

Egmore

Chennai-600 008

Sir.

Sub: SEIAA, TN - Environmental Clearance — Proposed establishment of Industrial Park at Thindivanam by M/s. State Industries Promotion Corporation of Tamil Nadu Limited at S.F. No. 1, 2, 3, 4, 5, 6, 10pt, 13pt, 14, 15, 16, 17, 18, 19, 20, 21pt, 22/1, 2, 32, 33, 34, 35, 36, 37, 38pt, 39, 40, 41,42,43/1pt, 2, 45, 46, 47, 48/1, 49, 50, 51, 52, 53, 54, 55, 56, 57, 60, 61/1, 2,3pt, 62, 63, 64, 118, 120, 121, 123, 125, 126, 129 of Pelakuppam Village, 46pt, 47pt, 48pt, 50pt, 51, 52pt, 53pt, 55pt of Venmaniyathoor Village, 181pt, 182, 183, 184, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 212, 213pt, 214, 237, 244, 245 & 246pt of Kollar Village, Thindivanam Taluk, Villupuram District, Tamil Nadu - Issued – Regarding.

Ref: 1. Your application for Terms of Reference dated: 01.02.2018

2. ToR Issued by SEIAA-TN Vide Lr.No.SEIAA-TN/F.No.6497/2018/8(b)/ToR-

506/2018 dated: 16.0

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- 3. EIA report submitted to SEIAA-TN on 05.04.2019
- 4. Minutes of the 133rd SEAC Meeting held on 25.07.2019
- 5. Proponent reply dated: 30.10.2019
- 6. Minutes of the 139th SEAC Meeting held on 23.11.2019
- 7. Minutes of the 362nd SEIAA Meeting held on 27.11.2019

This has reference to your application 1st cited, the proposal is for obtaining Environmental Clearance to establish a construction project under Category B2 and Schedule S.No. 8(b) under the Environment Impact Assessment Notification, 2006, as amended.

The Competent Authority and Authorized signatory furnished detailed information in Form 1 and Form 1A and liquidate enclosures are as Annexures:

Annexure 1

	PROJECT DETAILS				
SL No	Description	Details			
1)	Name of the Project proponent and	The Managing Director			
	address	M/s. State Industries Promotion			
	는 기계	Corporation of Tamil Nadu Limited.			
	7 7 7 7	19-A, Rukmani Lakshmipathy Road			
		Post Box no.7223			
		Egmore			
		Chennai-600 008			
2)	Proposed Activity	Proposed establishment of Industrial			
		Park at Thindivanam			
3)	Schedule No.	8(b)			
4)	Project Location				
	i)Survey No	1, 2, 3, 4, 5, 6, 10pt, 13pt, 14, 15, 16, 17,			
		18, 19, 20, 21pt, 22/1, 2, 32, 33, 34, 35,			
		36, 37, 38pt, 39, 40, 41,42,43/1pt, 2, 45,			
	SURROUMENT IMPACTA	6, 47, 48/1, 49, 50, 51, 52, 53, 54, 55,			

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7) Brief description of the project The proposal is an infrastructure development project. It inv				
	Total IP area		291.60	
		Water bodies (which will	not be encroached)	23.49
		Total developable area		268.1
	7	Solid Waste Management		10.00
	6	Green Belt along roadside		3.5
	5			26.8
	4 Commercial activities		14.5	
	3	Common amenities (EB, Water storage, Fire Services, Administrative Office, etc.)		4.3
	2	2 Roads and Storm water drainage		13.5
	1	Plot area Substitution		195.29
	Sl.No. Description		Area (Hectares)	
6)	Built up Area			
5)		Area of the Land	291.60.5 He	ctares
		iv)District	Villupura	am
		iii)Taluk	Thindivar	nam
			Village	
		ii)Revenue Village	Pelakuppam, Venmaniy	athoor, Kollar
			Kollar	.1 77 11
			213pt, 214, 237, 244,	243 & 240pt
			205, 206, 207, 208,	•
			197, 198, 199, 200, 20	
			181pt, 182, 183, 184,	•
			55pt of Venmaniyathoo	
			46pt, 47pt, 48pt, 50pt	. 51. 52nt. 53i
			Pelakuppam Village,	,
			120, 121, 123, 125	, 126, 129



MEMBER SECRETARY SEIAA-TN development, and such other amenities.

Industrial Park will house industries which do not fall under EIA Notification 2009 and amendments thereof. The proposed industries include the following:

- All General Engineering units such as fabrication, machining, forging, castings etc.,
- Auto components Industries.
- Food Processing Industries.
- Packaging units.

Any other industries that are not under the purview of EIA Notification, 2006

8)	La	nd Use Classification	Patta dry land & G	ovt Poramboke Land	
9)	Green B	elt			
	Sl.No.	Description		Area (Hectares)	
	1.	By SIPCOT outside the plot area By SIPCOT along the Road sides and Central meridian		58.59	
	2.			26.81	
	3.	By Member Industries (30 area allotted to Member Industries 195.29 Ha		3.51	
		Total		88.91	
		Percentage of Green Belt a developable Area of Indus hectares	~	33.16%	
10)	U.	TILITIES-WATER			
	a) '	Total Water Requirements	4 N	MLD	
	b)	Source from where the		Treatment Reverse	
i	water is proposed to be drawn		Osmosis (TTRO Thindivanam Munic 1 MLD for drinkin	<i>'</i>	
				and Drainage Board	
		c) Sewage system	All member units	will be mandated to	

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		11 W7 Ti
		install "Zero Liquid Discharge" based Effluent Treatment Plants to reclaim
		water for recycle/reuse in their utilities
		and green belt development.
		The quantity of sewage that will be
		generated from SIPCOT administrative
		office will be managed in septic tank
		followed by soak pit.
	d) ETP & Recycle line	All member units will be mandated to
		install "Zero Liquid Discharge" based
	·	Effluent Treatment Plants to reclaim
		water for recycle/reuse in their utilities
		and green belt development.
11)	Solid Waste Management	Area of 10Ha has been earmarked for
		establishing a solid waste management
		facility
		SIPCOT will identify a TSDF provider
		and facilitate to establish such a
		treatment, storage and disposal
		facility(TSDF) in line with guidelines of
		CPCB & MoEF & CC
		Solid waste generated will be disposed
		to the approved Municipal Solid Waste
		''
		Management or else SIPCOT will set up
		its facility through renowned agencies
		by outsourcing their services on annual
		contract basis
12)	Power requirement	50MW from TANGEDCO
13)	Project Cost	Rs. 300 Crores
14)	EMP Cost	For Operation Phase:
		Capital Cost -1 Crores,

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MEMBER SECRETARY SEIAA-TN Operation cost- 50 Lakhs per annum

Annexure 2- Affidavit

The Proponent has furnished affidavit in Twenty Rupees stamp paper attested by the Notary stating that

I Thiru. J.Kumargurubaran, IAS, Managing Director, Authorised Signatory, represent M/s. State Industries Promotion Corporation of Tamilnadu Limited (SIPCOT), 19-A, Rukmani Lakshmipathy Road, Egmore, Chennai - 600008.

We have proposed to establish an industrial park over an extent of 291.605 hetctares at Pelakuppam, Kollar & Venmaniyathur villages of Tindivanam taluk, Villupuram district. An application submitted by us seeking Environmental Clearance under the EIA Notification, 2006 is under scrutiny in the Authority. I am furnishing the following undertaking to the Authority, hereby solemnly affirm and state as follows:-

- 1. we will develop Green belt in OSR areas and along the roadsides in 11.31 % of the total developable area of 268.11 hectares i.e 30.32 hectares. Further, we will also ensure the development of green belt in 30% of the allotted area by the member units i.e 58.59 hectares, which is 21.85% of total developable area. It will be made as a mandatory condition in the land allotment order as well as the lease deed to be executed between SIPCOT and allottees. The net area of green belt of the proposed industrial park in the post project scenario will be 88.91 hectares, which is 33.16% of the total developable area of the park.
- 2. We commit to SEIAA that the total water requirement for the park is 4 MLD out of which potable water would be around I MLD and the balance 3 MLD would be for non potable purposes. The required potable water will be obtained from Tamil Nadu Water Supply and Drainage Board (TWAD) and non potable water from Tertiary Treatment Reverse Osmosis (TTRO) plant to be setup at Tindivanam. SIPCOT is already in discussion with Commissioner of Municipal Administration (CMA) for setting up of TTRO plant. We assure that the required permission from the competent Authority for supply of water for entire period of operation will be obtained before applying for Consent for Operation (CTO) from Tamilnadu Pollumontrol Board TNPCB).

MEMBER SECRETARY SEIAA-TN

- 3. We commit to SEIAA that all member units will be mandated to install "Zero Liquid Discharge" based Effluent Treatment Plants to reclaim water for recycle/reuse in their utilities and green belt development. We will mandate to member units to manage the sewage as per TNPCB norms. The solid waste stream will be sent to TNPCB approved vendors/TSDF for proper and ultimate disposal. The quantity of sewage that will be generated from SIPCOT administrative office will only be 1000 litres/day and it will be managed in septic tank followed by soak pit as onsite construction.
- 4. We commit to SEIAA that all member units will be mandated to provide rain water harvesting structures as per norms. SIPCOT will construct percolation tanks for harvesting the rainwater in the project office.
- 5. We commit to SEIAA that we will provide storm water drainage system as open concrete channels, all along the road side for ensuring proper collection of storm water and will let out in the nearby water bodies. We also assure that the storm water drain would not carry any untreated or treated sewage.
- 6. We commit to SEIAA that we will undertake CER activities as per norms with the approval of board of SIPCOT.
- 7. We also assure that our project site does not encroach any water bodies such as rivers, canals, nallas, lakes, ponds, tanks, etc., from its original boundary.
- 8. We are aware that we can be prosecuted under relevant Act and Rules, if we are not ensuring the adherence of the above commitment.

Commitment signed by me as an Authorized signatory of the Project Proponent before the SEIAA, Tamil Nadu.

The project activity is covered in 8(b) of the Schedule and is of B2 category. It does not require Public Consultation as per Para 7 III Stage (3) (i) (d) of EIA Notification, 2006.

The Authority after consideration all the requisite documents with status and data and based on SEAC appraisal and recommendations for issue of Environmental Clearance in its 139th meeting held on 23.11.2019, SEIAA placed the proposal in the



MEMBER SECRETARY
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362nd SEIAA meeting held on 27.11.2019 hereby conveyed Environmental Clearance along with the conditions containing four parts namely

Part - A -Common conditions applicable for Pre-construction, Construction and Operational Phases

Part - B - Specific Conditions - Pre construction phase

Part - C - Specific Conditions - Construction phase

Part – D - Specific Conditions – Operational Phase/Post constructional Phase / Entire life of the project.

Validity:

The SEIAA hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 as amended, with validity for Seven years from the date of issue of EC, subject to the compliance of the terms and conditions stipulated below:

<u>Part - A - Common conditions applicable for Pre-construction, Construction and Operational Phases:</u>

- 1. Any appeal against this environmental clearance shall lie with the Hon'ble National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
- 2. The construction of STP, Sond Waste Management facility, E-waste management facility, DG sets, etc., should be made in the earmarked area only. In any case, the location of these utilities should not be changed later on.
- 3. The Environmental safeguards contained in the application of the proponent /mentioned during the presentation before the State Level Environment Impact Assessment Authority / State Level Expert Appraisal Committee should be implemented in the letter and spirit.
- 4. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire and Rescue Services Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wild Life (Protection) Act, 1972, State / Ceptant Market Conservation Act, 1980 and Regulatory Zone

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- Authority, other statutory and other authorities as applicable to the project shall be obtained by project proponent from the concerned competent authorities.
- 5. The SEIAA reserves the right to add additional safeguard measures subsequently, if non-compliance of any of the EC conditions is found and to take action, including revoking of this Environmental Clearance as the case may be.
- 6. A proper record showing compliance of all the conditions of Environmental Clearance shall be maintained and made available at all the times.
- 7. The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company. The status of compliance of environmental clearance conditions and shall also be sent to the Regional Office of the Ministry of Environment and Forests, Chennai by e-mail.
- 8. The Regional Office of the Ministry located at Chennai shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information / monitoring reports.
- 9. "Consent for Establishment" shall be obtained from the Tamil Nadu Pollution Control Board and a copy shall be submitted to the SEIAA, Tamil Nadu.
- 10. In the case of any change(s) in the scope of the project, a fresh appraisal by the SEAC/SEIAA shall be obtained before implementation.
- 11. The conditions will be enforced inter-alia, under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Public Liability Insurance Act, 1991, along with their amendments, draft Minor Mineral Conservation & Development Rules, 2010 framed under MMDR Act 1957, National Commission for protection of Child Right Rules, 2006 and rules made there under and alexander orders passed by the Hon'ble Supreme

MEMBER SECRETARY SEIAA-TN

- Court of India/Hon'ble High Court of Madras and any other Courts of Law, including the Hon'ble National Green Tribunal relating to the subject matter.
- 12. The Environmental Clearance shall not be cited for relaxing the other applicable rules to this project.
- 13. Failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection) Act, 1986.
- 14. The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of MoEF, Chennai, the respective Zonal Office of CPCB, Bengaluru and the TNPCB. The criteria pollutant levels namely; PM10, PM2.5, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the project shall be monitored.
- 15. The SEIAA, TN may cancel the environmental clearance granted to this project under the provisions of EIA Notification, 2006, if, at any stage of the validity of this environmental clearance, if at is found or if it comes to the knowledge of this SEIAA, TN that the project proponent has deliberately concealed and/or submitted false or misleading information or inadequate data for obtaining the environmental clearance.
- 16. The Environmental Clearance does not imply that the other statutory / administrative clearances shall be granted to the project by the concerned authorities. Such authorities would be considering the project on merits and be taking decisions independently of the Environmental Clearance.
- 17. The SEIAA, TN may alter/modify the above conditions or stipulate any further condition in the interest of environment protection, even during the subsequent period.
- 18. The Environmental Clearance does not absolve the applicant/proponent of his obligation/requirement to obtain other statutory and administrative clearances from other statutory and administrative authorities.

MEMBER SECRETARY SEIAA-TN

- 19. Where the trees need to be cut, compensation plantation in the ratio of 1:10 (i.e. planting of 10 trees for every one tree that is cut) should be done with the obligation to continue maintenance.
- 20. A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive who will report directly to the Head of the Organization and the shortfall shall be strictly reviewed and addressed.
- 21. The EMP cost of Rs.1.5 Crores shall be deposited in a Nationalized bank by opening separate account and the head wise expenses statement shall be submitted to TNPCB with a copy to SEIAA annually.
- 22. The project activity should not cause any disturbance & deterioration of the local bio diversity.
- 23. The project activity should not impact the water bodies. A detailed inventory of the water bodies and forest should be evaluated and fact reported to the Forest Department & PWD for monitoring
- 24. All the assessed flora & fauna should be conserved and protected.
- 25. The proponent should strictly comply with, Tamil Nadu Government Order (Ms) No.84 Environment and forests (EC.2) Department dated 25.06.2018 regarding ban on one time use and throwaway plastics irrespective of thickness with effect from 01.01.2019 under Environment (Protection) Act, 1986.
- 26. As per MoEF & CC, GoI, Office Memorandum dated 30.03.2015, prior clearance from Forestry & Wildlife angle including clearance from obtaining committee of the National Board for Wildlife as applicable shall be obtained before starting the quarrying operation, if the project site is located within 10KM from National Park and Sanctuaries.
- 27. Traffic congestion near the entry and exit points from the roads adjoining the proposed project site must be avoided.
- 28. The safety measures proposed in the report should be strictly followed.

29. The Developer shall ensure that no allotment letter/ sale deed in any form shall be made to house category B industry as prescribed in the

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schedule of EIA notification 2006. However, in case any category A or category B type of industry as prescribed in the schedule of EIA notification 2006 is proposed then the individual unit shall apply and seek Environmental Clearance under the EIA notification 2006.

- 30. The Developer shall mandate the member industries of the Industrial Park to allot 33% of the plot area for green belt development and to install RWH structures.
- 31. The Developer has to ensure that all the member industries within the Industrial Park shall make their own arrangements to achieve zero discharge of the trade effluents, solid waste & E waste management, gaseous emission and noise control measures to achieve the standards prescribed by the TNPCB.
- 32. The project proponent shall ensure that the individual member units will not be allowed to carry out manufacturing of products stipulated in G.O. (Ms) No. 84 dated 25/06/2018 on banning of one time use on and throwaway plastics.
- 33. The project proponent must submit the permissible land use classification certificate obtained from competent authority for the proposed project before obtain the CTE from TNPCB.
- 34. The proponent shall obtain the necessary permission/ NOC of water supply from the TWAD Board/competent Authourity.
- 35. The CER fund shall be utilized as per the office memorandum of MoEF & CC dated 01.05.2018 before obtaining CTO from TNPCB.
- 36. The allotted industrial units shall obtain consent from the TNPCB separately for their establishment & operation in this industrial estate.
- 37. The project proponent shall ensure that 33% of the total area of the project site should be covered with green belt.
- 38. The proponent shall provide Rain Water Harvesting pits so as to recharge the ground water table.
- 39. Discharge of treated sewage shall conform to the norms & standards prescribed by the Tamil Nadu Pollution Control Board.



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- 40. It is the sole responsibility of the proponent that the treated sewage disposed for green belt development/ avenue plantation should not pollute the soil/ ground water/ adjacent canals/ lakes/ ponds, etc.
- 41. The Developer has to ensure that all the member industries within the Industrial Park shall make their own arrangements to achieve zero discharge of the trade effluents,
- 42. The project proponent shall ensure that all the member units should treat and dispose solid waste & E-waste as per the Solid Waste Management Rule2016 as amended and E-Waste Management Rules, 2016
- 43. There shall be no discharge of effluent outside the Industrial Park at any time.
- 44. The Developer shall mandate the member units of the Industrial Park to install adequate APC measures/Acoustic to achieve air emissions standards within permissible limits prescribed by the CPCB.

Part - B - Specific Conditions - Pre construction phase:

- 1. The project authorities should advertise with basic details at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of clearance. The press releases also mention that a copy of the clearance letter is available with the State Pollution Control Board and also at website of SEIAA, TN. The copy of the press release should be forwarded to the Regional Office of the Ministry of Environment and Forests located at Chennai and SEIAA-TN.
- 2. In the case of any change(s) in the scope of the project, a fresh appraisal by the SEAC/SEIAA shall be obtained before implementation.
- 3. A copy of the clearance letter shall be sent by the proponent to the Local Body.

 The clearance letter shall also be put on the website of the Proponent.
- 4. The approval of the competent authority shall be obtained for structural safety of the buildings during earthquake, adequacy of fire fighting equipments, etc as per National Building Code including protection measures from lightning etc before commencement of the work

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- All required sanitary and hygienic measures for the workers should be in place before starting construction activities and they have to be maintained throughout the construction phase.
- 6. Design of buildings should be in conformity with the Seismic Zone Classifications.
- 7. The Construction of the structures should be undertaken as per the plans approved by the concerned local authorities/local administration.
- 8. No construction activity of any kind shall be taken up in the OSR area.
- 9. Consent of the local body concerned should be obtained for using the treated sewage in the OSR area for gardening purpose. The quality of treated sewage shall satisfy the bathing quality prescribed by the CPCB.
- 10. The height and coverage of the constructions shall be in accordance with the existing FSI/FAR norms as per Coastal Regulation Zone Notification, 2011.
- 11. The Project Proponent shall provide car parking exclusively for the visiting guest in the proposed residential apartments as per CMDA norms.
- 12. The project proponent shall ensure the level of basement shall be above maximum flood level.
- 13. The proponent shall prepare completion plans showing Separate pipelines marked with different colours with the following details
 - i. Location of STP, compost system, underground sewer line.
 - ii. Pipe Line conveying the treated effluent for green belt development.
 - iii. Pipe Line conveying the treated effluent for toilet flushing
 - iv. Water supply pipeline
 - v. Gas supply pipe line, if proposed
 - vi. Telephone cable
 - vii. Power cable
 - viii. Strom water drains, and
 - ix. Rain water harvesting system, etc.,. and it shall be made available



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- 14. A First Aid Room shall be provided in the project site during the entire construction and operation phases of the project.
- 15. The present land use surrounding the project site shall not be disturbed at any point of time.
- 16. The green belt area shall be planted with indigenous native trees.
- 17. Natural vegetation listed particularly the trees shall not be removed during the construction/operation phase. In case any trees are likely to be disturbed, shall be replanted.
- 18. During the construction and operation phase, there should be no disturbance to the aquatic eco-system within and outside the area.
- 19. The Provisions of Forest conservation Act 1980, Wild Life Protection Act 1972& Bio diversity Act 2002 should not be violated.
- 20. There should be Fire fighting plan and all required safety plan.
- 21. Regular fire drills should be held to create awareness among owners/ residents.

cement in the

Part - C - Specific Conditions - Construction phase:

1. Construction Schedule:

i) The Project proponent shall have to furnish the probable date of commissioning of the project supported with necessary bar charts to SEIAA-TN.

2. Labour Welfare:

- All the labourers to be engaged for construction should be screened for health and adequately treated before and during their employment on the work at the site.
- ii) Personnel working in dusty areas should wear protective respiratory devices and they should also be provided with adequate training and information on safety and health aspects. Occupational health surveillance program of the workers should be undertaken periodically to observe any contradictions due to exposure to dust and take corrective measures, if need an extremely areas should wear protective respiratory devices and they should also be provided with adequate training and information on safety and health aspects. Occupational health surveillance program of the workers should be undertaken periodically to observe any contradictions due to exposure to dust and take corrective measures, if need to be a supplied to the contradiction of the workers and take corrective measures.

MEMBER SECRETARY SEIAA-TN iii) Periodical medical examination of the workers engaged in the project shall be carried out and records maintained. For the purpose, schedule of health examination of the workers should be drawn and followed accordingly. The workers shall be provided with personnel protective measures such as masks, gloves, boots etc.

3. Water Supply:

- i) The entire water requirement during construction phase may be met from ground water source from the source with approval of the PWD Department of water resources/may be out sourced.
- ii) Provision shall be made for the housing labour within the site with all necessary infrastructures and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.
- iii) Adequate drinking water and sannary facilities should be provided for construction workers at the site. The treatment and disposal of waste water shall be through dispersion trench after treatment through septic tank. The MSW generated shall be disposed through Local Body and the identified dumpsite only.
- iv) Water demand during construction should be reduced by use of premixed concrete, curing agents and other best practices prevalent.
- v) Fixtures for showers, toilet flushing and drinking water should be of low flow type by adopting the use of aerators / pressure reducing devises / sensor based control.

4. Solid Waste Management:

- In the solid waste management plan, the STP sludge management plan for direct use as manure for gardens is not acceptable; it must be cocomposted with biodegradables.
- ii) House hold hazardous waste such as batteries, small electronics, CFL bulbs, expired medical used cleaning solvent bottles should be

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- segregated at source, collected once in a month from residences and disposed as per the SWM rules 2016.
- iii) Domestic solid wastes to be regularly collected in bins or waste handling receptacles and disposed as per the solid waste management rules 2016.
- iv) No waste of any type to be disposed of in any watercourse including drains, canals and the surrounding environment.
- v) E-waste shall be disposed through Authorized vendor as per E-waste (Management and Handling) Rules, 2016 and subsequent amendment.

5. Top Soil Management:

i) All the top soil excavated during construction activities should be stored for use in horticulture/landscape development within the project site.

6. Construction Debris disposals

- i) Disposal of construction debris during construction phase should not create any adverse effect on the neighboring communities and be disposed off only in approved sites, with the approval of Competent Authority with necessary precautions for general safety and health aspects of the people. The construction and demolition waste shall be managed as per Construction & Demolition Waste Management Rules, 2016.
- ii) Construction spoils, including bituminous materials and other hazardous materials, must not be allowed to contaminate watercourses. The dump sites for such materials must be secured so that they should not leach into the adjacent land/ lake/ stream etc.

7. Diesel Generator sets:

i) Low Sulphur Diesel shall be used for operating diesel generator sets to be used during construction phase. The air and noise emission shall conform to the standards prescribed in the Rules under the Environment (Protection) Act, 1986, and the Rules framed thereon.



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- ii) The diesel required for operating stand by DG sets shall be stored in underground tanks fulfilling the safety norms and if required, clearance from Chief Controller of Explosives shall be taken.
- iii) The acoustic enclosures shall be installed at all noise generating equipments such as DG sets, air conditioning systems, cooling water tower etc.

8. Air & Noise Pollution Control:

- i) Vehicles hired for bringing construction materials to the site should be in good condition and should conform to air and noise emission standards, prescribed by TNPCB/CPCB. The vehicles should be operated only during non-peak hours.
- ii) Ambient air and noise levels should conform to residential standards prescribed by the TNPCB, both during day and night. Incremental pollution loads on the ambient air and noise quality should be closely monitored during the construction phase. The pollution abatement measures shall be strictly implemented.
- iii) Traffic congestion near the entry and exit points from the roads adjoining the proposed project site shall be avoided. Parking shall be fully internalized and no public space should be utilized. Parking plan to be as per DTCP norms. The traffic department shall be consulted and any cost effective traffic regulative facility shall be met before commissioning.
- iv) The buildings should have adequate distance between them to allow free movement of fresh air and passage of natural light, air and ventilation.

9. Building material:

- i) Fly-ash blocks should be used as building material in the construction as per the provision of Fly ash Notification of September, 1999 and amended as on 27th August, 2003 and Notification No. S.O. 2807 (E) dated: 03.11.2009.
- ii) Ready-mix concrete shall alone be used in building construction and necessary cube-tests conducted to ascertain their quality.

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iii) Use of glass shall be reduced up to 40% to reduce the electricity consumption and load on air conditioning. If necessary, high quality double glass with special reflecting coating shall be used in windows.

10. Storm Water Drainage:

- i) Storm water management around the site and on site shall be established by following the guidelines laid down by the storm water manual.
- ii) Storm water management plan shall be obtained by engaging the services of Anna University/IIT.

11. Energy Conservation Measures:

- i) Roof should meet prescriptive requirement as per Energy Conservation Building Code by using appropriate thermal insulation material, to fulfill the requirement.
- ii) Opaque wall should meet prescribed requirement as per Energy Conservation Building Code which is mandatory for all air conditioned spaces by use of appropriate thermal insulation material to fulfill the requirement.
- iii) All norms of Energy Conservation Building Code (ECBC) and National Building Code, 2005 as energy conservation have to be adopted Solar lights shall be provided for illumination of common areas.
- iv) Application of solar energy should be incorporated for illumination of common areas, lighting for gardens and street lighting. A hybrids system or fully solar system for a portion of the apartments shall be provided.
- v) A report on the energy conservation measures conforming to energy conservation norms prescribed by the Bureau of Energy Efficiency shall be prepared incorporating details about building materials & technology; R & U factors etc and submitted to the SEIAA in three month's time.
- vi) Energy conservation measures like installation of CFLs/TFLs for lighting the areas outside the building should be integral part of the project design and should be in plantaged project commissioning.

12. Fire Safety:

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- Adequate fire protection equipments and rescue arrangements should be made as per the prescribed standards.
- ii) Proper and free approach road for fire-fighting vehicles upto the buildings and for rescue operations in the event of emergency shall be made.

13. Green Belt Development:

- i) The Project Proponent shall plant tree species with large potential for carbon capture in the proposed green belt area based on the recommendation of the Forest department well before the project is completed.
- ii) The purpose of Green belt around the project is to capture the fugitive emissions and to attenuate the noise generated, in addition to the improvement in the absthetics. A wild range of indigenous plants species should be planted in and around the premise in consultation with the DFO, Viluppuram District / State Agriculture University. The plants species should have thick canopy cover, perennial green nature, native origin and large leaf areas. Medium size trees and small trees alternating with shrubs shall be planted. If possible Miyawaki method of planting i.e planting different types of trees at very close escapement may be tried which will give a good green cover. A total of 15% of the plot area should be designated for green belt which should be raised along the boundaries of the plot and in between blocks in an organized manner
- iii) The proponent shall develop the green belt as per the plan furnished and area earmarked for the greenbelt shall not be alter at any point of time for any other purpose.
- iv) The proponent has to earmark the greenbelt area with dimension and GPS coordinates for the green belt area and the same shall be included in the layout out plan to be submitted for DTCP approval

14. Sewage Treatment Plant:



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- i) The Sewage Treatment Plant (STP) installed should be certified by an independent expert/reputed Academic institutions for its adequacy and a report in this regard should be submitted to the SEIAA, TN before the project is commissioned for operation. Explore the less power consuming systems viz baffle reactor, etc., for the treatment of sewage.
- ii) The Proponent shall install STP as furnished. Any alteration to satisfy the bathing quality shall be informed to SEIAA-TN.
- iii) The project proponent shall operate and maintain the Sewage treatment Plant effectively to meet out the standards prescribed by the CPCB.
- iv) The project proponent shall continuously operate and maintain the Sewage treatment plant to achieve the standards prescribed by the CPCB.
- v) The project proponent has to ensure the complete recycling of treated sewage after achieving the standards prescribed by the CPCB.
- vi) The project proponent has to provide separate standby D.G set for the STP for the continuous operation of the STP in case of power failure.

15. Rain Water Harvesting:

- i) The proponent/ Owner of the Flats shall ensure that roof rain water collected from the covered roof of the buildings, etc shall be harvested so as to ensure the maximum beneficiation of rain water harvesting by constructing adequate sumps so that 100% of the harvested water shall be reused.
- ii) Rain water harvesting for surface run-off, as per plan submitted should be implemented. Before recharging the surface run off, pre-treatment with screens, settlers etc. must be done to remove suspended matter, oil and grease, etc.
- iii) The project activity should not cause any disturbance & deterioration of the local bio diversity.

16. Building Safety:

Lightning arrester shall be properly designed and installed at top of the building and where we consider the state of the building and where we consider the state of the building and where we consider the state of the building and where the building and where the state of the st

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<u>Part - D - Specific Conditions - Operational Phase/Post constructional phase/Entire life of the project:</u>

- 1. There should be Fire fighting plan and all required safety plan.
- 2. Regular fire drills should be held to create awareness among owners/ residents.
- House hold hazardous waste such as batteries, small electronics, CFL bulbs, expired medicines and used cleaning solvent bottles should be segregated at source, collected once in a month from residences and disposed as per the SWM rules 2016.
- 4. The building should not spoil the green views and aesthetics of surroundings and should provide enough clean air space.
- 5. The project proponent has to finnish the certificate stating that the proposed site had not encroached any water body (rivers, canals, lakes, ponds, tanks, etc) from its original boundary shall be obtained from the competent authority before obtaining CTE from TNPCB.
- 6. The project proponent shall obtain the necessary permission for drawl of ground water / surface water required for the project from the competent authority.
- 7. Solar energy saving shall be increased to atleast10% of total energy utilization.
- 8. The project proponent shall comply with the provisions contained in this Ministry's OM vide F.No. 22-65/2017-IA.III dated 1st May 2018, as applicable, regarding Corporate Environment Responsibility.
- 9. The company shall have a well laid down environmental policy duly approved by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest / wildlife norms / conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife norms / conditions and / or shareholders / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF & CC as a part of six-

monthly report.

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SELAA-TN

- 10. The EMP cost shall be printed in the Brochure / Pamphlet for the preparation of the sale of the property and should also mention the component involved.
- 11. The Project proponent shall get due permission from the wetland Authority before the commencement of the work, if applicable.
- 12. The project activities should in no way disturb the manmade structures.
- 13. The Proponent shall do afforestation/ restoration programme contemplated to strengthen the open spaces shall preferably include native species along with the financial forecast for planting and maintenance for 5 years.
- 14. "Consent to Operate" should be obtained from the Tamil Nadu pollution Control Board before the start of the operation of the project and copy shall be submitted to the SEIAA-TN.
- 15. Raw water quality to be checked for portability and if necessary RO plant shall be provided.
- 16. The Proponent should be responsible for the maintenance of common facilities including greening, rain water harvesting, sewage treatment and disposal, solid waste disposal and environmental monitoring including terrace gardening for a period of 3 years. Within one year after handing over the flats to all allottees a viable society or an association among the allottees shall be formed to take responsibility of continuous maintenance of all facilities with required agreements for compliance of all conditions furnished in Environment Clearance (EC) order issued by the SEIAA-TN or the Proponent himself shall maintain all the above facilities for the entire period. The copy of MOU between the buyers Association and proponent shall be communicated to SEIAA-TN.
- 17. The ground water level and its quality should be monitored and recorded regularly in consultation with Ground Water Authority.
- 18. Treated effluent emanating from STP shall be recycled / reused to the maximum extent possible. The treated sewage shall conform to the norms and standards for bathing quality laid down by CPCB irrespective of any use. Necessary measures should be made to mitigate the odour and mosquito problem from STP.



MEMBER SECRETARY SEIAA-TN

- 19. The Proponent shall operate STP continuously by providing stand by DG set in case of power failure.
- 20. Adequate measures should be taken to prevent odour emanating from solid waste processing plant and STP.
- 21. The E waste generated should be collected and disposed to a nearby authorized e-waste centre as per E- waste (Management & Handling), Rules 2016 as amended.
- 22. Diesel power generating sets proposed as source of back-up power during operation phase should be of enclosed type and conform to rules made under the Environment (Protection) Act, 1986. The height of stack of DG sets should be equal to the height needed for the combined capacity of all proposed DG sets.
- 23. The noise level shall be maintained as per MoEF/CPCB/TNPCB guidelines/norms both during day and night time.
- 24. Spent oil from D.G sets should be stored in HDPE drums in an isolated covered facility and disposed as per the Hazardous & other Wastes (Management & Transboundary Movement) Rules 2016. Spent oil from D.G sets should be disposed off through registered recycles.
- 25. The proponent is required to provide a house hold hazardous waste / E-waste collection and disposal mechanism.
- 26. The proponent/ Owner of the Flats shall ensure that storm water drain provided at the project site shall be maintained without choking or without causing stagnation and should also ensure that the storm water shall be properly disposed off in the natural drainage / channels without disrupting the adjacent public. Adequate harvesting of the storm water should also be ensured.
- 27. Used CFLs and TFLs should be properly collected and disposed off/sent for recycling as per the prevailing guidelines/rules of the regulatory authority to avoid mercury contamination.

28. A copy of the Environmental clearance (EC) letter shall be made available to all the allottees along with the sale deed.

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29. Failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection) Act, 1986.

MEMBER SECRETARY SEIAA-TN

Copy to:

- 1. The Principal Secretary to Government, Environment & Forests Dept, Govt. of Tamil Nadu, Fort St. George, Chennai 9.
- The Chairman, Central Pollution Control Board, Parivesh Bhavan,
 CBD Cum-Office Complex, East Arjun Nagar, New Delhi 110032.
- The Member Secretary, Tamil Nadu Pollution Control Board,
 Mount Salai, Guindy, Chennai-600 032.
- The APCCF (C), Regional Office, Ministry of Environment & Forest (SZ),
 HEPC Building, 1st& 2nd Floor, Cathedral Garden Road, Nungambakkam,
 Chennai 34.
- 5. Monitoring Cell, I A Division, Ministry of Environment & Forests, Paryavaran Bhavan, CGO Complex, New Delhi 110003.
- 6. The District Collector, Viluppuram District
- 7. Stock File.



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STATE INDUSTRIES PROMOTION CORPORATION OF TAMIL NADU LIMITED 19-A, RUKMANI LAKSHMIPATHY ROAD, EGMORE, CHENNAI-600 008.

OFFICE ORDER

O.O. No.31/2022

Date: 14.09.2022

Sub: SIPCOT Industrial Park, Tindivanam - Fixation of plot allotment rate for M/s.TANSIDCO - Revision of plot allotment rate for other allottees - Board's approval - Communication - reg.

Ref: 1. Circular No.40/2021 dated 12.04.2021

2. O.O.No.64/2021 dated 01.11.2021

3. Minutes of the Board meeting dated 24.08.2022

The Board of SIPCOT at its meeting held on 24.08.2022 has approved to fix the plot allotment rate for bulk allotment of 113 acres of undeveloped land to M/s.Tamil Nadu Small Industries Development Corporation Ltd. (TANSIDCO) at SIPCOT Industrial Park, Tindivanam at Rs.74.00 lakhs per acre and to allot the land to M/s.TANSIDCO without subsidy on outright sale basis by including clauses in the allotment order and sale deed that

- (i) the enhanced compensation, if any, incurred by SIPCOT for M/s.TANSIDCO land of 113 acres, will be claimed from M/s.TANSIDCO.
- (ii) the cost of infrastructure facilities, if any, provided for M/s.TANSIDCO should be borne by M/s.TANSIDCO.

Further, the Board has approved to revise the rate of allotment at Rs.150.00 lakhs per acre for other allottees (Developed land) and allot at the subsidized rate at Rs.75.00 lakhs per acre to eligible industries in SIPCOT Industrial Park, Tindivanam as Villupuram District comes under "C" District.

.2.

State Industries Promotion Corporation of Tamil Nadu Limited

(A Government of Tamil Nadu Undertaking) CIN: U74999TN1971SGC005967

Regd. Office: 19-A, Rukmani Lakshmipathy Road, Post Box No.7223, Egmore, Chennai - 600 008. Phone: 45261777, Fax: 45261796 Website: www.sipcot.tn.gov.in



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Accordingly, the fixation of plot allotment rate for other allottees (developed land) in SIPCOT Industrial Park, Tindivanam is given below:

Name of the SIPCOT Industrial Park	Plot Allotment Rate per acre	cost incentive @ 25% of plot allotment rate per acre extended by SIPCOT)	Cost Subsidy per acre to be reimbursed by Government (@ 25% of plot allotment rate per acre)	Subsidised plot allotment rate per acre
(Rupees in lakhs)				
Tindivanam	150.00	112.50	37.50	75.00

The above plot allotment rate is applicable for all other allottees at SIPCOT Industrial Park, Tindivanam for the allotments made with effect from 24.08.2022.

Further, the Board has approved to demand 50% capital cost on water supply system in addition to the plot allotment rate as and when the external water supply scheme is funded by SIPCOT.

Sd/-xxx MANAGING DIRECTOR

To
All General Managers
All HODs
PA to MD
PA to ED
IT Department – for necessary action

Copy to All the Project Officers, SIPCOT Industrial Parks.

/Forwarded by Order/

GENERAL MANAGER (F)

State Industries Promotion Corporation of Tamil Nadu Limited

(A Government of Tamil Nadu Undertaking)

CIN: U74999TN1971SGC005967

Regd. Office: 19-A, Rukmani Lakshmipathy Road, Post Box No.7223, Egmore, Chennai - 600 008.
Phone: 45261777, Fax: 45261796 Website: www.sipcot.tn.gov.in



File No: 10894

Government of India

Ministry of Environment, Forest and Climate Change (Issued by the State Environment Impact Assessment Authority(SEIAA), TAMIL NADU)





Dated 29/06/2024



To,

Ekambaranathan Ramanathan

OMEXA FORMULARY PRIVATE LIMITED

Kalyani Towers, 174 c, 2nd Avenue, Ashok Nagar, CHENNAI, TAMIL NADU, 600083

contact@omexa.in

Subject:

Grant of Terms of Reference with Public Hearing under the provision of the EIA Notification 2006,as amended-regarding.

Sir/Madam,

This is in reference to your application for Grant of Terms of Reference with Public Hearing under the provision of the EIA Notification 2006-regarding in respect of project Proposed manufacturing of Monoclonal Antibodies and formulation facility at plot No. 27 & 28, TANSIDCO Industrial Park of Pellakuppam Village, Tindivanam Taluk, Villupuram District, submitted to SEIAA-TN vide proposal number SIA/TN/IND3/472326/2024 dated 06/06/2024.

Ref:

- 1. Online Application No. SIA/TN/IND3/439141/2023 dated 05/08/2023
- 2. Your application for Terms of Reference dated: 20.05.2024
- 2. The particulars of the proposal are as below:

(i) TOR Identification No. TO24B2404TN5415769N

(ii) File No. 10894 (iii) Clearance Type TOR (iv) Category B1

(v) **Project/Activity Included Schedule No.** 5(f) Synthetic organic chemicals industry

(vii) Name of Project Proposed Manufacturing of Monoclonal Antibodies

and Formulation Facility

(viii) Name of Company/Organization OMEXA FORMULARY PRIVATE LIMITED

(ix) Location of Project (District, State) VILLUPURAM, TAMIL NADU

(x) Issuing Authority SEIAA
(xii) Applicability of Conoral Conditions

(xii) Applicability of General Conditions(xiii) Applicability of Specific Conditionsno

SIA/TN/IND3/472326/2024 Page 1 of 16

- 1.In view of the particulars given in the Para 1 above, the project proposal interalia including Form-1(Part A and B) were submitted to the SEIAA for an appraisal by the SEAC under the provision of EIA notification 2006 and its subsequent amendments.
- 2.The above-mentioned proposal has been considered by (SEIAA) Appraisal Committee of SEIAA in the meeting held on 25/06/2024. The minutes of the meeting and all the Application and documents submitted [(viz. Form-1 Part A, Part B,] are available on PARIVESH portal which can be accessed by scanning the QR Code above.
- 3. The State Expert Appraisal Committee (SEAC), based on the information & clarifications provided by the project proponent and after detailed deliberations on all technical aspects and public hearing issues and compliance thereto furnished by the Project Proponent, recommended the proposal for grant of Terms of Reference under the provision of EIA Notification, 2006 and as amended thereof subject to the stipulation of specific and general conditions as detailed in Annexure (2).
- 4.The SEIAA has examined the proposal in accordance with the Environment Impact Assessment (EIA) Notification, 2006 & further amendments thereto and after accepting the recommendations of the SEAC hereby decided to grant Terms of Reference for instant proposal of Thiru.S Ekambaranathan Ramanathan under the provisions of EIA Notification, 2006 and as amended thereof.
- 5. The Ministry/SEIAA-TN reserves the right to stipulate additional conditions, if found necessary.
- 6.The Terms of Reference to the aforementioned project is under provisions of EIA Notification, 2006. It does not tantamount to approvals/consent/permissions etc. required to be obtained under any other Act/Rule/regulation. The Project Proponent is under obligation to obtain approvals /clearances under any other Acts/ Regulations or Statutes, as applicable, to the project.
- 7. This issues with the approval of the Competent Authority.
- 8. The TORs with Public Hearing prescribed shall be valid for a period of three years from the date of issue, for submission of the EIA/EMP report as per OM No.J-11013/41/2006-IA-II(I)(part) dated 29th August 2017.

Copy To

- 1. The Additional Chief Secretary to Government, Environment, Climate Change and Forests Department, Govt. of Tamil Nadu, Fort St. George, Chennai 9.
- 2. The Chairperson, Central Pollution Control Board, Parivesh Bhavan,

CBD Cum-Office Complex, East Arjun Nagar, New Delhi - 110 032.

- 3. The Chairman, Tamil Nadu Pollution Control Board,
- 76, Mount Salai, Guindy, Chennai 600 032.
- 4. The APCCF (C), Regional Office, MoEF & CC (SZ), 34, HEPC Building, 1st & 2nd Floor, Cathedral Garden Road, Nungambakkam, Chennai 34.
- 5. Monitoring Cell, IA Division, Ministry of Environment, Forests & CC,

Paryavaran Bhavan, CGO Complex, New Delhi - 110 003.

- 6. The District Collector, Villupuram District.
- 7. Stock File.

Annexure 1

 $Specific\ Terms\ of\ Reference\ for\ (Synthetic\ Organic\ Chemicals\ Industry)$

1. Seac Conditions - Site Specific

S. No	Terms of Reference
	1. Every industry located in the SIPCOT shall be served individual notices regarding the schedule of public hearing.
1.1	2. The PP shall furnish the roadmap for achieving Net Zero waste.
	3. EIA shall contain stoichiometric material balance indicating any by -products. solid waste, etc

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S. No	Terms of Reference
	4. The proponent shall conduct the EIA study and submit the EIA report for the entire project area.
	5. The proponent shall ensure the proposed industrial shed meets green building norms and shall obtain a minimum of IGBC Gold ranking.
	6. The PP shall furnish action plan for harnessing 50% solar energy or shall purchase 50% renewable green energy from TNEB to meet the energy requirement.
	7. The physical and chemical characteristics of all the chemicals shall be listed in the EIA report.
	8. Necessary supporting documents including latest patta copy and land documents pertaining to all the subdivided S.F.Nos, approval from Competent Authority for supply of fresh water & drinking water shall be furnished.
	9. The PP shall furnish the drone video of the entire project site.
	10. The process flow diagram should include quantity of various items, the effluents air emissions / hazardous waste generated including the quantity and their characteristics. appropriate pollution control measures contemplated for controlling each category of pollution, the pollutants getting discharged into the environment including the quantity as well as the characteristics.
	11. The EIA should cover the possible impacts starting from unloading of chemicals. storage. process and finally letting into the environment.
	12. The EIA should concentrate on specific pollutants emanated from the industry in addition to the normal pollutants which are dealt with in EIA study.
	13. Details on how the reactors are cleaned and how the residues are collected and disposed shall be elaborated.
	14. Any washing of reactor with water is done such waste water shall be considered as effluent and the same shall be sent to the ETP. Accordingly, the project proponent shall design the ETP.
	15. The odour from the fugitive emissions will be a major problem. The project proponent should formulate measures to monitor and control the odour appropriately and submit the details in the EIA report.
	16. Hazardous waste generated shall be clearly identified and shall be disposed to TNPCB authorized recyclers. The project proponent shall famish the proposal for Hazardous waste management.
	17. Fugitive emissions generated from the other activities shall be collected through adequate ducting system and provided with wet scrubbers.
	18. Green belt development and CSR acclivities should be as per norms.
	19. Details of the procedures to be adopted for the regular health check-ups for the staff shall be famished.
	20. Details of extra safety standards against anticipated exhaust and exposures by the project proponent to be famished and its impact on workers including disorders and disabilities to be listed.

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S. No	Terms of Reference
	21. Will exposures have any impact on workers? Can it cause disorders and disabilities?
	22. Impact of anticipated vapours on the migratory birds and other bio-diversity and its harmful effect.
	23. Can anticipated seepages if any, cause disturbances to soil, micro flora and to plantations including agriculture and bio-diversity.
	24. Proper disaster management plan considering the worst-case scenario shall be famished.
	25. Details of litigations, if any pending against the project shall be furnished along with supporting documents.
	26. The proponent shall furnish the detailed sewage treatment technology available and furnish the design details of the STP treatment system. Adequacy report for ETP &STP for the proposed project obtained from any reputed Government institution such as IIT, Anna University, NIT shall be furnished.
	27. The proposal to construct a pond of appropriate size in the earmarked OSR land in consultation with the local body. The pond should be modelled like a temple tank with parapet walls, steps, etc. The pond is meant to play three hydraulic roles, namely (1) as a storage, which acted as insurance against low rainfall periods and also recharges groundwater in the surrounding area, (2) as a flood control measure, preventing soil erosion and wastage of runoff waters during the period of heavy rainfall, and (3) as a device which was crucial to the overall eco-system.
	28. The treated/untreated sewage water shall not be let-out from the unit premises accordingly revised water balance shall be incorporated.
	29. As per G.O. Ms. No. 142 approval from Central Ground Water Authority shall be obtained for withdrawal of water and furnish the copy of the same, if applicable.
	30. Commitment letter from competent authority for supply of water shall be furnished.
	31. Detailed Evacuation plan during emergency/natural disaster/untoward accidents shall be submitted.
	32. The space allotment for solid waste disposal and sewage treatment plant shall be furnished.
	33. Details of the Solid waste management plan shall be pre pared as per Solid Waste Management Rules, 2016 as amended and shall be furnished.
	34. Details of the E-waste management plan shall be prepared as per E-waste Management Rules, 2016 as amended and shall be furnished.
	35. Details of the Rain water harvesting system with cost estimation should be furnished.
	36. A detailed storm water management plan to drain out the storm water entering the premises during heavy rains period shall be prepared including main drains and sub-drains in accordance with the contour levels of the proposed project considering the water bodies around the proposed project site & the surrounding development. The storm water drain shall be designed in accordance with the guidelines prescribed by the Ministry of Urban Development.

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S. No	Terms of Reference
	37. The OSR area should not be included in the activity area and not be taken in to account for the green belt area.
	38. As per the MoEF&CC Office Memorandum F.No.22-65/2017-lA.llldated: 30.09.2020 and 20.10.2020, the proponent shall furnish the detailed EMP mentioning all the activities as directed by SEAC in the CER and furnish the same.
	39. The company shall have a well laid down environmental policy duly approved by the Board of Directors.
	40. Land requirement for the facility including its break up for various purposes, its availability and optimization.
	41. Details of proposed layout clearly demarcating various activities such as security.
	42. Details on collection and transportation of wastes to the disposal points, number of vehicles and feature of vehicles, etc.
	43. The PP shall furnish the compliance status of the directions/guidelines issued by competent authority with respect to pharmaceutical manufacturing units.
	44. Details on fuel requirement for incineration/combustion.
	45. Details on flue gas emissions discharge through stack analysis of toxic pollutants and proposed pollution control technologies.
	46. Details on residue/ash generation and management.
	47. Details of the proposed overall safety and health protection measures.
	48. Details of the existing access road(s)/walkways to the designed operations in the site and its layout.
	49. Land use map based on satellite imagery including location specific sensitivities such as national parks / wildlife sanctuary, villages, industries, etc.
	50. Surface water quality of nearby water bodies.
	51. Details on proposed groundwater monitoring wells, locations, frequency of monitoring, parameters, etc.
	52. Action plan for the greenbelt development in accordance with CPCB published guidelines. The PP shall no fruit bearing trees developed as part of green belt.
	53. Details on pollution control technologies and online monitoring equipments.
	54. Details of the emergency preparedness plan and on-site & off-site disaster management plan.
	55. The proponent shall conduct Socio-economic and health survey.
	56. A detailed incinerator design needs to be submitted on the likelihood of emission, possible types

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S. No	Terms of Reference
	of gases coming out of the process and its measures and mitigation.
	57. The proponent shall furnish SOP for the process.
	58. The proponent shall conduct a detailed study on water, land and Air quality.
	59. Proponent shall furnish the letter received from DFO concerned stating the proximity details of Reserve Forests, Protected Areas, Sanctuaries, Tiger reserve etc., up to a radius of 25 km from the proposed site.
	60. The Proponent shall carry out Bio diversity study through reputed Institution and the same shall be included in EIA Report.
	61. The Project Proponent shall conduct the hydro-geological study considering the contour map of the water table detailing the number of ground water pumping & open wells, and surface water bodies such as rivers, tanks, canals, ponds etc. within 1 km (radius) along with the collected water level data for both monsoon and non-monsoon seasons from the PWD / TWAD so as to assess the impacts on the wells due to proposed activity. Based on actual monitored data, it may clearly be shown whether working will intersect groundwater. Necessary data and documentation in this regard may be provided.
	62. The Proponent shall furnish the baseline data for the environmental and ecological parameters with regard to surface water/ground water quality, air quality, soil quality & flora/fauna including traffic/vehicular movement study.
	63. The Proponent shall carry out the Cumulative impact study due to project activity specifically with reference to the specific environment in terms of soil health, biodiversity, air pollution, water pollution, climate change and flood control & health impacts. Accordingly, the Environment Management plan should be prepared keeping the proposed site and the surrounding habitations in the mind.
	64. Rain water harvesting management with recharging details along with water balance (both monsoon & non-monsoon) be submitted.
	65. Land use of the study area delineating forest area, agricultural land, grazing land, wildlife sanctuary, national park, migratory routes of fauna, water bodies, human settlements and other ecological features should be indicated. Land use plan of the mine lease area should be prepared to encompass preoperational, operational and post operational phases and submitted. Impact, if any, of change of land use should be given.
	66. Proximity to Areas declared as 'Critically Polluted' (or) the Project areas which attracts the court restrictions for proposed operations, should also be indicated and where so required, clearance certifications from the prescribed Authorities, such as the TNPCB should be secured and furnished to the effect that the proposed project activities could be considered.
	67. Description of water conservation measures proposed to be adopted in the Project should be given. Details of rainwater harvesting proposed in the Project, if any, should be provided.
	68. Impact on local transport infrastructure due to the Project should be indicated.
	69. A tree survey study shall be carried out (nos., name of the species, age, diameter etc.,) at the project site.

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S. No	Terms of Reference
	70. Public Hearing points raised and commitments of the Project Proponent on the same along with time bound Action Plan with budgetary provisions to implement the same should be provided and also incorporated in the final EIA/EMP Report of the Project and to be submitted to SEIAA/SEAC with regard to the Office Memorandum of MoEF& CC accordingly.
	71. The Public hearing advertisement shall be published in one major National daily and one most circulated vernacular daily.
	72. The Proponent shall produce/display the EIA report, Executive summery and other related information with respect to public hearing in Tamil Language also.
	73. As a part of the study of flora and fauna around the vicinity of the proposed site, the EIA coordinator shall strive to educate the local students on the importance of preserving local flora and fauna by involving them in the study, wherever possible.
	74. The purpose of Greenbelt around the project is to capture the fugitive emissions, carbon sequestration and to attenuate the noise generated, in addition to improving the aesthetics. A wide range of indigenous plant species should be planted as given in the Appendix-I in consultation with the DFO, & Tamil Nadu Agriculture University. The plant species with dense/moderate canopy of native origin should be chosen. Species of small/medium/tall trees alternating with shrubs should be planted in a mixed manner.
	75. Taller/one year old Saplings raised in appropriate size of bags, preferably eco-friendly bags should be planted as per the advice of local forest authorities/botanist/Horticulturist with regard to site specific choices. The proponent shall earmark the greenbelt area with GPS coordinates all along the boundary of the project site with at least 3 meters wide and in between blocks in an organized manner.
	76. A Disaster management Plan and Risk Assessment and management Plan shall be prepared and included in the EIA/EMP Report.
	77. Occupational Health impacts of the Project should be anticipated and the proposed preventive measures spelt out in detail. Details of pre-placement medical examination and periodical medical examination schedules should be incorporated in the EMP. The project specific occupational health mitigation measures with required facilities proposed in the project site area may be detailed.
	78. Public health implications of the Project and related activities for the population in the impact zone should be systematically evaluated and the proposed remedial measures should be detailed along with budgetary allocations.
	79. The Socio-economic studies should be carried out within a 5 km buffer zone from the project site. Measures of socio-economic significance and influence to the local community proposed to be provided by the Project Proponent should be indicated. As far as possible, quantitative dimensions may be given with time frames for implementation.
	80. Details of litigation pending against the project, if any, with direction /order passed by any Court of Law against the Project should be given.
	81. Benefits of the Project if the Project is implemented should be spelt out. The benefits of the Project shall clearly indicate environmental, social, economic, employment potential, etc.

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S. No	Terms of Reference
	82. The Proponent shall prepare the EMP for the entire life of project and also furnish the sworn affidavit stating to abide the EMP for the entire life of project.
	83. Concealing any factual information or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this Terms of Conditions besides attracting penal provisions in the Environment (Protection) Act, 1986.

2. Seiaa Specific Conditions:

S. No	Terms of Reference
2.1	After detailed discussions, the Authority accepted the recommendation of SEAC and decided to grant Terms of Reference (ToR) with Public Hearing based on studies, assessments and records to be produced as sought by the SEAC and SEIAA, for undertaking the Environment Impact Assessment Study and preparation of Environment Management Plan subject to the following conditions and that recommended by SEAC & SEIAA 1. The PP shall carryout detailed LCA study for the drugs to be manufactured. 2. Global warming potential /safety norms and practices to be adopted. 3. Safety Standards and impacts of single use and multiuse machinery to be used for drug production. 4. Biosafety standard and protocols of the raw materials used, process and manufactured products. 5. Details of the energy conservation measures proposed. 6. Carbon dioxide reduction and sequestration technologies including GHG emissions and risk reduction to be adopted. 7. Storage and disposal of solid wastes such as broken vials, syringes etc 8. Storage and disposal of biomedical waste to be studied. 9. New technologies and innovative approaches adopted for sustainable production. 10. Air emission control technologies proposed. 11. Water use efficiency in the bioprocess. 12. Stability of the drugs and impact on air, water and other adsorption surfaces. 13. Study report on the economic impact assessment covering water, electricity, waste and labour. 14. Washing strategy for the machinery and safety protocols to be adopted. 15. Plastic usage reduction strategy. 16. Over all new innovative technologies to be adopted for production process. 17. Safe guards to sensitive wetland, lakes, waterbodies and the project site. 18. Study on safety protocols to prevent pollution threats to villages, habitations near project site. 19. Impacts on Energy requirement. 20. Impacts on terrestrial & aquatic habitats within and surrounding areas. 22. As per the MoEF& CC office memorandum F.No.22-65/2017-IA.III dated: 30.09.2020 and 20.10.2020 the proponent shall f

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S. No	Terms of Reference
	support the climatic action to make it safe and sustainable buildings/ and production unit. 28. The project proponent shall conduct detailed study of biodiversity flora & fauna including invasives /endemic vulnerable species. 29. The project proponent shall conduct detailed soil investigation including microflora /fauna and likely impact on soil microorganisms. 30. The project proponent shall study impact on livelihoods of locals. 31. The project proponent shall furnish List of trees available in the area. 32. The project proponent shall conduct studies on invasive and alien species. 33. Examine possibilities of increasing open space and green belt area. 34. Study to evaluate changes in land use and land cover within 10km of project area, wet lands, particularly to agriculture, plantation, streams, river, existing urban and rural infrastructure, nor geomorphology impact on the prevalent hydrogeology of the area. 35. Protocol to ensure there are no environmental impact on educational institutions, the existing industries, hospitals, government buildings and religious places and human habitations and other units within the SIDCO industrial park. 36. The cradle to grant assessment on syringes vials, Lyophilised vials, including formulation products and drug subsystem.

Standard Terms of Reference for (Synthetic organic chemicals industry)

1. Executive Summary

S. No	Terms of Reference
1.1	Executive Summary

2. Introduction

S. No	Terms of Reference
2.1	Details of the EIA Consultant including NABET accreditation
2.2	Information about the project proponent
2.3	Importance and benefits of the project

3. Project Description

S. No	Terms of Reference
3.1	Cost of project and time of completion.
3.2	Products with capacities for the proposed project.
3.3	If expansion project, details of existing products with capacities and whether adequate land is available for expansion, reference of earlier EC if any.
3.4	Details of existing products and production, if any, along with present product/production details in

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S. No	Terms of Reference
	tabular format, to verify the compliance of the EIA Notifications.
3.5	Details of existing products and production, if any, along with present product/production details in tabular format, to verify the compliance of the EIA Notifications.
3.6	List of raw materials required and their source along with mode of transportation.
3.7	Other chemicals and materials required with quantities and storage capacities
3.8	Details of Emission, effluents, hazardous waste generation and their management.
3.9	Requirement of water, power, with source of supply, status of approval, water balance diagram, man-power requirement (regular and contract)
3.10	Details of boiler/gensets (including stacks/exhausts) and fuels to be used
3.11	Process description along with major equipment's and machineries, process flow sheet (quantitative) from raw materials to products to be provided
3.12	Hazard identification and details of proposed safety systems.
3.13	 Expansion/modernization proposals: a. Copy of all the Environmental Clearance(s) including Amendments thereto obtained for the project from MOEF/SEIAA shall be attached as an Annexure. A certified copy of the latest Monitoring Report of the Integrated Regional Office of the Ministry of Environment, Forest and Climate Change as per circular dated 30th May, 2012 on the status of compliance of conditions stipulated in all the existing environmental clearances including Amendments shall be provided. In addition, copy of the latest CTO and status of compliance of Consent to Operate for the ongoing/existing operation of the project from SPCB shall be attached with the EIA-EMP report. b. In case the existing project has not obtained environmental clearance, reasons for not taking EC under the provisions of the EIA Notification 1994 and/or EIA Notification 2006 shall be provided. Copies of Consent to Establish/No Objection Certificate and Consent to Operate (in case of units operating prior to EIA Notification 2006, CTE and CTO of FY 2005-2006) obtained from the SPCB shall be submitted. Further, compliance report to the conditions of consents from the SPCB shall be submitted.

4. Site Details

S. No	Terms of Reference
4.1	Location of the project site covering village, Taluka/Tehsil, District and State, Justification for selecting the site, whether other sites were considered.
4.2	A topo-sheet of the study area of radius of 10km and site location on 1:50,000/1:25,000 scale on an A3/A2 sheet. (including all eco-sensitive areas and environmentally sensitive places)

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S. No	Terms of Reference
4.3	Details w.r.t. option analysis for selection of site
4.4	Co-ordinates (lat-long) of all four corners of the site.
4.5	Google map-Earth download of the project site.
4.6	Layout maps indicating existing unit as well as proposed unit indicating storage area, plant area, greenbelt area, utilities etc. If located within an Industrial area/Estate/Complex, layout of Industrial Area indicating location of unit within the Industrial area/Estate.
4.7	Photographs of the proposed and existing (if applicable) plant site. If existing, show photographs of plantation/greenbelt, in particular.
4.8	Land-use break-up of total land of the project site (identified and acquired), government/private - agricultural, forest, wasteland, water bodies, settlements, etc shall be included. (not required for industrial area)
4.9	A list of major industries with name and type within study area (10km radius) shall be incorporated. Land use details of the study area
4.10	Geological features and Geo-hydrological status of the study area shall be included.
4.11	Details of Drainage of the project upto 5km radius of study area. If the site is within 1 km radius of any major river, peak and lean season river discharge as well as flood occurrence frequency based on peak rainfall data of the past 30 years. Details of Flood Level of the project site and maximum Flood Level of the river shall also be provided. (mega green field projects)
4.12	Status of acquisition of land. If acquisition is not complete, stage of the acquisition process and expected time of complete possession of the land. Documents related to conversion of land for Industrial purpose.
4.13	R&R details in respect of land in line with state Government policy.

5. Forest, Wildlife And Crz Related Issues (If Applicable):

S. No	Terms of Reference
5.1	Permission and approval for the use of forest land (forestry clearance), if any, and recommendations of the State Forest Department. (if applicable)
5.2	Land-use map based on High resolution satellite imagery of the proposed site delineating the forestland (in case of projects involving forest land more than 40 ha)
5.3	Status of Application submitted for obtaining the stage I forestry clearance along with latest status shall be submitted.
5.4	The projects to be located within 10 km of the National Parks, Sanctuaries, Biosphere Reserves, Migratory Corridors of Wild Animals, the project proponent shall submit the map duly authenticated by Chief Wildlife Warden showing these features vis-à-vis the project location and

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S. No	Terms of Reference
	the recommendations or comments of the Chief Wildlife Wardenthereon
5.5	Wildlife Conservation Plan duly authenticated by the Chief Wildlife Warden of the State Government for conservation of Schedule I fauna, if any exists in the study area
5.6	Copy of application submitted for clearance under the Wildlife (Protection) Act, 1972, to the Standing Committee of the National Board for Wildlife
5.7	Recommendations and NOC from the concerned State/UT Coastal Zone Management Authority on CRZ angle

6. Environmental Status

S. No	Terms of Reference
6.1	Determination of atmospheric inversion level at the project site and site-specific micrometeorological data using temperature, relative humidity, hourly wind speed and direction and rainfall.P • AAQ data (except monsoon) at 8 locations for PM10, PM2.5, SO2, NOX, CO and other parameters relevant to the project shall be collected. The monitoring stations shall be based CPCB guidelines and take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests. Study should indicate minimum, maximum value of different parameters for the period (3 months) collected. Collected data should be supported by the reference data of either CPCB or SPCB. AAQ data & GLC of pollutants from stack emissions should suggest technology/ measures- Best Practiced Technology (BPT) indicating best achieved results.
6.2	Raw data of all AAQ measurement for 12 weeks of all stations as per frequency given in the NAQQM Notification of Nov. 2009 along with – min., max., average and 98% values for each of the AAQ parameters from data of all AAQ stations should be provided as an annexure to the EIA Report.
6.3	Surface water quality of nearby River (100m upstream and downstream of discharge point) and other surface drains at eight locations as per CPCB/MoEF&CC guidelines.
6.4	Whether the site falls near to polluted stretch of river identified by the CPCB/MoEF&CC, if yes give details.
6.5	Ground water monitoring at minimum at 8 locations shall be included.
6.6	Noise levels monitoring at 8 locations within the study area.
6.7	Soil Characteristic as per CPCB guidelines.
6.8	Traffic study of the area, type of vehicles, frequency of vehicles for transportation of materials, additional traffic due to proposed project, parking arrangement etc.
6.9	Detailed description of flora and fauna (terrestrial and aquatic) existing in the study area shall be given with special reference to rare, endemic and endangered species. If Schedule-I fauna are found within the study area, a Wildlife Conservation Plan shall be prepared and furnished.

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S. No	Terms of Reference
6.10	Socio-economic status of the study area.

7. Environment Impact And Environment Management Plan

S. No	Terms of Reference
7.1	Assessment of ground level concentration of pollutants from the stack emission based on site-specific meteorological features. In case the project is located on a hilly terrain, the AQIP Modelling shall be done using inputs of the specific terrain characteristics for determining the potential impacts of the project on the AAQ. Cumulative impact of all sources of emissions (including transportation) on the AAQ of the area shall be assessed. Details of the model used and the input data used for modelling shall also be provided. The air quality contours shall be plotted on a location map showing the location of project site, habitation nearby, sensitive receptors, if any.
7.2	Water Quality Modelling – in case of discharge in water body
7.3	Impact of the transport of the raw materials and end products on the surrounding environment shall be assessed and provided. In this regard, options for transport of raw materials and finished products and wastes (large quantities) by rail or rail-cum road transport or conveyor-cum-rail transport shall be examined.
7.4	A note on treatment of wastewater from different plant operations, extent recycled and reused for different purposes shall be included. Complete scheme of effluent treatment. Characteristics of untreated and treated effluent to meet the prescribed standards of discharge under E(P) Rules 1986.
7.5	Details of stack emission and action plan for control of emissions to meet standards
7.6	Measures for fugitive emission control
7.7	Details of hazardous waste generation and their storage, utilization and management. Copies of MOU regarding utilization of solid and hazardous waste in cement plant shall also be included. EMP shall include the concept of waste-minimization, recycle/reuse/recover techniques, Energy conservation, and natural resource conservation.
7.8	Proper utilization of fly ash shall be ensured as per Fly Ash Notification, 2009. A detailed plan of action shall be provided.
7.9	Action plan for the green belt development plan in 33 % area i.e. land with not less than 2,500 trees per ha. Giving details of species, width of plantation, planning schedule etc. shall be included. The green belt shall be around the project boundary and a scheme for greening of the roads used for the project shall also be incorporated.
7.10	Action plan for rainwater harvesting measures at plant site shall be submitted to harvest rainwater from the roof tops and storm water drains to recharge the ground water and also to use for the various activities at the project site to conserve fresh water and reduce the water requirement from other sources.
7.11	Total capital cost and recurring cost/annum for environmental pollution control measures shall be included.

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S. No	Terms of Reference
7.12	Action plan for post-project environmental monitoring shall be submitted.
7.13	Onsite and Offsite Disaster (natural and Man-made) Preparedness and Emergency Management Plan including Risk Assessment and damage control. Disaster management plan should be linked with District Disaster Management Plan.

8. Occupational Health

S. No	Terms of Reference
8.1	Plan and fund allocation to ensure the occupational health & safety of all contract and casual workers
8.2	Details of exposure specific health status evaluation of worker. If the workers' health is being evaluated by pre designed format, chest x rays, Audiometry, Spirometry, Vision testing (Far & Near vision, colour vision and any other ocular defect) ECG, during preplacement and periodical examinations give the details of the same. Details regarding last month analyzed data of above mentioned parameters as per age, sex, duration of exposure and department wise.
8.3	Details of existing Occupational & Safety Hazards. What are the exposure levels of hazards and whether they are within Permissible Exposure level (PEL). If these are not within PEL, what measures the company has adopted to keep them within PEL so that health of the workers can be preserved,
8.4	Annual report of health status of workers with special reference to Occupational Health and Safety.

9. Corporate Environment Policy

S. No	Terms of Reference
9.1	Does the company have a well laid down Environment Policy approved by its Board of Directors? If so, it may be detailed in the EIA report.
9.2	Does the Environment Policy prescribe for standard operating process / procedures to bring into focus any infringement / deviation / violation of the environmental or forest norms / conditions? If so, it may be detailed in the EIA.
9.3	What is the hierarchical system or Administrative order of the company to deal with the environmental issues and for ensuring compliance with the environmental clearance conditions? Details of this system may be given.
9.4	Does the company have system of reporting of non-compliances / violations of environmental norms to the Board of Directors of the company and / or shareholders or stakeholders at large? This reporting mechanism shall be detailed in the EIA report
9.5	Details regarding infrastructure facilities such as sanitation, fuel, restroom etc. to be provided to the labour force during construction as well as to the casual workers including truck drivers during operation phase.

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10. Corporate Environmental Responsibility (Cer)

S. No	Terms of Reference		
10.1	Adequate funds, as per the Ministry's OM/Guidelines, shall be earmarked towards the Corporate Environmental Responsibility based on Public Hearing issues/socioeconomic issues and item-wise details along with time bound action plan shall be included (CER activities shall be related to environment). Socio-economic development activities need to be elaborated upon. For the projects where public hearing is not conducted, CER plan shall be provided based on socio-economic study of the area.		

11. Additional Studies/measures To Be Considered

S. No	Terms of Reference			
11.1	Provide latest and ecofriendly technology for product manufacturing.			
11.2	Emphasize on Green chemistry/Clean Manufacturing			
11.3	Provide CAS No. of products along with product list.			
11.4	Provide details of amount of carbon sequestered in their unit through greenbelt/other modes, in case of expansion project.			
11.5	Life structure and sustainability for carbon and water foot print.			
11.6	Detailed pollution Load estimation.			
11.7	Transportation of Hazardous substance, effluents etc shall be carriedout through authorized and GPS enable vehicles/Trucks only.			
11.8	Category of Hazardous Wastes shall be mentioned in the EIA/EMP report and in presentation.			
11.9	Details of greenhouse gases and emissions shall be provided.			
11.10	Greenbelt shall be developed in the first year of the project and wind breaks shall be erected.			
11.11	Study area map shall be overlapped with all the associated features.			
11.12	Emphasize on green fuels.			
11.13	The project from NCR shall not use Coal as fuel. Further, PP shall avoid use of Coal in the CPAs and elsewhere also if alternatives are available.			
11.14	Provide the Cost-Benefit analysis with respect to the environment due to the project.			
11.15	Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation measures also needs to be analyzed and submitted for further appraisal of the SEAC			

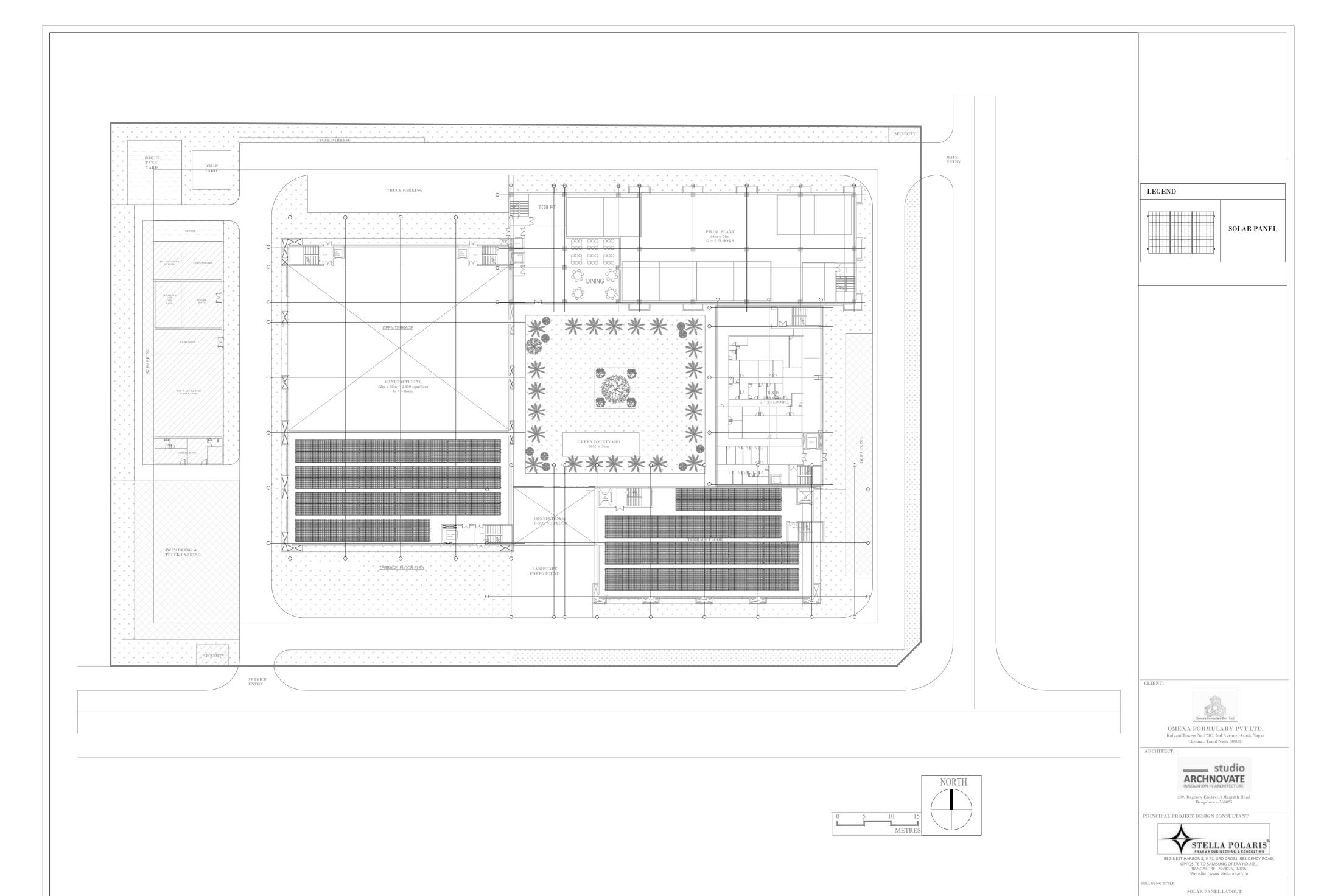
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S. No	Terms of Reference		
11.16	Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof shall also be included. Has the unit received any notice under the Section 5 of Environment (Protection) Act, 1986 or relevant Sections of Air and Water Acts? If so, details thereof and compliance/ATR to the notice(s) and present status of the case.		
11.17	A tabular chart with index for point wise compliance of above TORs and its details needs to be submitted in the EIA/EMP Report.		

12. Specific Condition

S. No	Terms of Reference			
12.1	Details on solvents to be used, measures for solvent recovery and for emissions control.			
12.2	Details of process emissions from the proposed unit and its arrangement to control.			
12.3	Ambient air quality data should include VOC, other process-specific pollutants* like NH3*,chlorine*,HC1*,HBr*,H2S*,HF*,etc.,(*-as applicable)			
12.4	Work zone monitoring arrangements for hazardous chemicals.			
12.5	Detailed effluent treatment scheme including segregation of effluent streams for units adopting 'Zero' liquid discharge.			
12.6	Action plan for odour control to be submitted.			
12.7	A copy of the Memorandum of Understanding signed with cement manufacturers indicating clearly that they co-process organic solid/hazardous waste generated.			
12.8	Authorization/Membership for the disposal of liquid effluent in CETP and solid/hazardous waste in TSDF, if any.			
12.9	Action plan for utilization of MEE/dryers salts.			
12.10	Material Safety Data Sheet for all the Chemicals are being used/will be used.			
12.11	Authorization/Membership for the disposal of solid/hazardous waste in TSDF.			
12.12	Details of incinerator if to be installed.			
12.13	Risk assessment for storage and handling of hazardous chemicals/solvents. Action plan for handling & safety system to be incorporated.			
12.14	Arrangements for ensuring health and safety of workers engaged in handling of toxic materials.			
12.15	Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation measures also needs to be analysed and submitted for further appraisal of the SEAC.			

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HEET SIZE

List of Raw Material requirement and Storage

Sl. No.	Raw materials	Approx Quantity per annum (In Kgs)	Source	Mode of transport
1	Sodium chloride	1800	Domestic/ Imported	Road
2	Potassium Chloride	10	Domestic/ Imported	Road
3	Sodium phosphate	60	Domestic/ Imported	Road
4	Potassium phosphate	10	Domestic/ Imported	Road
5	Citric acid	500	Domestic/ Imported	Road
6	Sodium Citrate	1150	Domestic/ Imported	Road
7	Tris Buffer	2300	Domestic/ Imported	Road
8	Sodium Acetate	600	Domestic/ Imported	Road
9	Sodium Hydroxide	1500	Domestic/ Imported	Road
10	Glucose	400	Domestic/ Imported	Road
11	Sodium bicarbonate	200	Domestic/ Imported	Road
12	Pluronic F68	100	Domestic/ Imported	Road
13	Cell culture media	2200	Domestic/ Imported	Road
14	L-Glutamine	30	Domestic/ Imported	Road
15	Sorbitol	200	Domestic/ Imported	Road
16	Ethanol	100	Domestic/ Imported	Road
17	Phosphoric Acid	60	Domestic/ Imported	Road
18	Acetic Acid	40	Domestic/ Imported	Road
19	Hydrochloric acid	150	Domestic/ Imported	Road
	Total	11410	-	-



MINOMOTO

SAFETY DATA SHEET:

L-GLUTAMINE

The information is provided as a service to our customers and is intended only for their use. This information is based on technical information believed to be reliable and will be revised as new knowledge or experience is gained.

Date of issue: January 6, 2003

November 26, 2020 Revision date: Version 12

Page 1of 4

Chemical Product and Company Identification

1.1. Identification of the substance: L-Glutamine

Use of the substance: Various use (drugs, nutritional, industrial) 1.2.

1.3. Detail of the supplier of the safety data sheet

Manufacturer's Name: Ajinomoto do Brasil Indústria e Comércio de Alimentos Ltda.

1.4 Contact for Correspondence Japan:

Aiinomoto Co., Inc.

15-1, Kyobashi 1-chome, Chuo-ku, Tokyo

104-8315, Japan

Tel N°: +81-(0)3-5250-8111 Fax N°: +81-(0)3-5250-0079

Contact for Correspondence Brazil:

Ajinomoto do Brasil Indústria e Comércio

de Alimentos Ltda.

Rua Vergueiro, 1737, Vila Mariana, 04101-001-São Paulo-SP, Brazil Tel N°: +55 11 5908-8778

Contact for Correspondence China:

Ajinomoto (China) Co., Ltd.

718 Rongle Dong Road, Songjiang, Shanghai 201613 P.R. China Tel N°:+86 21 5774-5353

Fax N°: +86 21 5774-0433

1.5. Emergency Telephone:

In continental U.S., Hawaii, Puerto Rico, Canada, Alaska and Virgin Islands contact

CHEMTREC at 1-800-424-9300.

Contact for Correspondence USA

Aiinomoto Health & Nutrition North America Inc.

4020 Ajinomoto Drive, Raleigh

N.C. 27610, U.S.A Tel N°: +919-325-1400 Fax N°: +919-325-1420

Contact for Correspondence Europe:

S.A. Ajinomoto Omnichem N.V. I Axis Park, Rue Emile Francqui 7 1435 Mont-Saint-Guibert, Belgium

Tel N°: +32(0)10 48 31 22 Fax N°: +32(0)10 45 62 27

Contact for Correspondence Asia, Oceania

Shanghai Ajinomoto Trading Co., Ltd. 718 Rongle Dong Road, Songjiang, Shanghai 201613 P.R. China Tel N°:+86 21 5774-5353

Fax N°: +86 21 5774-0433

For Japan, Brazil, Europe, China and Asia refer to

section 1.4

Hazards Identification

2.1 Classification of the substance

Physical hazards: Not applicable Health hazards: Not applicable Environmental hazards: Not applicable 2.2 Label elements (REGULATION (EC) No.1272/2008)

Not applicable

2.3 Other hazards: May cause eye and skin irritation.

It will increase the biological oxygen demand (BOD) of water.

Composition, Information on Ingredients

3.1. Substance

Common Chemical name: L-Glutamine

Synonyms: (S)-2-Aminoglutaramic acid

Formula: $C_5H_{10}N_2O_3$ Molecular Weight: 146.14 Composition: 99.0 - 101.0% 56-85-9 CAS No.: **EINECS No.:** 200-292-1 **IUPAC**: L-Gln, L-Glu(NH₂) L-Gln, L-Glu(NH₂) **IUPAC:**

L-GLUTAMINE

Page 2 of 4

4. First-Aid Measures

4.1 Description of first aid measures

<u>Inhalation</u>: Immediately relocate to a fresh air environment. Rinse mouth with water. If not breathing, give artificial respiration. If breathing becomes difficult, give oxygen and seek medical attention.

Skin Contact: Wash with soap and copious amounts of water. If irritation persists, seek medical attention.

Eye Contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. If contact lenses are being worn, remove lenses and

continue rinsing. Seek medical attention.

<u>Ingestion</u>: Rinse mouth with water and seek medical attention.

- 4.2 Most important symptoms and effects, both acute and delayed
- 4.3 Indication of any immediate medical attention and special treatment needed No information available.

5. Fire-fighting measures

5.1 Extinguishing media

Water spray, carbon dioxide, dry chemical powder/foam

5.2 Special hazards arising from the substance or mixture

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Upon combustion will result in carbon monoxide, carbon dioxide and nitrogen oxide being released.

5.3 Advice for fire-fighting No information available

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures.

Use personal protection, Make spills wet to prevent the generation of dust and then, sweep up into a closed container.

6.2 Environmental precautions

Do not discharge into sewer, river, underground water, etc.

6.3 Methods and material for containment and cleaning up

After recovering, wash away spilled area with plenty of water.

6.4 Reference to other sections
Personal protection: see section8

7. Handling and storage

7.1. Precautions for safe handling

Follow good industrial practice in housekeeping and personal hygiene. Wear personal protective equipment as outlined in section 8.

7.2. Conditions for safe storage, including any incompatibilities

Store in closed containers in a dry area. Avoid humidity, sunlight and high temperature.

8. Exposure controls/personal protection

8.1 Control parameters

Contains no substance with occupational exposure limit value

8.2 Exposure controls

Respiratory protection: Dust mask or appropriate respirator. Utilize local exhaust ventilation.

Protective gloves: Rubber

Eye protection: Chemical safety goggles.

Other protective equipment: Wear appropriate laboratory apparel, protect exposed skin.

Occupational exposure limits: Not established

MJINOMOTO

SAFETY DATA SHEET:

L-GLUTAMINE

Page 3 of 4

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: White crystals or crystalline powder

 $\begin{array}{lll} \mbox{Melting point:} & 185\text{-}186^{\circ}\mbox{C} & (\mbox{decomposes}) \\ \mbox{Solubility:} & 3.73 \mbox{ g/100g } \mbox{H}_2\mbox{O} & (20^{\circ}\mbox{C}) \\ \mbox{pH:} & 4.5\text{-}6.0 & (1.0g \mbox{ in } 50\mbox{mL of } \mbox{H}_2\mbox{O}) \\ \end{array}$

9.2 Other data

No data available

10. Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures; in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

Stable under normal temperature and pressures

10.3 Possibility of hazardous reactions

Nitrogen oxides (combustion)

10.4 Conditions to avoid

Humidity and high temperature. In presence of moisture, will oxidize and darken.

10.5 Incompatibility materials

Strong oxidizing agents

10.6 Hazardous decomposition products:

Nitrogen oxides (combustion)

11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity: LD₅₀: 7.5 g/kg rat, oral Sensitization: No data available Mutagenicity: No data available

Primary skin irritation: May cause skin irritation. No specific data available Primary eye irritation: May cause eye irritation. No specific data available

12. Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

BOD= 0.70 g/g

12.3 Bio accumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT and vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

WGK class (Europe):1 (group classification according to VwVwS / 17 May 1999, Germany)

13. Disposal considerations

Dispose of the material as you would with a non-hazardous material in accordance with all applicable national, state and local regulations.

14. Transport information

Avoid humidity and high temperature. Prevent damage of the container.

14.1-14.6 Not classified as dangerous in meaning of transport regulations.

14.7 Transport in Bulk according to Annex II of MARPOL 73/78 and the IBC code.



L-GLUTAMINE

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15. Regulatory information

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture *EU regulations*

<u> </u>	
Major Accident Hazard	96/82/EC
Legislation	Directive 96/82/EC does not apply
Regulation(EC) No.1005/2009 on substances that deplete the ozone layer	not regulated
Regulation(EC) No.850/2004 of the European Parliament and of the Council of 29 April 2004 on Directive 79/117/EEC	not regulated
Regulation (EC) No689/2008 concerning the export and import of dangerous chemicals.	not regulated
Substance of very high concern(SVHC)	This product does not contain substance of very high concern above the respective regulatory limit (> 0.1% (w/w) Regulation (EC) No.1907/2006(REACH), Article 57).

Other National Legislation

None especially.

The information given in this Safety Data Sheet does not replace the users own assessment of workplace risk as required by national, state and local health and safety legislation.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

16. Other information

The information contained in this SDS is, to the best of our knowledge true and accurate. Any recommendations or suggestions made are without guarantee, since the conditions of use are beyond our control.

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 30.03.2016 Print Date 22.12.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Phosphoric acid solution

Product Number : W290017 Brand : Aldrich

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Corrosive to metals (Category 1), H290 Skin corrosion (Category 1B), H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word Danger

Hazard statement(s)

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statement(s)

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

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Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for

breathing. Immediately call a POISON CENTER/doctor.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Molecular weight : 98 g/mol

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Phosphoric acid			
CAS-No. EC-No.	7664-38-2 231-633-2	Met. Corr. 1; Skin Corr. 1B; H290, H314	>= 80 - < 90 %
Index-No.	015-011-00-6	Concentration limits:	
		>= 25 %: Skin Corr. 1B,	
		H314; 10 - < 25 %: Skin Irrit. 2, H315; 10 - < 25 %: Eye Irrit.	
		2, H319;	

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Aldrich - W290017 Page 2 of 7

5.2 Special hazards arising from the substance or mixture

Oxides of phosphorus

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid inhalation of vapour or mist.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage class (TRGS 510): Non combustible liquids, corrosive

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

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Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (US) or type ABEK (EN 14387) respirator cartridges as a backup to enginee protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: clear, liquid
b)	Odour	No data available
c)	Odour Threshold	No data available
d)	рН	No data available
e)	Melting point/freezing point	No data available
f)	Initial boiling point and boiling range	No data available
g)	Flash point	No data available
h)	Evaporation rate	No data available
i)	Flammability (solid, gas)	No data available
j)	Upper/lower flammability or explosive limits	No data available
k)	Vapour pressure	No data available
I)	Vapour density	No data available
m)	Relative density	1.685 g/cm3
n)	Water solubility	No data available
o)	Partition coefficient: n- octanol/water	No data available

p) Auto-ignition

temperature

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No data available

q) Decomposition No data available temperature

r) Viscosity No data available
 s) Explosive properties No data available
 t) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong bases, Powdered metals

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Oxides of phosphorus Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Aldrich - W290017 Page 5 of 7

Additional Information

RTECS: Not available

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin., spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, burning sensation, Cough, wheezing, laryngitis, Shortness of breath, Headache, Nausea

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 1805 IMDG: 1805 IATA: 1805

14.2 UN proper shipping name

ADR/RID: PHOSPHORIC ACID SOLUTION IMDG: PHOSPHORIC ACID SOLUTION Phosphoric acid, solution

14.3 Transport hazard class(es)

ADR/RID: 8 IMDG: 8 IATA: 8

14.4 Packaging group

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Aldrich - W290017 Page 6 of 7

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Aldrich - W290017 Page 7 of 7



Creation Date 20-Jul-2010 Revision Date 20-Jul-2010 Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name PLURONIC F-68 SOLUTION

Cat No. SH30594

Synonyms No information available.

Recommended Use In vitro methods

Company HyClone U.K Ltd

Unit 9 Atley Way

Cramlington, Northumberland, Great

Britain NE23 1WA Tel: 01700-734-093

Emergency Telephone Number INFOTRAC - 24 Hour Number: 1-800-535-5053

Outside of the United States, call 24 Hour Number: 001-352-323-3500 (Call Collect)

2. HAZARDS IDENTIFICATION

Not a hazardous substance or preparation according to EC-directives 67/548/EEC or 1999/45/EC.

R -phrase(s)

none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Haz/Non-haz

Component	Weight %	EC No.	Classification
Pluronic F-68 prill surfactant 9003-11-6	< / = 15 %	-	-
Process water 7732-18-5	> / = 85 %	-	-

For the full text of the R phrases mentioned in this Section, see Section 16



PLURONIC F-68 SOLUTION

Revision Date 20-Jul-2010

4. FIRST AID MEASURES

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Ingestion Do not induce vomiting. Obtain medical attention.

Inhalation Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if

symptoms occur.

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Substance is nonflammable; use agent most appropriate to extinguish surrounding fire..

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

Flash Point Not applicable

MethodNo information available.Autoignition TemperatureNo information available.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Use personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes

and clothing.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Soak up with inert absorbent material Keep in suitable and closed containers for disposal

Up



PLURONIC F-68 SOLUTION

Revision Date 20-Jul-2010

7. HANDLING AND STORAGE

Handling Wear personal protective equipment. Ensure adequate ventilation. Do not breathe vapors or

spray mist. Avoid contact with skin, eyes and clothing.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Specific use(s) No information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits

The product does not contain any hazardous materials with occupational exposure limits established.

Occupational exposure controls

Engineering Measures Ensure adequate ventilation, especially in confined areas Ensure that eyewash stations and

safety showers are close to the workstation location

Personal Protective Equipment

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN

149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits

are exceeded or if irritation or other symptoms are experienced

Eye Protection Tightly fitting safety goggles

Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure

Hand Protection Protective gloves

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice

Environmental exposure controls No information available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State Liquid

AppearanceNo information availableodorNo information available

pH Not applicable
Boiling Point/Range Not applicable

Melting Point/Range No information available.

Flash Point Not applicable

10. STABILITY AND REACTIVITY



PLURONIC F-68 SOLUTION

Revision Date 20-Jul-2010

10. STABILITY AND REACTIVITY

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Excess heat.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO₂)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions . None under normal processing.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation		
Pluronic F-68 prill surfactant	5700 mg/kg (Rat)				

Chronic Toxicity

Carcinogenicity There are no known carcinogenic chemicals in this product

SensitizationNo information available.Neurological EffectsNo information available.Mutagenic EffectsNo information available.Reproductive EffectsNo information available.Developmental EffectsNo information available.

Target Organs None known.

Other Adverse Effects The toxicological properties have not been fully investigated.. See actual entry in RTECS for

complete information.



PLURONIC F-68 SOLUTION

Revision Date 20-Jul-2010

12. ECOLOGICAL INFORMATION

Ecotoxicity

Do not empty into drains.

Persistence and Degradability No information available

Bioaccumulative Potential No information available.

Mobility No information available.

13. DISPOSAL CONSIDERATIONS

Waste from Residues / Unused

Products

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national

hazardous waste regulations to ensure complete and accurate classification

Contaminated Packaging Empty containers should be taken for local recycling, recovery or waste disposal

14. TRANSPORT INFORMATION

IMDG/IMO Not regulated

ADR Not regulated

IATA Not regulated

15. REGULATORY INFORMATION

Not a hazardous substance or preparation according to EC-directives 67/548/EEC or 1999/45/EC

Labelling

R -phrase(s)

none



PLURONIC F-68 SOLUTION

Revision Date 20-Jul-2010

S -phrase(s)

S24/25 - Avoid contact with skin and eyes

International Inventories

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
Pluronic F-68 prill surfactant	-	-		XU	Х	-	Х	Х	Х	Х	KE-24574 X
Process water	-	-		Х	Х	-	Х	-	Х	Х	х

16. OTHER INFORMATION

Prepared By Regulatory Affairs

 Creation Date
 20-Jul-2010

 Revision Date
 20-Jul-2010

Revision Summary "***", and red text indicates revision

Restrictions on use No information available.

Training advice No information available.

Literary reference No information available.

Disclaimer

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 08.11.2016 Print Date 22.12.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Potassium dihydrogen phosphate

Product Number : NIST200B Brand : Sigma-Aldrich

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 7778-77-0

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards - none

SECTION 3: Composition/information on ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

No data available

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

Sigma-Aldrich - NIST200B Page 1 of 4

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

No data available

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

No data available

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For personal protection see section 8.

6.2 Environmental precautions

No data available

6.3 Methods and materials for containment and cleaning up

No data available

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

No data available

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: solid
b) Odour No data available
c) Odour Threshold No data available
d) pH No data available
e) Melting point/freezing No data available

point

No data available

f) Initial boiling point and boiling range

g range

g) Flash pointh) Evaporation rateNo data available

Sigma-Aldrich - NIST200B Page 2 of 4

i) Flammability (solid, gas) No data available

j) Upper/lower flammability or explosive limits

No data available

k) Vapour pressure No data available Vapour density No data available No data available m) Relative density No data available n) Water solubility

o) Partition coefficient: noctanol/water

No data available

p) Auto-ignition temperature

No data available

q) Decomposition temperature

No data available

Viscosity No data available r) s) Explosive properties No data available Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 **Chemical stability**

No data available

Possibility of hazardous reactions 10.3

No data available

Conditions to avoid 10.4

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Skin corrosion/irritation

Serious eye damage/eye irritation

Respiratory or skin sensitisation

Germ cell mutagenicity

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Sigma-Aldrich - NIST200B Page 3 of 4 Reproductive toxicity

Specific target organ toxicity - single exposure

Specific target organ toxicity - repeated exposure

Aspiration hazard

Additional Information

RTECS: Not available

SECTION 12: Ecological information

- 12.1 Toxicity
- 12.2 Persistence and degradability
- 12.3 Bioaccumulative potential
- 12.4 Mobility in soil
- 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No data available

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Sigma-Aldrich - NIST200B Page 4 of 4



Creation Date 07-Aug-2009 Revision Date 26-Dec-2021 Revision Number 5

1. Identification

Product Name Potassium chloride

Cat No.: AC418200000; AC418200025; AC418205000

CAS No 7447-40-7 Synonyms KCI.

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410

Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410

Fair Lawn, NJ 07410

Tel: (201) 796-7100

Emergency Telephone Number For information US call: 001-800-ACROS-01 / Europe call: +32 14 57 52 11

Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Potassium chloride	7447-40-7	>95

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur. If not breathing,

give artificial respiration.

Ingestion Do NOT induce vomiting. Get medical attention if symptoms occur.

Most important symptoms and

effects

No information available.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Unsuitable Extinguishing Media No information available

Flash Point Method -No information available

No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Potassium oxides. Hydrogen chloride gas.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards101N/A

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust

formation.

Environmental Precautions Should not be released into the environment. See Section 12 for additional Ecological

Information.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible

Materials. Strong oxidizing agents.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures None under normal use conditions.

Personal Protective Equipment

Eve/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Solid
Appearance White
Odor Odorless

Odor Threshold
pHNo information available
6 50g/L (20°C)

Melting Point/Range 770 °C / 1418 °F

Boiling Point/Range 1420 $^{\circ}$ C / 2588 $^{\circ}$ F @ 760 mmHg

Flash Point No information available

Evaporation Rate Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

UpperNo data availableLowerNo data availableVapor PressureNo information available

Vapor DensityNot applicableDensity1.987 g/cm3

Specific Gravity No information available

SolubilityPartially solublePartition coefficient; n-octanol/waterNo data availableAutoignition TemperatureNo information availableDecomposition TemperatureNo information available

Viscosity Not applicable

Molecular Formula CI K Molecular Weight 74.54

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Hygroscopic.

Conditions to Avoid Incompatible products. Excess heat. Avoid dust formation. Exposure to moist air or water.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Potassium oxides, Hydrogen chloride gas

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component LD50 Oral		LD50 Dermal	LC50 Inhalation		
	Potassium chloride	LD50 = 2600 mg/kg (Rat)	Not listed	Not listed	

Toxicologically Synergistic

No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation May cause skin, eye, and respiratory tract irritation

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	IARC NTP		OSHA	Mexico	
Potassium chlorid	e 7447-40-7	Not listed					

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental Effects No information available.

Teratogenicity No information available.

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

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Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
Potassium chloride	EC50: 2500 mg/L/72h	Lepomis macrochirus: LC50: 1060 mg/L /96h	Not listed	EC50: 825 mg/L/48h
		Pimephales promelas: LC50:		

750 - 1020 mg/L /96h

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOTNot regulatedTDGNot regulatedIATANot regulatedIMDG/IMONot regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags	
Potassium chloride	7447-40-7	X	ACTIVE	-	

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Potassium chloride	7447-40-7	Х	-	231-211-8	Х	Х	Χ	Х	Х	KE-29086

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): Ν DOT Marine Pollutant Ν **DOT Severe Marine Pollutant** Ν

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Potassium chloride

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV Persistent Organic Pollutant		Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Potassium chloride	7447-40-7	Listed	Not applicable	Not applicable	Not applicable
Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)

16. Other information

7447-40-7

Regulatory Affairs **Prepared By**

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

Not applicable

07-Aug-2009 **Creation Date** 26-Dec-2021 **Revision Date** 26-Dec-2021 **Print Date**

This document has been updated to comply with the US OSHA HazCom 2012 Standard **Revision Summary**

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Not applicable

Not applicable

Not applicable

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS



Creation Date 01-Feb-2010 Revision Date 13-Oct-2023 Revision Number 7

1. Identification

Product Name Potassium phosphate, monobasic

Cat No.: P285-10; P285-250LB; P285-3; P285-3LC; P285-50; P285-500

CAS No 7778-77-0

Synonyms Potassium dihydrogen phosphate

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company One Reagent Lane Fair Lawn, NJ 07410 Tel: (201) 796-7100

Emergency Telephone Number

CHEMTREC®, Inside the USA: 800-424-9300 CHEMTREC®, Outside the USA: 001-703-527-3887

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Dihydrogen potassium phosphate	7778-77-0	<=100

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin ContactWash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

•

None reasonably foreseeable.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Substance is nonflammable; use agent most appropriate to extinguish surrounding fire.

Unsuitable Extinguishing Media No information available

Flash PointNo information availableMethod -No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Oxides of phosphorus. Phosphorus trihydride (phosphine).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards001N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

Keep containers tightly closed in a dry, cool and well-ventilated place. Store under an inert Storage.

atmosphere. Protect from moisture. Incompatible Materials. Strong oxidizing agents.

Strong bases. Strong acids.

8. Exposure controls / personal protection

This product does not contain any hazardous materials with occupational exposure **Exposure Guidelines**

limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

> EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Particle filter. Recommended Filter type:

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Solid **Appearance** White Odor Odorless

Odor Threshold No information available

4.4-4.7 @ 20°C 5% aq.sol pН

253 °C / 487.4 °F Melting Point/Range **Boiling Point/Range** No information available Flash Point No information available

Evaporation Rate Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

No data available Upper Lower No data available **Vapor Pressure** No information available

Vapor Density Not applicable

No information available **Specific Gravity**

Solubility Soluble in water No data available Partition coefficient; n-octanol/water

Autoignition Temperature No information available

Decomposition Temperature > 250°C **Viscosity** Not applicable Molecular Formula H2 K O4 P

136.09 **Molecular Weight**

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Hygroscopic.

Avoid dust formation. Incompatible products. Excess heat. Exposure to moist air or water. **Conditions to Avoid**

Incompatible Materials Strong oxidizing agents, Strong bases, Strong acids

Hazardous Decomposition Products Oxides of phosphorus, Phosphorus trihydride (phosphine)

Hazardous Polymerization Hazardous polymerization does not occur.

None under normal processing. **Hazardous Reactions**

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component LD50 Oral		LD50 Dermal	LC50 Inhalation	
	Dihydrogen potassium phosphate	LD50 = 3200 mg/kg(Rat)	LD50 > 4640 mg/kg (Rabbit)	LC50 > 0.83 mg/L (Rat) 4 h

Toxicologically Synergistic

Products

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Dihydrogen potassium	7778-77-0	Not listed				
phosphate						

Mutagenic Effects No information available

Reproductive Effects No information available. **Developmental Effects** No information available. **Teratogenicity** No information available.

STOT - single exposure None known

STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Potassium phosphate, monobasic

Do not empty into drains. .

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ AccumulationNo information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOTNot regulatedTDGNot regulatedIATANot regulatedIMDG/IMONot regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Dihydrogen potassium phosphate	7778-77-0	X	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Dihydrogen potassium phosphate	7778-77-0	Х	-	231-913-4	X	X	Х	Х	Х	KE-28622

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

Potassium phosphate, monobasic

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Not applicable

Component		REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Dihydrogen potassium phosphate	7778-77-0	-	-	-

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Dihydrogen potassium phosphate	7778-77-0	Listed	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Dihydrogen potassium phosphate	7778-77-0	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

 Creation Date
 01-Feb-2010

 Revision Date
 13-Oct-2023

 Print Date
 13-Oct-2023

Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 30.03.2016 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Sodium Acetate anhydrous

Product Number : W302406 Brand : Aldrich

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 127-09-3

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

No components need to be disclosed according to the applicable regulations.

Aldrich - W302406 Page 1 of 7

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Sodium oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

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7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Storage class (TRGS 510): Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle r (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form: crystalline a) Appearance

Colour: white

b) Odour No data available

d) рΗ 8.5 - 9.9 at 246 g/l at 25 °C

Melting point/freezing

Odour Threshold

point

Melting point/range: > 300 °C

Initial boiling point and f)

boiling range

No data available

No data available

g) Flash point > 250 °C - closed cup

h) Evaporation rate No data available

Flammability (solid, gas) No data available i) i)

Upper/lower flammability or explosive limits No data available

Vapour pressure No data available No data available 1) Vapour density

m) Relative density 1.528 g/cm3

n) Water solubility 246 g/l at 20 °C - completely soluble

Partition coefficient: n-

octanol/water

log Pow: -4.22

p) Auto-ignition

temperature

No data available

Decomposition

temperature

No data available

No data available r) Viscosity s) Explosive properties No data available No data available t) Oxidizing properties

9.2 Other safety information

> Bulk density 320 - 470 kg/m3

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 **Chemical stability**

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

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10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Sodium oxides Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 3,530 mg/kg(Sodium acetate)

LC50 Inhalation - Rat - 1 h - > 30,000 mg/m3(Sodium acetate)

LD50 Dermal - Rabbit - > 10,000 mg/kg(Sodium acetate)

Skin corrosion/irritation

Skin - Rabbit(Sodium acetate) Result: Mild skin irritation - 24 h

Serious eye damage/eye irritation

Eyes - Rabbit(Sodium acetate) Result: Mild eye irritation

Respiratory or skin sensitisation

No data available(Sodium acetate)

Germ cell mutagenicity

No data available(Sodium acetate)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Sodium acetate)

Specific target organ toxicity - single exposure

No data available(Sodium acetate)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Sodium acetate)

Additional Information

RTECS: AJ4300010

Abdominal pain, Nausea, Vomiting(Sodium acetate)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.(Sodium acetate)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 13,330 mg/l - 120 h(Sodium

acetate)

LC50 - Lepomis macrochirus (Bluegill) - 5,000 mg/l - 24 h(Sodium acetate)

Toxicity to daphnia and

EC50 - Daphnia magna (Water flea) - > 1,000 mg/l - 48 h(Sodium acetate)

other aquatic invertebrates

12.2 Persistence and degradability

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12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Sodium acetate)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held

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liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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according to Regulation (EC) No. 1907/2006 Version 6.3 Revision Date 06.02.2017 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Sodium chloride

Product Number : S7653

Brand : Sigma-Aldrich

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 7647-14-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : NaCl
Molecular weight : 58.44 g/mol
CAS-No. : 7647-14-5
EC-No. : 231-598-3

No components need to be disclosed according to the applicable regulations.

Sigma-Aldrich - S7653 Page 1 of 7

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Hydrogen chloride gas, Sodium oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

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7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Storage class (TRGS 510): Non Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

Sigma-Aldrich - S7653 Page 3 of 7

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: solid

Colour: colourless

b) Odour No data available

c) Odour Threshold No data available

d) pH 7

e) Melting point/freezing

point

Melting point/range: 801 °C

f) Initial boiling point and

boiling range

1,413 °C

g) Flash point No data available
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

j) Upper/lower flammability or explosive limits No data available

k) Vapour pressure 1.00 mmHg at 865 °C

I) Vapour density No data available

m) Relative density 2.1650 g/cm3

n) Water solubility 358 g/l at 20 °C - soluble

o) Partition coefficient: n-

octanol/water

No data available

p) Auto-ignition

temperature

No data available

No data available

q) Decomposition

temperature

r) Viscosity No data availables) Explosive properties No data availablet) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

Sigma-Aldrich - S7653 Page 4 of 7

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Hydrogen chloride gas, Sodium oxides Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 3,550 mg/kg(Sodium chloride)

LC50 Inhalation - Rat - 1 h - > 42,000 mg/m3(Sodium chloride)

LD50 Dermal - Rabbit - > 10,000 mg/kg(Sodium chloride)

Skin corrosion/irritation

No data available(Sodium chloride)

Serious eye damage/eye irritation

No data available(Sodium chloride)

Respiratory or skin sensitisation

No data available(Sodium chloride)

Germ cell mutagenicity

No data available(Sodium chloride)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Sodium chloride)

Specific target organ toxicity - single exposure

No data available(Sodium chloride)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Sodium chloride)

Additional Information

RTECS: VZ4725000

Vomiting, Diarrhoea, Dehydration and congestion may occur in internal organs. Hypertonic salt solutions can produce inflammatory reactions in the gastrointestinal tract., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. (Sodium chloride)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Lepomis macrochirus (Bluegill) - 5,840 mg/l - 96 h(Sodium chloride)

Toxicity to daphnia and NOEC - Daphnia (water flea) - 1,500 mg/l - 7 d(Sodium chloride)

other aquatic invertebrates

LC50 - Daphnia magna (Water flea) - 1,661 mg/l - 48 h(Sodium chloride)

12.2 Persistence and degradability

No data available

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12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Sodium chloride)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Sigma-Aldrich - S7653 Page 6 of 7

Sigma-Aldrich - S7653 Page 7 of 7

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 30.03.2016 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Sodium hydroxide

Product Number : S8045 Brand : SIGALD Index-No. : 011-002-00-6

REACH No. : 01-2119457892-27-XXXX

CAS-No. : 1310-73-2

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12.

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Corrosive to metals (Category 1), H290 Skin corrosion (Category 1A), H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word Danger

Hazard statement(s)

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statement(s)

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

SIGALD - S8045 Page 1 of 7

Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for

breathing. Immediately call a POISON CENTER/doctor.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : Caustic soda

Formula : NaOH

Molecular weight : 40.00 g/mol

CAS-No. : 1310-73-2

EC-No. : 215-185-5

Index-No. : 011-002-00-6

Registration number : 01-2119457892-27-XXXX

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Sodium hydroxide			
CAS-No. EC-No. Index-No. Registration number	1310-73-2 215-185-5 011-002-00-6 01-2119457892-27-XXXX	Met. Corr. 1; Skin Corr. 1A; H290, H314 Concentration limits: >= 5 %: Skin Corr. 1A, H314; 2 - < 5 %: Skin Corr. 1B, H314; 0.5 - < 2 %: Skin Irrit. 2, H315; 0.5 - < 2 %: Eye Irrit. 2, H319;	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Sodium oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): Non-combustible, corrosive hazardous materials

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

Application Area	Exposure routes	Health effect	Value
Workers	Inhalation	Long-term local effects	1 mg/m3
Consumers	Inhalation	Long-term local effects	1 mg/m3

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

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Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls. If th full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: pellets

Colour: white

b) Odour odourless

c) Odour Threshold No data availabled) pH 14 at 50 g/l at 20 °C

e) Melting point/freezing

point

Melting point/range: 318 °C

f) Initial boiling point and

boiling range

1.390 °C

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Flash point Not applicable g) h) Evaporation rate No data available Flammability (solid, gas) No data available i) Upper/lower No data available flammability or explosive limits

< 18.00 mmHg at 20 °C k) Vapour pressure

3.00 mmHg at 37 °C

Vapour density 1.38 - (Air = 1.0)1) m) Relative density 2.1300 g/cm3

n) Water solubility ca.1,260 g/l at 20 °C

o) Partition coefficient: n-

octanol/water

p) Auto-ignition

No data available No data available

temperature

q) Decomposition

No data available

temperature

No data available Viscosity r) s) Explosive properties No data available No data available Oxidizing properties

9.2 Other safety information

> Bulk density ca.1,150 kg/m3 1.38 - (Air = 1.0)Relative vapour density

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents, Strong acids, Organic materials

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Sodium oxides Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data availableSodium hydroxide

Skin corrosion/irritation

Skin - Rabbit(Sodium hydroxide)

Result: Causes severe burns. - 24 h

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Serious eye damage/eye irritation

Eyes - Rabbit(Sodium hydroxide)

Result: Corrosive - 24 h

Respiratory or skin sensitisation

Will not occur(Sodium hydroxide)

Germ cell mutagenicity

No data available(Sodium hydroxide)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Sodium hydroxide)

Specific target organ toxicity - single exposure

No data available(Sodium hydroxide)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Sodium hydroxide)

Additional Information

RTECS: WB4900000

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin.(Sodium hydroxide)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Gambusia affinis (Mosquito fish) - 125 mg/l - 96 h(Sodium hydroxide)

LC50 - Oncorhynchus mykiss (rainbow trout) - 45.4 mg/l - 96 h(Sodium

hydroxide)

Toxicity to daphnia and

other aquatic

Immobilization EC50 - Daphnia (water flea) - 40.38 mg/l - 48 h(Sodium

hydroxide)

invertebrates

12.2 Persistence and degradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Sodium hydroxide)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Harmful to aquatic life.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 1823 IMDG: 1823 IATA: 1823

14.2 UN proper shipping name

ADR/RID: SODIUM HYDROXIDE, SOLID IMDG: SODIUM HYDROXIDE, SOLID Sodium hydroxide, solid

14.3 Transport hazard class(es)

ADR/RID: 8 IMDG: 8 IATA: 8

14.4 Packaging group

ADR/RID: II IMDG: II IATA: II

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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according to Regulation (EC) No. 1907/2006 Version 6.1 Revision Date 06.02.2017 Print Date 22.12.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Sodium sulfate

Product Number : 238597 Brand : SIGALD

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 7757-82-6

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : Na₂O₄S Molecular weight : 142.04 g/mol CAS-No. : 7757-82-6 EC-No. : 231-820-9

No components need to be disclosed according to the applicable regulations.

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SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Sulphur oxides, Sodium oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): Non Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

No special environmental precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: powder

Colour: white

b) Odour odourless

c) Odour Threshold No data available

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d)) pH	5.2 - 8 at 50 g/l at 20 °C
----	------	----------------------------

e) Melting point/freezing Melting point/range: 884 °C point

f) Initial boiling point and boiling range

> 1,700 °C - Decomposition

g) Flash point Not applicable
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

j) Upper/lower flammability or explosive limits No data available

k) Vapour pressure < 0.1 hPa at 20 °C
 l) Vapour density No data available
 m) Relative density 2.68 g/mL at 25 °C
 n) Water solubility 185 g/l - soluble

o) Partition coefficient: noctanol/water log Pow: 3.0

p) Auto-ignition temperature

No data available

q) Decomposition temperature

No data available

r) Viscosity No data available
 s) Explosive properties No data available
 t) Oxidizing properties No data available

9.2 Other safety information

Bulk density 1,400 kg/m3

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong acids, Aluminum, Magnesium

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Sulphur oxides, Sodium oxides Other decomposition products - No data available

In the event of fire: see section 5

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Mouse - 5,989 mg/kg(Sodium sulfate)

Skin corrosion/irritation

Skin - Rabbit(Sodium sulfate) Result: No skin irritation (OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit(Sodium sulfate)

Result: No eye irritation

Respiratory or skin sensitisation

Maximisation Test - Guinea pig(Sodium sulfate) Result: Does not cause skin sensitisation.

(OECD Test Guideline 406)

Germ cell mutagenicity

No data available(Sodium sulfate)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Sodium sulfate)

Specific target organ toxicity - single exposure

No data available(Sodium sulfate)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Sodium sulfate)

Additional Information

RTECS: WE1650000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.(Sodium sulfate)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Gambusia affinis (Mosquito fish) - 120 mg/l - 96 h(Sodium sulfate)

LC50 - Lepomis macrochirus - 4,380 mg/l - 96 h(Sodium sulfate)

Toxicity to daphnia and

other aquatic invertebrates

EC50 - Daphnia magna (Water flea) - 2,564 mg/l - 48 h(Sodium sulfate)

12.2 Persistence and degradability

The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No data available

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12.4 Mobility in soil

No data available(Sodium sulfate)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixtureThis safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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Thermo Fisher SCIENTIFIC

SAFETY DATA SHEET

Page 1/7
Creation Date 29-Jan-2010
Revision Date 15-Dec-2020
Version 4

ACR21712

Sodium bicarbonate

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

产品说明: 碳酸氢钠

Product Description: Sodium bicarbonate

Cat No.: 217120000; 217120010; 217120025; 217120250; 217125000

Synonyms Sodium hydrogen carbonate

CAS No 144-55-8 Molecular Formula C H Na O3

Supplier UK entity/business name

Fisher Scientific UK Bishop Meadow Road,

Loughborough, Leicestershire LE11 5RG, United Kingdom

General info; Tel: +44 (0)1509 231166

EU entity/business name Acros Organics BVBA

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium General Info; Tel: +32-14-57 52 11 (info@acros.com)

Technical Support; Tel +32-14-56 56 00 (acros.techsupport@thermofisher.com)

Emergency Telephone Number For information US call: 001-800-ACROS-01 / Europe call: +32 14 57 52 11

Emergency Number **US:**001-201-796-7100 / **Europe:** +32 14 57 52 99 **CHEMTREC** Tel. No.**US:**001-800-424-9300 / **Europe:**001-703-527-3887

E-mail address begel.sdsdesk@thermofisher.com

Recommended Use Laboratory chemicals. Uses advised against No Information available

SECTION 2. HAZARD IDENTIFICATION

Physical StateAppearanceOdorPowder SolidWhiteOdorless

Emergency Overview

May be harmful if swallowed. Hygroscopic.

Classification of the substance or mixture

Acute Oral Toxicity Category 5

Label Elements

None required

Hazard Statements

H303 - May be harmful if swallowed

Precautionary Statements

Sodium bicarbonate

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Prevention

P270 - Do not eat, drink or smoke when using this product

Response

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Storage

P403 - Store in a well-ventilated place

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Physical and Chemical Hazards

Hygroscopic.

Health Hazards

May be harmful if swallowed.

Environmental hazards

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants. Will likely be mobile in the environment due to its water solubility. The product is water soluble, and may spread in water systems.

Other Hazards

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Sodium bicarbonate	144-55-8	>95

SECTION 4. FIRST AID MEASURES

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.

Inhalation

Remove to fresh air. Get medical attention immediately if symptoms occur.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

Most important symptoms and effects

None reasonably foreseeable.

Self-Protection of the First Aider

No special precautions required.

Notes to Physician

Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes.

Sodium bicarbonate

te

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Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

Environmental Precautions

Should not be released into the environment.

Methods for Containment and Clean Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

Refer to protective measures listed in Sections 8 and 13.

SECTION 7. HANDLING AND STORAGE

Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid ingestion and inhalation. Avoid contact with skin, eyes or clothing. Avoid dust formation.

Storage

Keep containers tightly closed in a dry, cool and well-ventilated place.

Specific Use(s)

Use in laboratories

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

Exposure Controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location. .

Personal protective equipment

Eye Protection Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Natural rubber Nitrile rubber Neoprene PVC	See manufacturers recommendations	-	EN 374	(minimum requirement)

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Sodium bicarbonate

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Skin and body protection Long sleeved clothing

No protective equipment is needed under normal use conditions. **Respiratory Protection**

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits Large scale/emergency use

are exceeded or if irritation or other symptoms are experienced

Recommended Filter type: Particle filter

Maintain adequate ventilation Small scale/Laboratory use

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

No information available. **Environmental exposure controls**

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

0.1M aq. solution

White **Appearance** Powder Solid **Physical State**

Odorless Odor

Odor Threshold No data available

pН 8.3

Melting Point/Range 270 °C / 518 °F

Softening Point No data available

Boiling Point/Range No information available

No information available Method - No information available Flash Point

Not applicable **Evaporation Rate** Solid No information available

No data available **Explosion Limits**

Vapor Pressure No information available

Vapor Density Not applicable Solid

Specific Gravity / Density No data available No data available **Bulk Density Water Solubility** 9 a/100ml (20°C)

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Flammability (solid,gas)

Autoignition Temperature No data available

Decomposition Temperature > 50°C

Not applicable Viscosity Solid

No information available **Explosive Properties** No information available **Oxidizing Properties**

CHNaO3 **Molecular Formula Molecular Weight** 84.01

SECTION 10. STABILITY AND REACTIVITY

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Sodium bicarbonate

Stability Hygroscopic.

Hazardous Reactions
Hazardous Polymerization
None under normal processing.
No information available.

Conditions to Avoid Avoid dust formation. Incompatible products. Exposure to moist air or water. Excess heat.

Temperatures above 50°C.

Materials to avoid Strong oxidizing agents. Acids.

Hazardous Decomposition Products Sodium oxides.

SECTION 11. TOXICOLOGICAL INFORMATION

Product Information

(a) acute toxicity;

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation		
Sodium bicarbonate	LD50 = 4220 mg/kg (Rat)				

(b) skin corrosion/irritation; Based on available data, the classification criteria are not met

(c) serious eye damage/irritation; Based on available data, the classification criteria are not met

(d) respiratory or skin sensitization;

Respiratory B
Skin B

Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met

(e) germ cell mutagenicity; Based on available data, the classification criteria are not met

(f) carcinogenicity; Based on available data, the classification criteria are not met

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Based on available data, the classification criteria are not met

(h) STOT-single exposure; Based on available data, the classification criteria are not met

(i) STOT-repeated exposure; Based on available data, the classification criteria are not met

Target Organs None known.

(j) aspiration hazard; Not applicable

Solid

Symptoms / effects,both acute and No information available

delayed

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox

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Sodium bicarbonate

Sodium bicarbonate	LC50: 8250 - 9000	EC50: 2350 mg/L/48h	EC50: 650 mg/L/120h	-	
	mg/L, 96h static				
	(Lepomis macrochirus)				

Persistence and Degradability

Persistence Degradability Soluble in water, Persistence is unlikely, based on information available.

Not relevant for inorganic substances.

Bioaccumulative Potential Bioaccumulation is unlikely

Mobility in soil The product is water soluble, and may spread in water systems Will likely be mobile in the

environment due to its water solubility Highly mobile in soils

Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13. DISPOSAL CONSIDERATIONS

Waste from Residues/Unused

Products

Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

Contaminated Packaging

Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use

empty containers.

Other Information

Waste codes should be assigned by the user based on the application for which the product

was used.

SECTION 14. TRANSPORT INFORMATION

Road and Rail Transport Not Regulated

IMDG/IMO Not regulated

IATA Not regulated

Special Precautions for User No special precautions required

SECTION 15. REGULATORY INFORMATION

International Inventories

X = listed, China (IECSC), Europe (EINECS/ELINCS/NLP), U.S.A. (TSCA), Canada (DSL/NDSL), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), Korea (KECL).

	The Inventory of Hazardous Chemicals (2015 Edition)	goods GB	TCSI	IECSC	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	AICS	KECL
Sodium bicarbonate	-	-	Χ	Х	205-633-8	Х	Χ	Х	Χ	Х	Χ	KE-31360

Sodium bicarbonate

National Regulations

SECTION 16. OTHER INFORMATION

Creation Date29-Jan-2010Revision Date15-Dec-2020Revision SummaryNot applicable.

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Legend

CAS - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b)
Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

Substances/EU List of Notified Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Substances List

ENCS - Japanese Existing and New Chemical Substances

AUCS - Australian Inventory of Chemical Substances

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AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level **RPE** - Respiratory Protective Equipment

LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water **vPvB** - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships

ATE - Acute Toxicity Estimate

VOC (volatile organic compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet



Creation Date 20-Jul-2009 Revision Date 24-Dec-2021 Revision Number 6

1. Identification

Product Name Sodium Acetate Anhydrous

Cat No.: BP333-1; BP333-500

CAS No 127-09-3 Synonyms Sodium acetate

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company One Reagent Lane Fair Lawn, NJ 07410 Tel: (201) 796-7100

Emergency Telephone Number CHEMTREC®, Inside the USA: 800-424-9300

CHEMTREC®, Outside the USA: 001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust Yes

Label Elements

Signal Word

Warning

Hazard Statements

May form combustible dust concentrations in air

Precautionary Statements

Storage

Store in a well-ventilated place. Keep container tightly closed

·

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Sodium acetate	127-09-3	>95

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Get medical attention immediately if symptoms occur. Wash off immediately with plenty of

water for at least 15 minutes.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

None reasonably foreseeable.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray. Carbon dioxide (CO2). Dry chemical. Chemical foam.

Unsuitable Extinguishing Media No information available

Flash Point > 250 °C / > 482 °F

Method - No information available

Autoignition Temperature 607 °C / 1124.6 °F

Explosion Limits

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Dust can form an explosive mixture with air. Fine dust dispersed in air may ignite.

Hazardous Combustion Products

None known.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards011N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage. Protect from moisture. Store under an inert atmosphere. Keep container tightly closed in a

dry and well-ventilated place. Incompatible Materials. Strong acids. Fluorine.

8. Exposure controls / personal protection

Exposure GuidelinesThis product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location. Use explosion-proof

electrical/ventilating/lighting equipment.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical StatePowder SolidAppearanceWhiteOdorvinegar-like

Odor Threshold No information available

Evaporation Rate Not applicable

Flammability (solid,qas)

No information available

Flammability or explosive limits

Upper No data available
Lower No data available
Vapor Pressure No information available

Vapor Density Not applicable

Specific Gravity

No information available

Solubility $500 \text{ g/L } (20^{\circ}\text{C})$

Sodium Acetate Anhydrous

No data available 607 °C / 1124.6 °F

No information available

Partition coefficient; n-octanol/water

Autoignition Temperature Decomposition Temperature

Viscosity

Not applicable C2 H3 Na O2 Molecular Formula **Molecular Weight** 82.03

10. Stability and reactivity

Reactive Hazard None known, based on information available

Hygroscopic. Stability

Conditions to Avoid Avoid dust formation. Incompatible products. Exposure to moist air or water.

Strong acids, Fluorine **Incompatible Materials**

Hazardous Decomposition Products None known

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component LD50 Oral		LD50 Dermal	LC50 Inhalation		
Sodium acetate	LD50 = 3530 mg/kg (Rat)	LD50 > 10 g/kg (Rabbit)	LC50 > 30 g/m³(Rat)1 h		

Toxicologically Synergistic

No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

The table below indicates whether each agency has listed any ingredient as a carcinogen. Carcinogenicity

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Sodium acetate	127-09-3	Not listed				

No information available **Mutagenic Effects**

No information available. **Reproductive Effects Developmental Effects** No information available. **Teratogenicity** No information available.

STOT - single exposure None known STOT - repeated exposure None known

No information available **Aspiration hazard**

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects

The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

. Do not empty into drains.

Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea		
Sodium acetate	Sodium acetate -		= 7200 mg/L EC50	EC50: > 1000 mg/L, 48h		
		semi-static (Danio rerio)	Pseudomonas putida 18 h	(Daphnia magna)		

Persistence and Degradability

Persistence is unlikely

Bioaccumulation/ Accumulation

No information available.

Mobility

. Will likely be mobile in the environment due to its water solubility.

Component	log Pow			
Sodium acetate	-4.22			

13. Disposal considerations

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information					
DOT	Not regulated				
DOT TDG IATA	Not regulated				
IATA	Not regulated				
IMDG/IMO	Not regulated				
15 Regulatory information					

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags	
Sodium acetate	127-09-3	Χ	ACTIVE	-	

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Sodium acetate	127-09-3	Χ	-	204-823-8	Χ	Χ	Χ	Х	Χ	KE-00061

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

Sodium Acetate Anhydrous

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Component

Sodium acetate

Mexico - Grade No information available

CAS No

127-09-3

Authorisation/Restrictions according to EU REACH

Safety, health and environmental regulations/legislation specific for the substance or mixture

			Pollutant	Potentiai	Substances (RoHS)
Sodium acetate	127-09-3	Listed	Not applicable	Not applicable	Not applicable
Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities	Seveso III Directive (2012/18/EC) - Qualifying Quantities	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
		for Major Accident Notification	for Safety Report Requirements		

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

Not applicable

OECD HPV

 Creation Date
 20-Jul-2009

 Revision Date
 24-Dec-2021

 Print Date
 24-Dec-2021

Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Persistent Organic

Not applicable

Ozone Depletion

Not applicable

Restriction of

Not applicable

Harmonized System of Classification and Labeling of Chemicals (GHS).

Revision Date 24-Dec-2021

Disclaimer

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End of SDS



SAFETY DATA SHEET

Creation Date 09-Dec-2009 Revision Date 13-Oct-2023 Revision Number 2

1. Identification

Product Name Sodium Citrate Dihydrate

Cat No.: BP327-1, BP327-500

CAS No 6132-04-3

Synonyms 2-Hydroxy-1,2,3-Propanetricarboxylic Acid Trisodium Salt.

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company One Reagent Lane Fair Lawn, NJ 07410 Tel: (201) 796-7100

Emergency Telephone Number

CHEMTREC®, Inside the USA: 800-424-9300 CHEMTREC®, Outside the USA: 001-703-527-3887

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust Yes

Label Elements

Signal Word

Warning

Hazard Statements

May form combustible dust concentrations in air

Precautionary Statements

Storage

Store in a well-ventilated place. Keep container tightly closed

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Citrate, sodium, dihydrate	6132-04-3	>95
Sodium citrate	68-04-2	-

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention if symptoms occur.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur. If not breathing,

give artificial respiration.

Ingestion Do NOT induce vomiting. Get medical attention immediately if symptoms occur.

Most important symptoms and

effects

No information available.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature 500 °C / 932 °F

Explosion Limits

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors. Dust can form an explosive mixture with air. Fine dust dispersed in air may ignite.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO2). Sodium oxides.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards110N/A

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin and eyes. Use

personal protective equipment as required.

Environmental Precautions No special environmental precautions required. See Section 12 for additional Ecological

Information.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Handling Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and

inhalation. Avoid dust formation.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible

Materials. Strong oxidizing agents. Strong reducing agents. Acids. Bases.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face ProtectionWear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Recommended Filter type: Particle filter.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical StateSolidAppearanceWhiteOdorOdorless

Odor Threshold

No information available

pH 8.4 @ 20°C 5% aq. solution

Melting Point/Range >300 °C / 572 °F

Boiling Point/Range No information available
Flash Point No information available

Evaporation Rate Not applicable

Flammability (solid,gas)

No information available Flammability or explosive limits

Upper No data available

Sodium Citrate Dihydrate

Lower No data available
Vapor Pressure No information available

Vapor DensityNot applicableSpecific GravityNo information available

Solubility Soluble in water Partition coefficient; n-octanol/water No data available

Autoignition Temperature500 °C / 932 °FDecomposition Temperature> 230 °CViscosityNot applicable

Molecular Formula C6 H5 Na3 O7 . 2 H2 O

Molecular Weight 294.09

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Excess heat. Avoid dust formation.

Incompatible Materials Strong oxidizing agents, Strong reducing agents, Acids, Bases

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO2), Sodium oxides

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous ReactionsNone under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Citrate, sodium, dihydrate	LD50 = 5400 mg/kg (Mouse)	LD50 = > 2000 mg/kg (Rat) (OECD	Not listed
-	(OECD 401)	402)	
Sodium citrate	5400 mg/kg (Mouse)	Not listed	Not listed

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation May cause skin, eye, and respiratory tract irritation

Sensitization No information available

CarcinogenicityThe table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Citrate, sodium,	6132-04-3	Not listed				
dihydrate						
Sodium citrate	68-04-2	Not listed				

Mutagenic Effects No information available

Reproductive Effects

No information available.

Developmental Effects

No information available.

Developmental EffectsNo information available.

Teratogenicity No information available.

STOT - single exposure None known

Sodium Citrate Dihydrate

STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects, both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

.

Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
Sodium citrate	Not listed	LC50: 18000 - 32000 mg/L,	EC50 1800 - 3200 mg/L 8 h	EC50: 5600 - 10000 mg/L,
		96h (Poecilia reticulata)		48h (Daphnia magna)

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

	14. Transport information						
DOT	Not regulated						
DOT TDG IATA	Not regulated						
IATA	Not regulated						
IMDG/IMO	Not regulated						
	15. Regulatory information						

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Citrate, sodium, dihydrate	6132-04-3	•	•	-
Sodium citrate	68-04-2	Χ	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Citrate, sodium, dihydrate	6132-04-3	-	-	-	Х	Χ		Х	Х	-
Sodium citrate	68-04-2	X	-	200-675-3	Х	Χ	Х	X	Χ	KE-20843

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH Not applicable

	Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
	Citrate, sodium, dihydrate	6132-04-3	-	-	-
ſ	Sodium citrate	68-04-2	-	-	-

Safety, health and environmental regulations/legislation specific for the substance or mixture

	Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Ī	Citrate, sodium, dihydrate	6132-04-3	Not applicable	Not applicable	Not applicable	Not applicable
I	Sodium citrate	68-04-2	Listed	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities	, , ,	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
		for Major Accident Notification	for Safety Report Requirements		
Citrate, sodium, dihydrate	6132-04-3	Not applicable	Not applicable	Not applicable	Not applicable
Sodium citrate	68-04-2	Not applicable	Not applicable	Not applicable	Not applicable

16	Other	inform	nation	
IO.	Orner		nalion	

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

 Creation Date
 09-Dec-2009

 Revision Date
 13-Oct-2023

 Print Date
 13-Oct-2023

Revision Summary

This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

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End of SDS



SAFETY DATA SHEET

Creation Date 02-Feb-2010 Revision Date 24-Dec-2021 Revision Number 8

1. Identification

Product Name Sodium phosphate, dibasic

Cat No.: AC204850000; AC204850050; AC204851000; AC204855000

CAS No 7558-79-4

Synonyms Disodium hydrogen phosphate

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company Acros Organics
One Reagent Lane One Reagent Lane
Fair Lawn, NJ 07410 Fair Lawn, NJ 07410

Tel: (201) 796-7100

Emergency Telephone Number For information US call: 001-800-ACROS-01 / Europe call: +32 14 57 52 11

Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Sodium phosphate dibasic	7558-79-4	>95

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

None reasonably foreseeable.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes.

Hazardous Combustion Products

Oxides of phosphorus. Sodium oxides.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards101N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

Up

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible

Materials. Strong oxidizing agents. Strong acids. Strong bases.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical StatePowder SolidAppearanceWhiteOdorOdorless

Odor Threshold No information available

pH 8.7-9.3 @ 20°C (5%)
Melting Point/Range No data available
Boiling Point/Range No information available
Flash Point No information available

Evaporation Rate Not applicable

Flammability (solid,gas)

No information available

Flammability or explosive limits

Upper No data available
Lower No data available
apor Pressure No information available

Vapor PressureNo information availaVapor DensityNot applicable

Specific GravityNo information availableSolubilitySlightly soluble in waterPartition coefficient; n-octanol/waterNo data available

Autoignition Temperature No information available

Decomposition Temperature > 240°C
Viscosity Not applicable

Molecular FormulaH Na2 O4 PMolecular Weight141.96

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Hygroscopic.

Conditions to Avoid Incompatible products. Excess heat. Exposure to moist air or water.

Incompatible Materials Strong oxidizing agents, Strong acids, Strong bases

Hazardous Decomposition Products Oxides of phosphorus, Sodium oxides

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium phosphate dibasic	LD50 = 17 g/kg (Rat)	Not listed	Not listed

Toxicologically Synergistic

Products

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

IrritationNo information availableSensitizationNo information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

- [Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
	Sodium phosphate dibasic	7558-79-4	Not listed				

Mutagenic Effects No information available

Reproductive Effects

No information available.

Developmental Effects

No information available.

Teratogenicity No information available.

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Sodium phosphate, dibasic

Do not empty into drains. .

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT Not regulated
TDG Not regulated
IATA Not regulated
IMDG/IMO Not regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Sodium phosphate dibasic	7558-79-4	X	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Sodium phosphate dibasic	7558-79-4	X	-	231-448-7	X	X	Х	Х	Х	KE-12344

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act)

Component	CWA - Hazardous Substances	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants
Sodium phosphate dibasic	X	5000 lb	-	-

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Component	Hazardous Substances RQs	CERCLA EHS RQs
Sodium phosphate dibasic	5000 lb	-

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Component	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Sodium phosphate	X	X	X	-	-
dibasic					

U.S. Department of Transportation

Reportable Quantity (RQ): Υ **DOT Marine Pollutant** Ν **DOT Severe Marine Pollutant** Ν

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Sodium phosphate dibasic	7558-79-4	Listed	Not applicable	Not applicable	Not applicable
Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Sodium phosphate dibasic	7558-79-4	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Regulatory Affairs Prepared By

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

Creation Date 02-Feb-2010 **Revision Date** 24-Dec-2021 24-Dec-2021 **Print Date**

Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the

Revision Date 24-Dec-2021

date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 30.03.2016 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Tromethamine

Product Number : T6687 Brand : Sigma

REACH No. : 01-2119957659-16-XXXX

CAS-No. : 77-86-1

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : Tris

Formula : C₄H₁₁NO₃

Molecular weight : 121.14 g/mol
CAS-No. : 77-86-1
EC-No. : 201-064-4

Registration number : 01-2119957659-16-XXXX

No components need to be disclosed according to the applicable regulations.

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SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NOx)

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Hygroscopic.

Storage class (TRGS 510): Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: crystalline

Colour: colourlesswhite

b) Odourc) Odour ThresholdNo data available

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d) pH 10.5 - 12

e) Melting point/freezing

point

Melting point/range: 169 °C

f) Initial boiling point and

boiling range

288 °C at 1,013 hPa - Decomposes below the boiling point.

g) Flash point No data available
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

j) Upper/lower flammability or explosive limits No data available

k) Vapour pressure No data available
 l) Vapour density No data available
 m) Relative density No data available
 n) Water solubility 678 g/l at 20 °C

 o) Partition coefficient: noctanol/water

- log

log Pow: -2.31 at 20 °C

p) Auto-ignition temperature

The substance or mixture is not classified as self heating.

q) Decomposition temperature

No data available

r) Viscosity Not applicables) Explosive properties Not explosive

t) Oxidizing properties The substance or mixture is not classified as oxidizing.

9.2 Other safety information

Bulk density 800 kg/m3

Dissociation constant 8.22 at 25 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Exposure to moisture

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - No data available

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx) In the event of fire: see section 5

Sigma - T6687 Page 4 of 7

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - > 3,000 mg/kg(Tris (hydroxymethyl) aminomethane) LD50 Dermal - Rat - > 5,000 mg/kg(Tris (hydroxymethyl) aminomethane) (OECD Test Guideline 402)

Skin corrosion/irritation

Skin - Rabbit(Tris (hydroxymethyl) aminomethane)

Result: No skin irritation (OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit(Tris (hydroxymethyl) aminomethane)

Result: No eye irritation (OECD Test Guideline 405)

Respiratory or skin sensitisation

Buehler Test - Guinea pig(Tris (hydroxymethyl) aminomethane)

Does not cause skin sensitisation.

(OECD Test Guideline 406)

Germ cell mutagenicity

Result: Not mutagenic in Ames Test

in vitro assay(Tris (hydroxymethyl) aminomethane)

Result: negative

In vitro tests did not show mutagenic effects (Tris (hydroxymethyl) aminomethane)

Result: In vivo tests did not show any chromosomal changes.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Tris (hydroxymethyl) aminomethane)

Specific target organ toxicity - single exposure

No data available(Tris (hydroxymethyl) aminomethane)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Tris (hydroxymethyl) aminomethane)

Additional Information

Repeated dose toxicity - Rat - Oral - No observed adverse effect level - 1,000 mg/kg(Tris (hydroxymethyl) aminomethane)

RTECS: TY2900000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.(Tris (hydroxymethyl) aminomethane)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to daphnia and EC50 - Daphnia (water flea) - > 980 mg/l - 48 h(Tris (hydroxymethyl)

other aquatic aminomethane)

invertebrates

Toxicity to algae EC50 - Algae - 397 mg/l - 72 h(Tris (hydroxymethyl) aminomethane)

NOEC - Algae - 100 mg/l - 72 h(Tris (hydroxymethyl) aminomethane)

12.2 Persistence and degradability

Biodegradability Result: - Readily biodegradable

(OECD Test Guideline 301F)

12.3 Bioaccumulative potential

No bioaccumulation is to be expected (log Pow <= 4).

12.4 Mobility in soil

No data available(Tris (hydroxymethyl) aminomethane)

12.5 Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

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SECTION 16: Other information

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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www.sigmaaldrich.com



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.4 Revision Date 02.08.2023 Print Date 02.08.2023

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Cell Culture Media 4CHO Sample Kit

Product Number : 103882 Brand : Millipore

REACH No. : This product is a mixture. REACH Registration Number see

section 3.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Pharmaceutical production and analysis

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone

Emergency Phone # : +91 98802 05043

This is a summary SDS for a kit. For the full SDS for each of the components listed in section 16 please visit our website.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Millipore- 103882 Page 1 of 10



Signal Word Danger

Hazard statement(s)

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

Precautionary statement(s)

P261 Avoid breathing dust.

P264 Wash skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the

workplace.

P280 Wear protective gloves/ eye protection/ face protection.

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing.

Supplemental Hazard

Statements

none

Reduced Labeling (<= 125 ml)

Pictogram

Signal Word Danger

Hazard statement(s)

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

Precautionary statement(s)

P261 Avoid breathing dust.

P272 Contaminated work clothing should not be allowed out of the

workplace.

P280 Wear protective gloves/ eye protection/ face protection.

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing.

Supplemental Hazard

Statements

none

2.3 Other hazards - none

SECTION 3: Composition/information on ingredients

Refer to component SDS

SECTION 4: First aid measures

Refer to component SDS

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SECTION 5: Firefighting measures

Refer to component SDS

SECTION 6: Accidental release measures

Refer to component SDS

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

Storage class

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

Refer to component SDS

SECTION 9: Physical and chemical properties

Refer to component SDS

SECTION 10: Stability and reactivity

Refer to component SDS

SECTION 11: Toxicological information

Refer to component SDS

SECTION 12: Ecological information

Refer to component SDS

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A

SECTION 13: Disposal considerations

Refer to component SDS

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Refer to component SDS

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Kit Components:			
Cellvento® 4CHO COMP	Millipore	1.03795	Eye Irrit. 2; Skin Sens. 1; H317,
Chemically defined cell			H319
culture medium			
Cellvento® 4Feed COMP	Millipore	1.03796	
chemically defined cell			
culture feed			
Cellvento® 4CHO-X	Sigma	1.03840	Eye Irrit. 2; H319
COMP Expansion Medium			
EX-CELL® Advanced	Millipore	104075	Eye Irrit. 2; H319
CHO Fed-batch Medium			

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EX-CELL® Advanced CHO Feed1 (without	Millipore	104076	Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; H315, H317, H318
glucose)			26.16. 17 1.0137 1.0177 1.016
EX-CELL® Adv HD	Millipore	104071	Skin Irrit. 2; Eye Irrit. 2; H315,
Perfusion			H319

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM -American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. -Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS -Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Classification of t	he mixture	Classification procedure:
Skin Irrit.2	H315	Calculation method
Eye Dam.1	H318	Calculation method
Skin Sens.1	H317	Calculation method

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to

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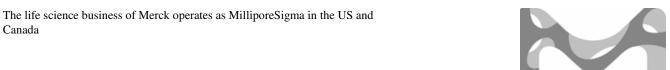
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SAFC_®

Kit Components:

Cellvento® 4CHO COMP Chemically defined cell culture medium					
Product	Pictogram	Signal	Hazard	Precautionary	Supplemental
identifier		Word	Statements	Statements	information
Millipore -		Warning	May cause an	Avoid breathing	
1.03795	\•\		allergic skin	dust. IF ON	
	~		reaction.	SKIN: Wash	
			Causes serious	with plenty of	
			eye irritation.	water. Wash	
				skin thoroughly	
				after handling.	
				IF IN EYES:	
				Rinse cautiously	
				with water for	
				several minutes.	
				Remove contact	
				lenses, if	
				present and	
				easy to do.	
				Continue	
				rinsing.	
				Contaminated	
				work clothing	
				should not be	
				allowed out of	
				the workplace.	
				Wear protective	
				gloves/ eye	
				protection/ face	
				protection.	

Cellvento®	Cellvento® 4Feed COMP chemically defined cell culture feed					
Product	Pictogram	Signal	Hazard	Precautionary	Supplemental	
identifier		Word	Statements	Statements	information	
Millipore -					Not a hazardous	
1.03796					substance or	
					mixture	
					according to	
					Regulation (EC)	
					No 1272/2008.	

Millipore- 103882 Page 7 of 10



Cellvento® 40	Cellvento® 4CHO-X COMP Expansion Medium						
Product	Pictogram	Signal	Hazard	Precautionary	Supplemental		
identifier		Word	Statements	Statements	information		
Sigma -		Warning	Causes serious	Wash skin			
1.03840	•		eye irritation.	thoroughly after			
	•			handling. IF IN			
				EYES: Rinse			
				cautiously with			
				water for			
				several minutes.			
				Remove contact			
				lenses, if			
				present and			
				easy to do.			
				Continue			
				rinsing. Wear			
				eye protection/			
				face protection.			
				If eye irritation			
				persists: Get			
				medical advice/			
				attention.			

Product	Advanced CHO Pictogram	Signal	Hazard	Precautionary	Supplemental
	rictogram	_		•	
identifier		Word	Statements	Statements	information
Millipore -		Warning	Causes serious	Wash skin	
104075	•		eye irritation.	thoroughly after	
	•			handling. IF IN	
				EYES: Rinse	
				cautiously with	
				water for	
				several minutes.	
				Remove contact	
				lenses, if	
				present and	
				easy to do.	
				Continue	
				rinsing. Wear	
				eye protection/	
				face protection.	
				If eye irritation	
				persists: Get	
				medical advice/	
				attention.	

EX-CELL® Advanced CHO Feed1 (without glucose)					
Product	Pictogram	Signal	Hazard	Precautionary	Supplemental
identifier		Word	Statements	Statements	information
Millipore -		Danger	Causes skin	Avoid breathing	
104076	- E		irritation.	dust. IF ON	

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•	May cause an allergic skin reaction. Causes serious eye damage.	SKIN: Wash with plenty of water. Wash skin thoroughly after handling. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/ eye
		protection/ face protection.

Product	Pictogram	Signal	Hazard	Precautionary	Supplemental
identifier		Word	Statements	Statements	information
Millipore - 104071	!	Warning	Causes skin irritation. Causes serious eye irritation.	Wash skin thoroughly after handling. IF ON SKIN: Wash with plenty of water. Wear protective gloves/ eye protection/ face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin irritation occurs: Get medical advice/	IIIIOIIIIALIOII

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	attention. If
	eye irritation
	persists: Get
	medical advice/
	attention.

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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 30.03.2016 Print Date 22.12.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Citric acid monohydrate

Product Number : 27102

Brand : Sigma-Aldrich

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 5949-29-1

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Eye irritation (Category 2), H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word Warning

Hazard statement(s)

H319 Causes serious eye irritation.

Precautionary statement(s)

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard

Statements

none

Sigma-Aldrich - 27102 Page 1 of 7

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : $C_6H_8O_7 \cdot H_2O$ Molecular weight : 210.14 g/mol CAS-No. : 5949-29-1 EC-No. : 201-069-1

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Citric acid monohyo	drate		
CAS-No. EC-No.	5949-29-1 201-069-1	Eye Irrit. 2; H319	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

Sigma-Aldrich - 27102 Page 2 of 7

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): Non Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Sigma-Aldrich - 27102 Page 3 of 7

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374. contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle r (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form: Small beads a) Appearance

Colour: white

No data available b) Odour Odour Threshold No data available

рΗ 1.8 at 50 g/l at 20 °C d)

Melting point/freezing e)

point

No data available

Initial boiling point and f)

boiling range

No data available

q) Flash point 173.9 °C - closed cup

h) Evaporation rate No data available

Flammability (solid, gas) No data available

Upper/lower flammability or explosive limits No data available

k) Vapour pressure No data available Vapour density 7.26 - (Air = 1.0)

m) Relative density No data available No data available n) Water solubility

o) Partition coefficient: noctanol/water

No data available

No data available p) Auto-ignition temperature

q) Decomposition temperature

No data available

No data available Viscosity r) Explosive properties No data available No data available

t) Oxidizing properties

Sigma-Aldrich - 27102 Page 4 of 7

9.2 Other safety information

Bulk density 900 kg/m3 at 20 °C

Relative vapour density 7.26 - (Air = 1.0)

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Oxidizing agents, Bases, Reducing agents, Nitrates

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides

Other decomposition products - No data available

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data availableCitric acid monohydrate

LD50 Intraperitoneal - Rat - 375 mg/kg(Citric acid monohydrate)

Skin corrosion/irritation

No data available(Citric acid monohydrate)

Serious eye damage/eye irritation

Eyes - Rabbit(Citric acid monohydrate)

Result: Irritating to eyes.

Respiratory or skin sensitisation

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.(Citric acid monohydrate)

Germ cell mutagenicity

No data available(Citric acid monohydrate)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Citric acid monohydrate)

Specific target organ toxicity - single exposure

No data available(Citric acid monohydrate)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Citric acid monohydrate)

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Additional Information

RTECS: GE7810000

Vomiting, Diarrhoea, Damage to tooth enamel., Dermatitis(Citric acid monohydrate)

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Citric acid monohydrate)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

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SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H319 Causes serious eye irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.1 Revision Date 06.02.2017

Print Date 22.12.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Dextrose

Product Number : D9434 Brand : Sigma

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 50-99-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards - none

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : D-(+)-Glucose

Dextrose

Formula : C<SB>6</>H<SB>12</>O<SB>6</>

Molecular weight : 180.16 g/mol CAS-No. : 50-99-7 EC-No. : 200-075-1

No components need to be disclosed according to the applicable regulations.

Sigma - D9434 Page 1 of 6

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): Non Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

Sigma - D9434 Page 2 of 6

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: Crystalline powder

Colour: white

b) Odourc) Odour Thresholddata availableNo data available

Sigma - D9434 Page 3 of 6

d) pH No data available

e) Melting point/freezing Melting point/range: 150 - 152 °C

point

f) Initial boiling point and

boiling range

No data available

g) Flash point No data available
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

j) Upper/lower flammability or explosive limits No data available

k) Vapour pressure No data available
 l) Vapour density No data available
 m) Relative density No data available

n) Water solubility soluble

o) Partition coefficient: noctanol/water No data available

p) Auto-ignition temperature

No data available

q) Decomposition temperature

No data available

r) Viscosity No data available
 s) Explosive properties No data available
 t) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides Other decomposition products - No data available

In the event of fire: see section 5

Sigma - D9434 Page 4 of 6

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 25,800 mg/kg(Glucose)

Remarks: Behavioral:Coma. Cyanosis Diarrhoea

Skin corrosion/irritation

No data available(Glucose)

Serious eye damage/eye irritation

No data available(Glucose)

Respiratory or skin sensitisation

No data available(Glucose)

Germ cell mutagenicity

Mouse(Glucose)

lymphocyte

Mutation in mammalian somatic cells.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Glucose)

Specific target organ toxicity - single exposure

No data available(Glucose)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Glucose)

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.(Glucose)

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Glucose)

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

Sigma - D9434 Page 5 of 6

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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SAFETY DATA SHEET

Creation Date 06-Nov-2009 Revision Date 28-Dec-2021 Revision Number 4

1. Identification

Product Name D(+)-Glucose monohydrate

Cat No.: AC450740000; AC450740010; AC450740050; AC450740250

CAS No 14431-43-7

Synonyms D-Glucose monohydrate (Crystalline Powder/USP/EP/BP)

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company Acros Organics
One Reagent Lane One Reagent Lane
Fair Lawn, NJ 07410 Fair Lawn, NJ 07410

Tel: (201) 796-7100

Emergency Telephone Number For information US call: 001-800-ACROS-01 / Europe call: +32 14 57 52 11

Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Dextrose monohydrate	14431-43-7	100
Glucose	50-99-7	-

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur. If not breathing,

give artificial respiration.

Ingestion Do NOT induce vomiting. Get medical attention.

Most important symptoms and

effects

No information available.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point Not applicable

Method - No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

None known.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO2).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

HealthFlammabilityInstabilityPhysical hazards110N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

dust formation. Do not breathe dust. Avoid contact with skin, eyes or clothing.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible

Materials. Strong oxidizing agents.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures None under normal use conditions.

Personal Protective Equipment

Eve/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

5.9 (0.5M)

No data available

Not applicable

Physical State Solid
Appearance White
Odor Odorless

Odor Threshold No information available

pH
Melting Point/Range

Boiling Point/Range No information available Flash Point Not applicable

Evaporation Rate

Flammability (solid,gas) No information available

Flammability or explosive limits

UpperNo data availableLowerNo data availableVapor Pressurenegligible

Vapor Density

Specific Gravity

Solubility

Partition coefficient; n-octanol/water

Not applicable
1.54 (H2O=1)
Soluble in water
No data available

Autoignition TemperatureNo information availableDecomposition TemperatureNo information available

Viscosity
Not applicable
Molecular Formula
C6H12O6.H2O

Molecular Weight 198.18

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Avoid dust formation, Incompatible products, Excess heat,

Strong oxidizing agents **Incompatible Materials**

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO2)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information No acute toxicity information is available for this product

Oral LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. **Dermal LD50** Based on ATE data, the classification criteria are not met. ATE > 5 mg/l. Mist LC50

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Glucose	25.8 g/kg (Rat)	Not listed	Not listed
Toxicologically Synergistic	No information available		

Toxicologically Synergistic

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

No information available Irritation

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Dextrose monohydrate	14431-43-7	Not listed				
Glucose	50-99-7	Not listed				

Mutagenic Effects Mutagenic effects have occurred in experimental animals.

Reproductive Effects No information available.

Developmental Effects No information available.

No information available. **Teratogenicity**

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

No information available **Endocrine Disruptor Information**

Other Adverse Effects Tumorigenic effects have been reported in experimental animals.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

D(+)-Glucose monohydrate

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOTNot regulatedTDGNot regulatedIATANot regulatedIMDG/IMONot regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Dextrose monohydrate	14431-43-7	-	-	-
Glucose	50-99-7	X	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Dextrose monohydrate	14431-43-7	-	-	-	Х	-		Х	Х	-
Glucose	50-99-7	Х	-	200-075-1	Χ	Χ	Χ	Х	Х	KE-17727

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Dextrose monohydrate	14431-43-7	Listed	Not applicable	Not applicable	Not applicable
Glucose	50-99-7	Listed	Not applicable	Not applicable	Not applicable

Component	CAS No	Seveso III Directive	Seveso III Directive	Rotterdam	Basel Convention
		(2012/18/EC) -	(2012/18/EC) -	Convention (PIC)	(Hazardous Waste)
		Qualifying Quantities	Qualifying Quantities		
		for Major Accident	for Safety Report		
		Notification	Requirements		
Dextrose monohydrate	14431-43-7	Not applicable	Not applicable	Not applicable	Not applicable
Glucose	50-99-7	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

 Creation Date
 06-Nov-2009

 Revision Date
 28-Dec-2021

 Print Date
 28-Dec-2021

Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 Version 6.0 Revision Date 09.11.2016 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Ethyl alcohol, Pure, 200 proof, meets ACS and USP

testing specifications

Product Number : 792780
Brand : Sigma-Aldrich
Index-No. : 603-002-00-5

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Flammable liquids (Category 2), H225 Eye irritation (Category 2), H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word Danger

Hazard statement(s)

H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation.

Precautionary statement(s)

P210 Keep away from heat, hot surfaces, sparks, open flames and other

Sigma-Aldrich - 792780 Page 1 of 7

ignition sources. No smoking.

P280 Wear eye protection/ face protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P403 + P235 Store in a well-ventilated place. Keep cool.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Molecular weight : 46.07 g/mol EC-No. : 200-578-6 Index-No. : 603-002-00-5

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Ethanol			
CAS-No. EC-No. Index-No.	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; Eye Irrit. 2; H2 H319	225, >= 90 - <= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Sigma-Aldrich - 792780 Page 2 of 7

5.2 Special hazards arising from the substance or mixture

Carbon oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage class (TRGS 510): Flammable liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Sigma-Aldrich - 792780 Page 3 of 7

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Full contact

Material: butvl-rubber

Minimum laver thickness: 0.3 mm Break through time: 480 min

Material tested:Butoject® (KCL 897 / Aldrich Z677647, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.2 mm Break through time: 38 min

Material tested: Dermatril® P (KCL 743 / Aldrich Z677388, Size M)

Body Protection

Impervious clothing, Flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (US) or type ABEK (EN 14387) respirator cartridges as a backup to enginee protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: liquid, clear

Colour: colourless

b) Odour No data available Odour Threshold No data available d) pН No data available

Melting point/freezing

point

-143.99 °C

Initial boiling point and

78.0 - 80.0 °C

boiling range

q) Flash point 13 °C - closed cup h) Evaporation rate No data available Flammability (solid, gas) No data available

Upper/lower Upper explosion limit: 19 %(V) flammability or Lower explosion limit: 3.3 %(V)

explosive limits

k) Vapour pressure 44.6 mmHg at 20.0 °C

No data available Vapour density m) Relative density 0.7974 g/cm3

n) Water solubility completely soluble

Sigma-Aldrich - 792780 Page 4 of 7 o) Partition coefficient: n- log Pow: -0.349 at 24 °C

octanol/water

temperature

p) Auto-ignition 363.0 °C temperature

q) Decomposition No data available

r) Viscosity No data availables) Explosive properties No data availablet) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

Alkali metals, Oxidizing agents, Peroxides

10.6 Hazardous decomposition products

Other decomposition products - No data available

Hazardous decomposition products formed under fire conditions. - Carbon oxides

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

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Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Burn in a chemical incinerator equipped with an afterburner and scrubber b highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 1170 IMDG: 1170 IATA: 1170

14.2 UN proper shipping name

ADR/RID: ETHANOL IMDG: ETHANOL IATA: Ethanol

14.3 Transport hazard class(es)

ADR/RID: 3 IMDG: 3 IATA: 3

14.4 Packaging group

ADR/RID: II IMDG: II IATA: II

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

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SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 Version 6.1 Revision Date 02.01.2017 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Glacial Acetic Acid

Product Number : PHR1748
Brand : Sigma-Aldrich
Index-No. : 607-002-00-6

REACH No. : A registration number is not available for this substance as the substance

or its uses are exempted from registration, the annual tonnage does not

require a registration or the registration is envisaged for a later

registration deadline.

CAS-No. : 64-19-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Flammable liquids (Category 3), H226 Skin corrosion (Category 1A), H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word

Danger

Hazard statement(s)

H226 Flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

Precautionary statement(s)

P210 Keep away from heat, hot surfaces, sparks, open flames and other

Sigma-Aldrich - PHR1748 Page 1 of 7

ignition sources. No smoking.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for

breathing. Immediately call a POISON CENTER/doctor.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P403 + P235 Store in a well-ventilated place. Keep cool.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

 Molecular weight
 : 60.05 g/mol

 CAS-No.
 : 64-19-7

 EC-No.
 : 200-580-7

 Index-No.
 : 607-002-00-6

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Acetic acid			
CAS-No. EC-No. Index-No.	64-19-7 200-580-7 607-002-00-6	Flam. Liq. 3; Met. Corr. 1; Ski Corr. 1A; H226, H290, H314 Concentration limits: >= 90 %: Skin Corr. 1A, H314; 25 - < 90 %: Skin Corr 1B, H314; 10 - < 25 %: Skin Irrit. 2, H315; 10 - < 25 %: Ey Irrit. 2, H319;	

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

Sigma-Aldrich - PHR1748 Page 2 of 7

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid inhalation of vapour or mist.

Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Store at Room Temperature.

Storage class (TRGS 510): Flammable liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Sigma-Aldrich - PHR1748 Page 3 of 7

Personal protective equipment

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, Flame retardant antistatic protective clothing., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (US) or type ABEK (EN 14387) respirator cartridges as a backup to enginee protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance Form: liquid

Colour: colourless

b) Odour pungent

c) Odour Threshold No data availabled) pH 2.4 at 60.05 g/l

e) Melting point/freezing

point

16.2 °C

f) Initial boiling point and

boiling range

117.0 - 118.0 °C

g) Flash point 40.0 °C - closed cup
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

j) Upper/lower Upper explosion limit: 19.9 %(V) flammability or Lower explosion limit: 4 %(V)

explosive limits

k) Vapour pressure 55.0 mmHg at 50.0 °C 11.4 mmHg at 20.0 °C

I) Vapour density No data available

m) Relative density 1.05 g/cm3

n) Water solubility completely miscible

o) Partition coefficient: n-

octanol/water

log Pow: -0.169

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p) Auto-ignition 485.0 °C

temperature

q) Decomposition No data available

temperature

r) Viscosity No data available
 s) Explosive properties No data available
 t) Oxidizing properties No data available

9.2 Other safety information

Surface tension 28.8 mN/m at 10.0 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

Oxidizing agents, Soluble carbonates and phosphates, Hydroxides, Metals, Peroxides, permanganates, e.g. potassium permanganate, Amines, Alcohols, Nitric acid

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 3,310 mg/kg(Acetic acid)

LC50 Inhalation - Mouse - 1 h - 5620 ppm(Acetic acid)

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Conjunctive irritation.

Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Other. Blood: Other changes.

LC50 Inhalation - Rat - 4 h - 11.4 mg/l(Acetic acid)

LD50 Dermal - Rabbit - 1,112 mg/kg(Acetic acid)

Skin corrosion/irritation

Skin - Rabbit(Acetic acid)
Result: Causes severe burns.

Serious eye damage/eye irritation

Eyes - Rabbit(Acetic acid) Result: Corrosive to eyes

Respiratory or skin sensitisation

No data available(Acetic acid)

Germ cell mutagenicity

No data available(Acetic acid)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

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probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available(Acetic acid)

Specific target organ toxicity - single exposure

No data available(Acetic acid)

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available(Acetic acid)

Additional Information

RTECS: Not available

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin., spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, burning sensation, Cough, wheezing, laryngitis, Shortness of breath, Headache, Nausea, Vomiting, Ingestion or inhalation of concentrated acetic acid causes damage to tissues of the respiratory and digestive tracts. Symptoms include: hematemesis, bloody diarrhea, edema and/or perforation of the esophagus and pylorus, pancreatitis, hematuria, anuria, uremia, albuminuria, hemolysis, convulsions, bronchitis, pulmonary edema, pneumonia, cardiovascular collapse, shock, and death. Direct contact or exposure to high concentrations of vapor with skin or eyes can cause: erythema, blisters, tissue destruction with slow healing, skin blackening, hyperkeratosis, fissures, corneal erosion, opacification, iritis, conjunctivitis, and possible blindness., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. (Acetic acid)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish semi-static test LC50 - Oncorhynchus mykiss (rainbow trout) - > 1,000 mg/l -

96 h(Acetic acid)

(OECD Test Guideline 203)

Toxicity to daphnia and

other aquatic invertebrates

EC50 - Daphnia magna (Water flea) - > 300.82 mg/l - 48 h(Acetic acid)

(OECD Test Guideline 202)

12.2 Persistence and degradability

aerobic - Exposure time 30 d(Acetic acid) Biodegradability

> Result: 99 % - Readily biodegradable. Remarks: Expected to be biodegradable

Biochemical Oxygen

880 mg/g(Acetic acid)

Demand (BOD)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Acetic acid)

Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects

Additional ecological

No data available

information

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Burn in a chemical incinerator equipped with an afterburner and scrubber b highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 2789 IMDG: 2789 IATA: 2789

14.2 UN proper shipping name

ADR/RID: ACETIC ACID, GLACIAL IMDG: ACETIC ACID, GLACIAL IATA: Acetic acid, glacial

14.3 Transport hazard class(es)

ADR/RID: 8 (3) IMDG: 8 (3) IATA: 8 (3)

14.4 Packaging group

ADR/RID: II IMDG: II IATA: II

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 Version 6.1 Revision Date 15.07.2016 Print Date 27.09.2017

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Hydrochloric acid

Product Number : H1758 Brand : Sigma

Index-No. : 017-002-01-X

REACH No. : 01-2119484862-27-XXXX

CAS-No. : 7647-01-0

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited

Industrial Area, Anekal Taluka

Plot No 12,

12 Bommasandra - Jigani Link Road

560100 BANGALORE

INDIA

1.4 Emergency telephone number

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Corrosive to metals (Category 1), H290 Skin corrosion (Category 1B), H314

Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

2.1

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal word

Danger

Hazard statement(s)

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

Precautionary statement(s)

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

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protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for

breathing. Immediately call a POISON CENTER/doctor.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard

Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Formula : HCl

Molecular weight : 36.46 g/mol

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Hydrochloric acid			
CAS-No. EC-No. Index-No.	7647-01-0 231-595-7 017-002-01-X 01-2119484862-27-XXXX	Met. Corr. 1; Skin Corr. 1B; STOT SE 3; H290, H314, H335 Concentration limits: >= 25 %: Skin Corr. 1B, H314; 10 - < 25 %: Skin Irrit. 2, H315; 10 - < 25 %: Eye Irrit. 2, H319; >= 10 %: STOT SE 3, H335; >= 0.1 %: Met. Corr. 1, H290;	>= 30 - < 50 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Hydrogen chloride gas

Hydrogen chloride gas

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage class (TRGS 510): Non-combustible, corrosive hazardous materials

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

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Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard FN 374 derived from it

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de,

test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industria situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use (US) or type ABEK (EN 14387) respirator cartridges as a backup to enginee protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form: liquid Appearance

Colour: light yellow

b) Odour pungent

Odour Threshold No data available No data available d) pН

-30 °C Melting point/freezing

point

Initial boiling point and

> 100 °C - lit.

boiling range

g) Flash point Not applicable

h) Evaporation rate No data available

Flammability (solid, gas) i) No data available Upper/lower j)

flammability or explosive limits No data available

Sigma - H1758 Page 4 of 7 k) Vapour pressure 170 mmHg at 21.1 °C

410 mmHg at 37.7 °C

I) Vapour density No data availablem) Relative density 1.2 g/cm3 at 25 °C

n) Water solubility soluble

o) Partition coefficient: noctanol/water

No data available

p) Auto-ignition temperature

No data available

q) Decomposition temperature

No data available

r) Viscosity No data available
 s) Explosive properties No data available
 t) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Bases, Amines, Alkali metals, Metals, permanganates, e.g. potassium permanganate, Fluorine, metal acetylides, hexalithium disilicide

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Hydrogen chloride gas Other decomposition products - No data available

Hazardous decomposition products formed under fire conditions. - Hydrogen chloride gas In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data availableHydrochloric acid

Inhalation: Inhalation may provoke the following symptoms: Respiratory irritation Cough Difficulty in breathing Pneumonia(Hydrochloric acid)

Skin corrosion/irritation

Skin - Rabbit(Hydrochloric acid)

Result: Causes burns.

Serious eye damage/eye irritation

Eyes - Rabbit(Hydrochloric acid)

Result: Corrosive to eyes

Respiratory or skin sensitisation

Did not cause sensitisation on laboratory animals.(Hydrochloric acid)

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Germ cell mutagenicity

No data available(Hydrochloric acid)

Carcinogenicity

This product is or contains a component that is not classifiable as to its classification.(Hydrochloric acid) (Hydrochloric acid)

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (Hydrochloric acid)

Reproductive toxicity

No data available(Hydrochloric acid)

Specific target organ toxicity - single exposure

The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.(Hydrochloric acid)

Specific target organ toxicity - repeated exposure

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration hazard

No aspiration toxicity classification(Hydrochloric acid)

Additional Information

RTECS: MW4025000

Inhalation of vapors may cause:, burning sensation, Cough, wheezing, Shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema(Hydrochloric acid)

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Lepomis macrochirus (Bluegill) - 24.6 mg/l - 96 h(Hydrochloric acid)

Toxicity to daphnia and

EC50 - Daphnia magna (Water flea) - 4.91 mg/l - 48 h(Hydrochloric acid)

other aquatic invertebrates

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available(Hydrochloric acid)

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

May be harmful to aquatic organisms due to the shift of the pH. Do not empty into drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

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Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 1789 IMDG: 1789 IATA: 1789

14.2 UN proper shipping name

ADR/RID: HYDROCHLORIC ACID IMDG: HYDROCHLORIC ACID Hydrochloric acid

14.3 Transport hazard class(es)

ADR/RID: 8 IMDG: 8 IATA: 8

14.4 Packaging group

ADR/RID: II IMDG: II IATA: II

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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Safety Data Sheet

European Format

Herceptin Intravenous

Preparation Date 28-Mar-2008 Revision Date 28-Mar-2008 Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name Herceptin Intravenous

Common NameNot availableChemical NameNot applicableSynonymsNot available

Product Use Pharmaceutical product Classification Pharmaceutical product Antineoplastic Agent

Supplier Wyeth

P.O. Box 8299

Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300

Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Trastuzumab	180288-69-1	None assigned	440 mg/vial	None assigned

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical powder

Physical State Solid

Odor Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause mechanical eye irritation.

SkinNot availableInhalationNot available

Ingestion The most common effects may include fast or irregular heartbeat, cough increase, shortness of

breath, swelling of feet or lower legs, unusual weakness, mild diarrhea, nausea, pain, vomiting, allergic reactions, angioedema, urticaria, Adult Respiratory Distress Syndrome (ARDS), bronchospasm, anemia, difficult or labored breathing, tightness of chest, hypotension, fever or chills, hoarseness, lower back pain, chest pain, difficult, fast, noisy breathing, pulmonary infiltrates, trouble in sleeping, loss of appetite, numbness or tingling of hands or feet, runny

nose, and skin rash.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Systemic.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical

advice.

Skin Contact Take off contaminated clothing and shoes immediately. Wash off immediately with soap and

plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist,

call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never

give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Not flammable

Extinguishing Media

Suitable Extinguishing Media

Unsuitable Extinguishing

Media

Use water spray, foam, dry chemical or carbon dioxide.

Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with

water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment

for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill

cannot be contained.

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal. Clean contaminated

surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and

safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline

Trastuzumab 100 mcg/m³

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust

ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face ProtectionProvide eye protection based on risk assessment.Skin ProtectionWear nitrile or latex gloves. Wear protective garment.Respiratory ProtectionBase respirator selection on a risk assessment..

General Hygiene When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands

Considerations before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material Consult a health and

safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

AppearancePharmaceutical powderPhysical StateSolid

Color White to pale yellow Odor Not available

Odor Threshold Not available

pH Not available

Specific GravityNot applicableWater SolubilityNot availableSolubilityNot applicableEvaporation RateNot applicablePartition CoefficientNot availableVapor PressureNot applicable

(n-octanol/water)

 Boiling Point
 Not available
 Autoignition Temperature
 Not available

 Flash Point
 Not available
 Melting Point
 Not available

Flammability Limits in Air Upper Not applicable Lower Not applicable Explosion Limits Upper Not applicable Lower Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid No materials to be especially mentioned.

Hazardous Decomposition Products None under normal use.Possibility of Hazardous Reactions None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Trastuzumab

LD50 OralNot applicableAcute Dermal IrritationNot applicablePrimary Eye IrritationNot applicableSensitizationNot applicable

Multiple Dose Toxicity

Trastuzumab

No Toxicologic Effect
Dose/Species/Study Length:

See Developmental Toxicity

Maximum Tolerated Dose (MTD), Oral

Trastuzumab

Carcinogenicity No carcinogenicity studies have been performed.

Genetic Toxicity No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.

Reproductive Toxicity See Developmental Toxicity.

Developmental Toxicity Reproduction studies in monkeys at doses up to 25 times the weekly human maintenance

dose found no effect on fertility, and no harm to the fetus.

Trastuzumab

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety

Format This MSDS was prepared in accordance with Directive 2001/58/EC.

16. OTHER INFORMATION

List of References Product Profiles
Revision Summary Changes to Section 8

Disclaimer:

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End of MSDS



evision Number: 9 Date Issued 18-Jul-2023

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

1.1 Product identifier

Product Name: Prolia® Denosumab

Chemical Name: Immunoglobulin G2 Human Monoclonal Antibody to RANK Ligand

Synonyms: AMG 162, denosumab

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use: Pharmaceutical

Uses advised against: No information available

Manufacturer: Emergency Telephone Number:

Amgen Inc. Chemtrec

One Amgen Center Drive NORTH AMERICA 1-800-424-9300, Thousand Oaks, California 91320-1799 INTERNATIONAL 1-703-527-3887

1-805-447-7233 1-805-447-1000

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains denosumab, an active pharmaceutical ingredient for the treatment of osteoporosis or to increase bone mass in certain oncology patients undergoing treatment. Avoid inhalation, skin contact, eye contact, and ingestion.

2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Does not meet GHS classification criteria and therefore is not classified. Not classified

2.2 Label elements

Does not meet GHS classification criteria and therefore is not classified. Not classified

2.3 Other Hazards No information available



Revision Number: 9 Date Issued 18-Jul-2023

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Drug product is supplied in a prefilled syringe (PFS) that contains 60 mg/mL denosumab,

acetate, and sorbitol at a pH of 5.2.

Chemical Name: Immunoglobulin G2 Human Monoclonal Antibody to RANK Ligand

CAS-No: 615258-40-7

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical

advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and

shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never

give anything by mouth to an unconscious person.

Notes to Physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Flammable Properties: Not applicable/aqueous solution.

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous Combustion Products: None

5.3 Advice for firefighters

Protective Equipment and As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH

Precautions for Firefighters: (approved) and full protective gear.



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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Spill Procedures:

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handling and Storage:

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an

occupational exposure limit (OEL) of $60 \mu g/m^3$ as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Denosumab has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound ($20 \mu g/m^3 - 100$

 $\mu g/m^3$).

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective

local exhaust ventilation or within a chemical hood.

8.2 Exposure controls

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side

shields and a full-face shield to prevent contact with eyes. The choice of protection should

be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with

formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin

contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly

handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be

based on the job activity and the potential for exposure.

Other: Wash hands, face and other potentially exposed areas after handling material (especially

before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

8.3 Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear colorless to slightly yellow

Physical State: Liquid
Molecular Weight: ~147kD

Odor: No information available Odor Threshold: No information available

pH: 5.2

Melting point (°C) VALUE No information available

Flash Point: Not applicable

Evaporation Rate:

Lower explosive limit:

Upper explosive limit:

Vapor Pressure:

Vapor Density (air = 1):

Relative density:

No information available
No information available
No information available
No information available

Water Solubility: Not applicable

Partition Coefficient (log Kow): No information available Viscosity: No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity No information available

10.2 Chemical stability Stable

10.3 Possibility of hazardous No information available

reactions

10.4 Conditions to avoid No Information available

10.5 Incompatible materials No information available

10.6 Hazardous No information available

decomposition products

10.7 Other information None

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity: Does not meet GHS classification criteria and therefore is not classified. Does not meet GHS Classification Criteria and therefore is not classified. Skin corrosion/irritation: Serious eye damage/eye irritation: Does not meet GHS Classification Criteria and therefore is not classified. Respiratory or skin sensitization: Does not meet GHS Classification Criteria and therefore is not classified. Germ cell mutagenicity: Does not meet GHS Classification Criteria and therefore is not classified. Does not meet GHS Classification Criteria and therefore is not classified. Carcinogenicity: Reproductive toxicity: Based on available data, the GHS classification criteria are not met. STOT - single exposure: Does not meet GHS Classification Criteria and therefore is not classified. STOT - repeated exposure: Does not meet GHS Classification Criteria and therefore is not classified. **Aspiration Hazard:** Does not meet GHS Classification Criteria and therefore is not classified.



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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects: No information available

12.2 Persistence and degradability

Persistence/Degradability: No information available

12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

12.4 Mobility in soil

Mobility in Environmental Media: No information available

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

12.6 Other adverse effects

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Disposal Method: Dispose of waste according to prescribed federal, state, local and competent authority

guidelines.

14. TRANSPORT INFORMATION

DOT: Not regulated by U.S. DOT, IATA, or IMDG.

AMGEN°

Prolia® Safety Data Sheet

Revision Number: 9 Date Issued 18-Jul-2023

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

TSCA: EINECS/ELINCS DSL/NDSL PICCS: ENCS: CHINA: AICS: KECL: -

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

15.2 Chemical safety assessment

No CSA has been conducted.

AMGEN®

Prolia® Safety Data Sheet

Date Issued 18-Jul-2023

16. OTHER INFORMATION

Revision Number: 9

To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

This information is provided without warranty or guarantee of any kind, whether express, implied or statutory, including without limitation warranty of fitness or merchantability for a particular purpose or noninfringement. No representation, warranty, or guarantee is made, and no liability is assumed, with respect to the material or the information contained in this SDS including without limitation its accuracy or completeness or the hazards of, or results obtained from, use of the material or the information contained here. Caution should be used in the handling, using, processing, storing, transporting, and disposing of the material.

Infliximab Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 13.09.2019

 1.15
 16.10.2020
 19288-00016
 Date of first issue: 07.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Infliximab Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 70 -< 90
Infliximab	170277-31-3	>= 10 -< 20

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

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In case of skin contact : Wash with water and soap.

Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Contact with dust can cause mechanical irritation or drying of

acute and the skin.

delayed
Protection of first-aiders

Dust contact with the eyes can lead to mechanical irritation.

No special precautions are necessary for first aid responders.

: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Notes to physician

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

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> Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

> Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling Do not breathe dust.

> Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	PEL (long term)	10 mg/m3	SG OEL
		TWÁ	10 mg/m3	ACGIH
Infliximab	170277-31-3	TWA	150 μg/m3	Internal

Ensure adequate ventilation, especially in confined areas. **Engineering measures**

> Minimize workplace exposure concentrations. Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Particulates type

Hand protection

Material

Remarks For prolonged or repeated contact use protective gloves.

Chemical-resistant gloves

Wash hands before breaks and at the end of workday.

Eye protection Wear the following personal protective equipment:

Safety goggles

Skin and body protection

Skin should be washed after contact.

If exposure to chemical is likely during typical use, provide Hygiene measures

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Amorphous powder Appearance

Colour white

Odour No data available

Odour Threshold No data available

7.2 pН

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flash point No data available

No data available Evaporation rate

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure No data available

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Relative vapour density : No data available

Relative density : No data available

Density : 1 g/cm3

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Sucrose:

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Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Infliximab:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Infliximab:

Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Infliximab:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosomal aberration Test system: human lymphoblastoid cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Method: OECD Test Guideline 474

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Infliximab:

Effects on fertility : Test Type: Fertility

Species: Mouse

Application Route: Intravenous injection Fertility: NOAEL: 40 mg/kg body weight Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse, female

Application Route: Intravenous injection Duration of Single Treatment: 6 - 12 d

General Toxicity Maternal: NOAEL: 40 mg/kg body weight

Teratogenicity: NOAEL F1: 40 mg/kg body weight

Developmental Toxicity: NOAEL F1: 40

Embryo-foetal toxicity: NOAEL: 40 mg/kg body weight

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Infliximab:

Species : Mouse
NOAEL : 40 mg/kg
Application Route : Intravenous
Exposure time : 6 Months
Number of exposures : daily

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Infliximab:

Inhalation : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea,

Fatigue, Headache, Back pain

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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Infliximab:

Ecotoxicology Assessment

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

: Not applicable

: Not applicable

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore, Workplace Safety and Health Act - First Schedule

Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-

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cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN



Pembrolizumab Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.20
 30.09.2023
 49580-00025
 Date of first issue: 23.01.2015

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pembrolizumab Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Immune system)

GHS label elements

Hazard pictograms

Signal word : Danger

Hazard statements : H360D May damage the unborn child.

H373 May cause damage to organs (Immune system) through

prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.

P280 Wear protective gloves/ protective clothing/ eye protec-



Pembrolizumab Liquid Formulation

SDS Number: Date of last issue: 04.04.2023 Version Revision Date: 4.20 30.09.2023 49580-00025 Date of first issue: 23.01.2015

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 1 -< 10
Pembrolizumab	1374853-91-4	>= 1 -< 10

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

In case of eye contact

May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure if swallowed. delaved

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.



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5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Carbon oxides

Hazardous combustion products

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE



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Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	PEL (long term)	10 mg/m3	SG OEL
		TWA	10 mg/m3	ACGIH
Pembrolizumab	1374853-91- 4	TWA	450 μg/m3 (OEB 2)	Internal

Engineering measures : Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous sub-



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stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Eye protection : Wear the following personal protective equipment:

Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : Colorless to pale yellow

Odour : No data available

Odour Threshold : No data available

pH : 5.5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available



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Relative density No data available

Density No data available

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, dynamic No data available

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle size No data available

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac- :

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation exposure Skin contact

Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

Sucrose:



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Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage the unborn child.

Components:

sessment

Pembrolizumab:

Reproductive toxicity - As-

May damage the unborn child., Based on data from similar

materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

Components:

Pembrolizumab:

Target Organs : Immune system

Assessment : Causes damage to organs through prolonged or repeated

exposure.



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Repeated dose toxicity

Components:

Pembrolizumab:

Species : Monkey
NOAEL : 200 mg/kg
Application Route : Intravenous
Exposure time : 180 d

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 200 mg/kg
Application Route : Intravenous

Exposure time : 180 d

Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Pembrolizumab:

Inhalation : Target Organs: Immune system

Symptoms: Cough, Fatigue, Nausea, pruritis, Rash, constipation, joint pain, Diarrhoea, Pneumonia, decrease in appetite, Fever, anemia, neutropenia, musculoskeletal pain, Vomiting, confusion, Headache, Shortness of breath, Hypofunction of thyroid gland, May cause respiratory arrest., May cause, immune-mediated pneumonitis, colitis, hepatitis, nephritis

Remarks: Damage to fetus possible

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n-

: Pow: < 1

octanol/water

Mobility in soil

No data available



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Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

UN number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable



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15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable

Regulations

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

Sources of key data used to compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Not applicable

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-



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tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk: IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN



RITUXAN(R) Vials (500 mg/50 ml)

Version Revision Date: Date of last issue: 02-10-2020 1.4 04-26-2021 Date of first issue: 06-10-2017

SECTION 1. IDENTIFICATION

Product name : RITUXAN(R) Vials (500 mg/50 ml)

Product code : 00010063481

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way

South San Francisco, CA 94080

USA

Telephone : 001-(650) 225-1000 E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone

US Chemtrec phone (800)-424-9300

number

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Substance name : MABTHERA 1,0% aqueous solution of Rituximab with

excipients

CAS-No. : Not Assigned

Components

Chemical name	CAS-No.	Concentration (% w/w)
Rituximab	174722-31-7	1.0
Sodium chloride (NaCl)	7647-14-5	0.9
Sodium citrate	6132-04-3	0.74
Sorbitan, mono-(9Z)-9-	9005-65-6	0.07



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octadecenoate, poly(oxy-1,2ethanediyl) derivs.

Water 7732-18-5 > 97.0

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Rinse mouth with water.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Storage temperature : Protected from heat and light

Further information on

storage stability

No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, glass, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Rituximab	174722-31-7	IOEL	0.04 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally



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required.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution, Clear liquid, Sterile liquid

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 6.5

Melting point/range : No data available

Boiling point/boiling range : No data available

Evaporation rate : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available



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Relative density : No data available

Density : 1,012 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Incompatible materials : No data available

Hazardous decomposition

products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Components:

Rituximab:

Acute oral toxicity : Remarks: Not bioavailable by oral administration

Acute toxicity (other routes of :

administration)

Maximum tolerated dose (Mouse): > 100 mg/kg

Application Route: i.p.



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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information

Components:

Rituximab:

Remarks : Globular proteins are generally well biodegradable

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

Components:

Rituximab:



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Biodegradability : Result: Globular proteins are generally well biodegradable

Bioaccumulative potential

Components:

Rituximab:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Mobility in soil
No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Components:

Rituximab:

Additional ecological

information

Monoclonal antibodies are proteins with highly specific affinity

to a certain antigen; therefore, no appreciable ecotoxic

potential is to be expected

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code



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Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Water 7732-18-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals



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Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Rituximab

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

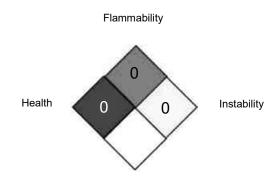
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

RITUXAN(R) Vials (500 mg/50 ml)

Version Revision Date: Date of last issue: 02-10-2020 1.4 04-26-2021 Date of first issue: 06-10-2017

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG -International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL -Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Cooperation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT -Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA -Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature: SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative



RITUXAN(R) Vials (500 mg/50 ml)

Version Revision Date: Date of last issue: 02-10-2020 1.4 04-26-2021 Date of first issue: 06-10-2017

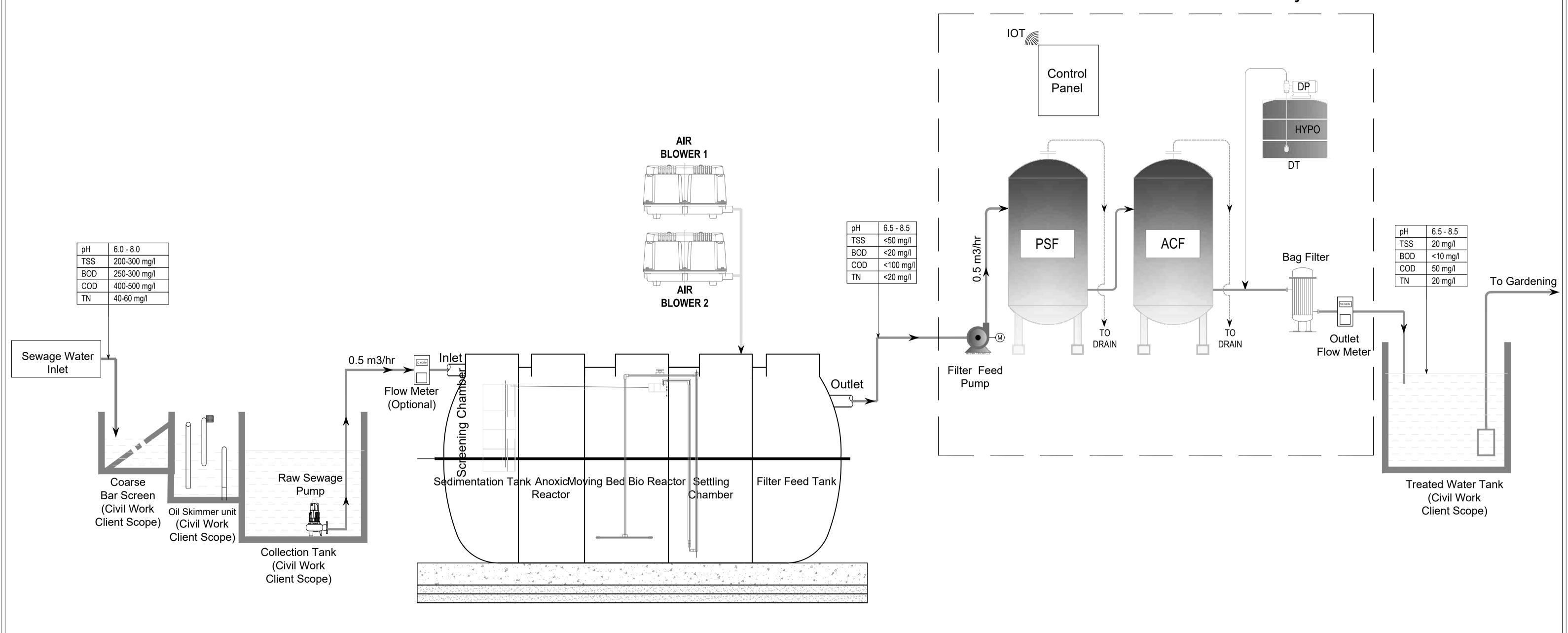
Revision Date : 04-26-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2004

PROCESS FLOW DIAGRAM

HECS Skid Mounted Outdoor TTP System



	REVISION					
REV	BY	DATE	DESCRIPTION	EDIT		
0	GSH	10.07.24	ISSUED FOR PROPOSAL			

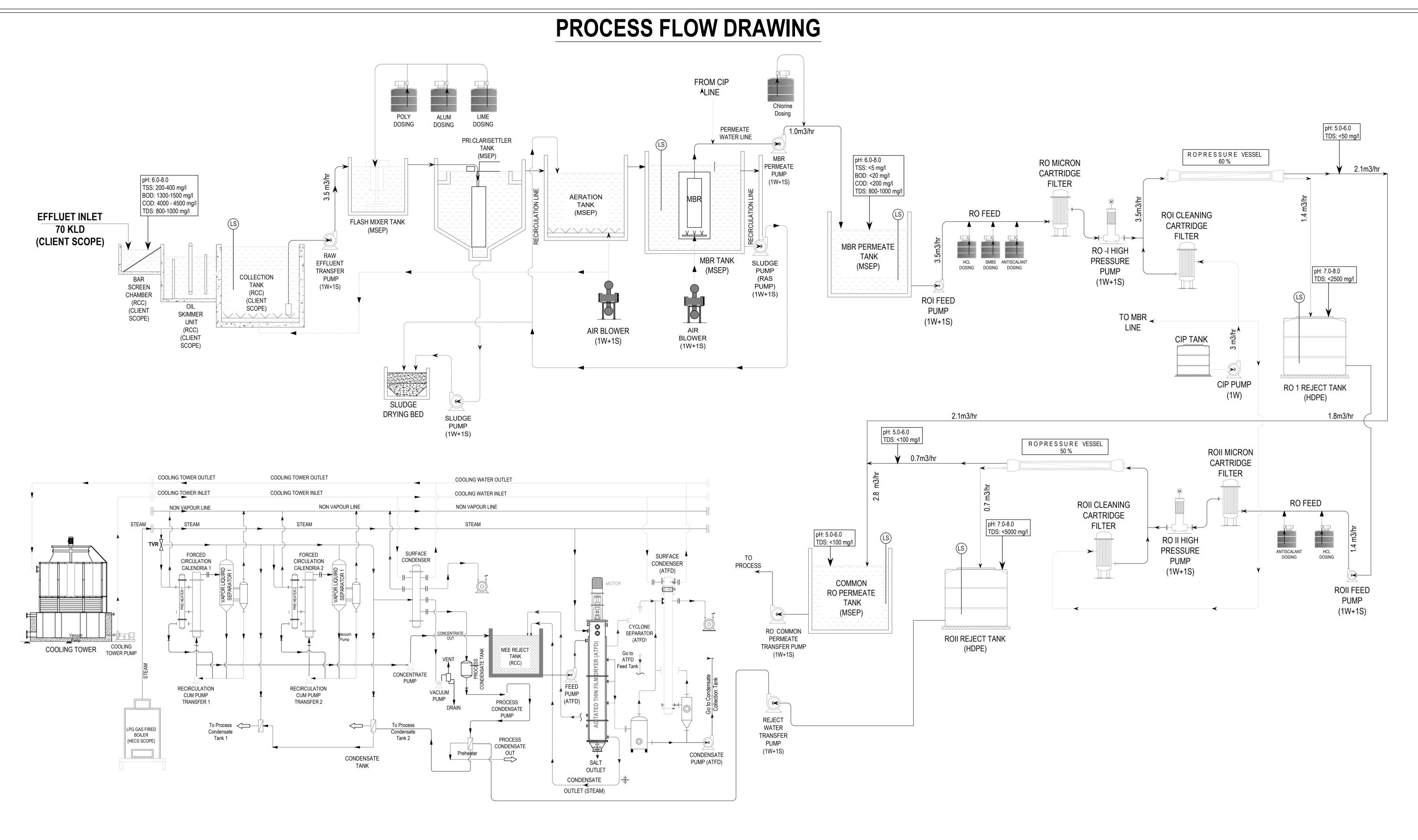
HECS FRP PACKAGED PSTP - 6 KLD

TITLE:

CLIENT:

M/S. OMEXA FORMULARY PVT. LTD,.
TINDIVANAM

HECS(P)Ltd			APPROVED/DATE			
	NAME	DATE		ENGINEERING CHECKED/DATE		ED/DATE
DRAWN	GSH	10.07.24		LINGII	NELIXING GITLOR	LUIDATE
DESIGNED	DI	10.07.24		Di	DRAFTING CHECKED/DATE	
CHECKED	CEO	10.07	10.07.24			
IMO No.		CLAS		S I.D	SCALE	REV
		_				0
DWG NO: [DWG NO: DD - HECS - STP - PFD - 001					



	REVISION					
REV	BY	DATE	DESCRIPTION	EDIT		
0	GSH	09.05.24	ISSUED FOR PROPOSAL			

TITLE:

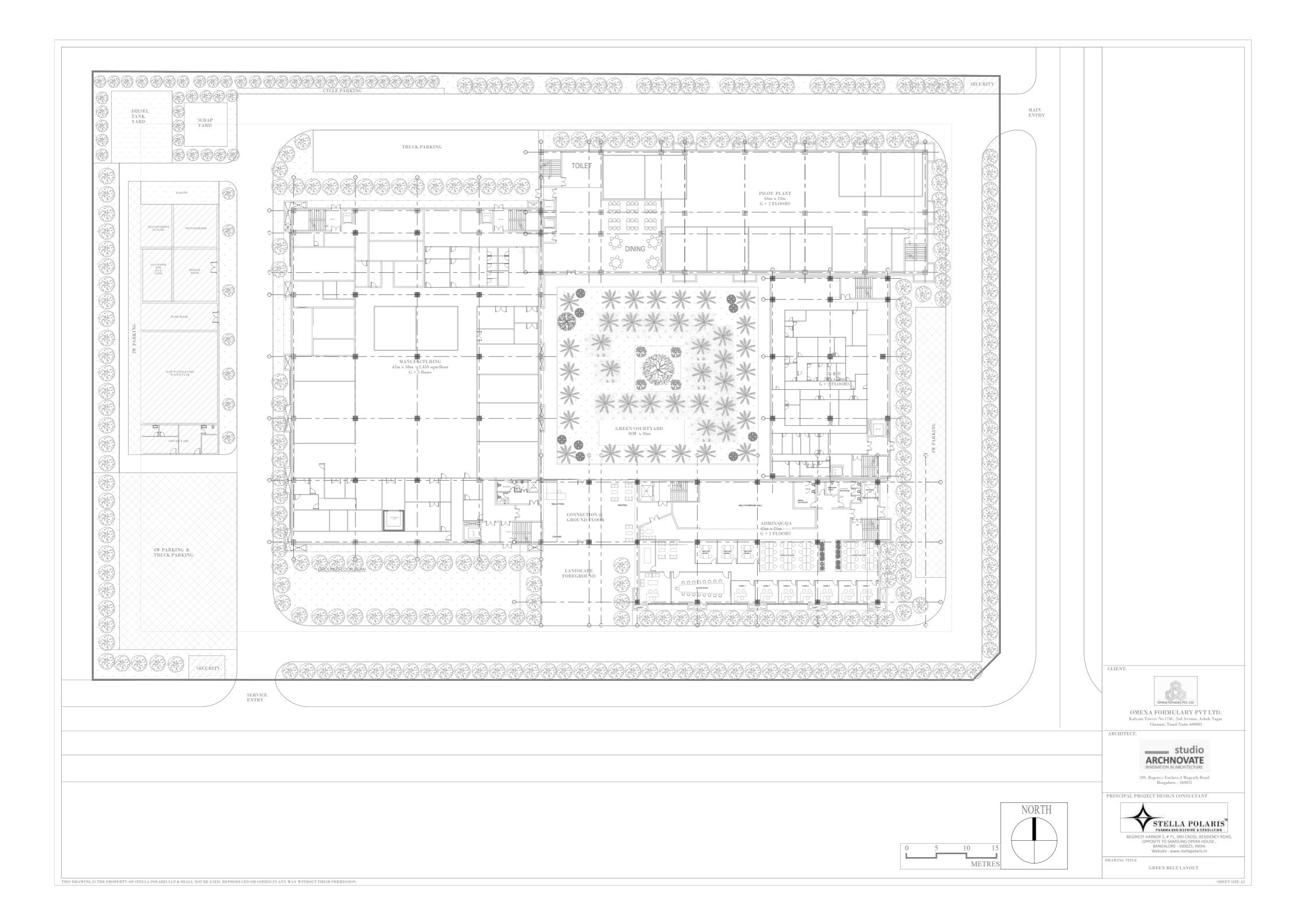
PROCESS FLOW DRAWING

MBR ETP & RO SYSTEM PLANT - 70 KLD

CLIENT:

M/S. OMEXA FORMULARY PVT. LTD,.
TINDIVANAM

HECS(P)Ltd				APPROVED/DAT	E	
	NAME	DATE		ENGI	NEERING CHECK	ED/DATE
DRAWN	GSH	09.05.24		LINGII	NELINING GITLOR	LUIDATE
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RISK ASSESSMENT REPORT (RA) STUDY

For

"Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility"

At

Plot No. 27 & 28, TANSIDCO Industrial Park

Village: Pellakuppam Taluk: Tindivanam District: Villupuram

By

State: Tamil Nadu



M/S. OMEXA FORMULARY PVT LTD

Category: B1, Schedule 5 (f)- Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates

PREPARED BY



M/s. HUBERT ENVIRO CARE SYSTEMS (P) LTD

JULY 2024

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1. INTRODUCTION

M/s. Omexa Formulary Private Limited has proposed a new unit for manufacturing of Monoclonal antibodies with Capacity of 520 kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Lakh/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State.

M/s. Omexa Formulary Private Limited is located at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamilnadu State and having a registered office at Kalyani towers, 174c, 2nd Avenue, Ashok Nagar, Chennai-600083 and Tamil Nadu State.

The project proposes to manufacture of bulk drugs & intermediates (Monoclonal antibodies) with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Lakh/Month. The project has been put up in a declared industrial area which has also been declared in Tamilnadu namely TANSIDCO Industrial Park. The project cost for the proposed project is expected to around Rs. 95 Crores and is a Green Field Project by first generation entrepreneur with outstanding career as a technocrat in the chemical Industries.

Omexa Formulary Private Limited is at the forefront of biosimilar innovation, dedicated to producing high-quality alternatives to brand-name biologics, through scientific excellence, unwavering commitment, and technological innovation, we aim to empower healthcare providers and reach patients worldwide, ensuring they receive dependable, effective, and cost-efficient therapies.

Our mission is to enhance patient access to vital treatments while ensuring safety, efficacy, and affordability. Harnessing advanced technologies and rigorous scientific methodologies, we bridge the future of healthcare with today's needs. Omexa's vision is to be the global benchmark in biosimilar healthcare, where every patient has access to sustainable, state-of-the-art, and affordable treatments, fostering a world where quality healthcare knows no boundaries.

1.1. PURPOSE OF THE REPORT

Risk assessment is an indispensable part of Process Safety Management (PSM). PSM must be invariably invoked when involved in handling, using, storing, moving, or manufacturing of highly hazardous chemicals. The M/S. OMEXA FORMULARY PVT LTD, handles

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several solvents which pose health and flammability hazard. Thus, the risk associated with production facility was assessed and to be elaborated in this report. The Risk Assessment study has been performed as dictated by the IS15656:2006 "HAZARD IDENTIFICATION AND RISK ANALYSIS - CODE OF PRACTICE" to give crucial insights on the hazards involved in the facility line of production.

Based on the available studies & plant layout, the potential scenarios which can cause significant consequences like Dispersion of Vapour cloud, fire and explosion scenarios were identified.

The purpose of the study includes the following:

- > To identify those hazards that pose health and flammability risks as per NFPA rating.
- ➤ To eliminate or reduce to as Low as Reasonably Practicable (ALARP) the risk to human health, risk of injury, risk of damage to plant, equipment and environment, business interruption or loss etc.
- > To Suggest On-site Mitigation Measures.

1.2. PROJECT DESCRIPTION

M/s. Omexa Formulary Private Limited has proposed a new unit for manufacturing of Monoclonal antibodies with Capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Lakh/Month at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State. This is a Greenfield Project for a manufacturing facility by a new entrepreneur in a declared TANSIDCO Industrial Park which is not linked with any other Project and is not interdependent with any of the project

The project is termed under schedule 5 (f) Bulk drugs & intermediates - Category "B1" as per the EIA Notification, 2006.

1.3. SCOPE OF THE STUDY

Hazard Identification and Risk Analysis including identification, screening of scenarios, consequence analysis of the various risk scenarios, recommendation and preparation of

Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility Risk assessment report

reports and relevant drawing showing damage and risk contours.

The scope of the study mainly involves:

- > Identifications of Hazards
- > Consequence modelling of:
 - ✓ Dispersion of Vapour cloud
 - ✓ Flash fire
 - ✓ Pool fire
 - ✓ Jet fire
- > Impact limits identifications
- > Contour mapping of the risk on the layouts.
- > Mitigating measures for handling and storage to reduce impacts & prevent incidents.

1.4. METHODOLOGY ADOPTED

The following Risk Modelling software to aid the Risk assessment:

> PHAST software 8.1 developed by DNV.

1.5. PROJECT LOCATION

The proposed project is located at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State.

The site is located about ~ 0.37 km (S) from NH-77(Tindivanam-Krishnagiri)/NH179B (Chennai- Tindivanam-Harur). The nearest railway station is Tindivanam RS ≈ 4.31 km (SE).

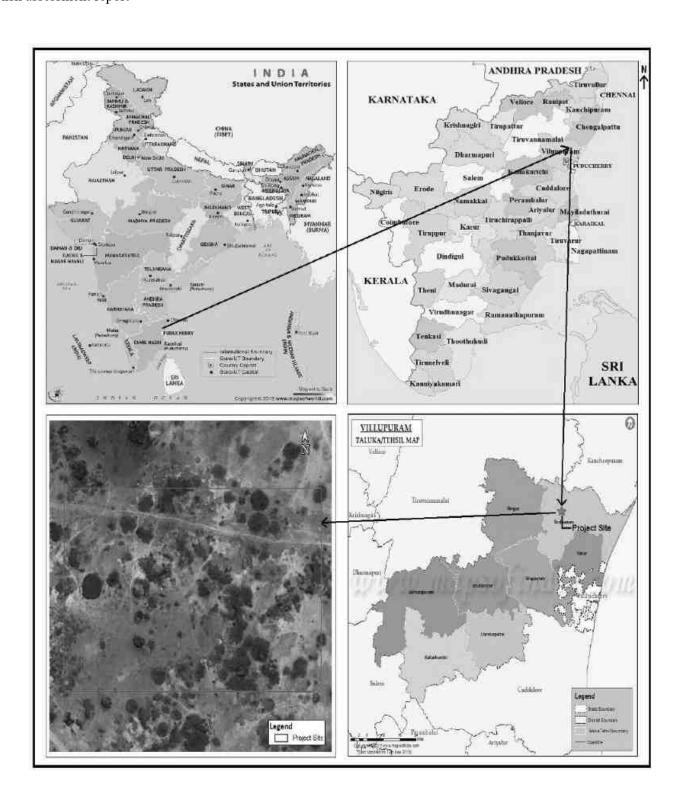


FIGURE 1: PROJECT LOCATION MAP

1.6. PROJECT LAYOUT

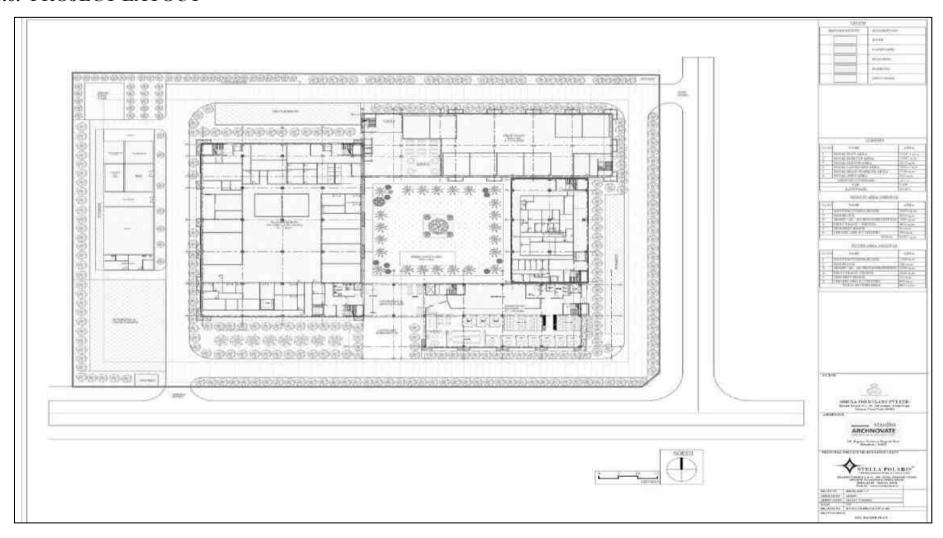


FIGURE 2: PROJECT LAYOUT

1.7. STORAGE DETAILS

TABLE 1: STORAGE DETAILS

Sl. No.	Raw materials	Approx. Quantity per annum (InKgs)	Source	Mode of transport
1	Sodium chloride	1800	Domestic/Imported	Road
2	Potassium Chloride	10	Domestic/Imported	Road
3	Sodium phosphate	60	Domestic/Imported	Road
4	Potassium phosphate	10	Domestic/Imported	Road
5	Citric acid	500	Domestic/Imported	Road
6	Sodium Citrate	1150	Domestic/Imported	Road
7	Tris Buffer	2300	Domestic/Imported	Road
8	Sodium Acetate	600	Domestic/Imported	Road
9	Sodium Hydroxide	1500	Domestic/Imported	Road
10	Glucose	400	Domestic/Imported	Road
11	Sodium bicarbonate	200	Domestic/Imported	Road
12	Pluronic F68	100	Domestic/Imported	Road
13	Cell culture media	2200	Domestic/Imported	Road
14	L-Glutamine	30	Domestic/Imported	Road
15	Sorbitol	200	Domestic/Imported	Road
16	Ethanol	100	Domestic/Imported	Road
17	Phosphoric Acid	60	Domestic/Imported	Road
18	Acetic Acid	40	Domestic/Imported	Road
19	Hydrochloric acid	150	Domestic/Imported	Road

For Utilities:

1. Petroleum Storage Tank (HSD) -1x 20 KL (Cap)

2. RISK ASSESSMENT METHODOLOGY

2.1. IDENTIFICATION OF HAZARDS & RELEASE SCENARIOS

A technique commonly used to generate an incident list is to consider potential leaks and ruptures of all process pipelines and vessels/tanks. The following data were collected to envisage scenarios:

- > Type of chemical used.
- > Capacity of the storage and process.
- > Atmospheric conditions viz. Temperature, Humidity and Wind direction

2.1.1. SELECTION

The goal of selection is to limit the total number of incident outcome cases to be studied to a manageable size. The purpose of incident outcome selection is to develop a set of incident outcomes that must be studied for each incident included in the finalized incident study list. Each incident needs to be considered separately. Using the list of incident outcomes, the risk analyst needs to determine which may result from each incident. While the analyst can decide whether an incident involving the loss of a process chemical to the atmosphere needs to be examined using dispersion analysis because of potential toxic gas effects, what happens if the same material is immediately ignited on release.

2.1.2. CHARACTERIZING THE FAILURES

Accidental release of flammable or toxic Vapours can result in severe consequences. Delayed ignition of flammable Vapours can result in blast overpressures covering large areas. This may lead to extensive loss of life and property. Toxic clouds may cover yet larger distances due to the lower threshold values in relation to those in case of explosive clouds (the lower explosive limits). In contrast, fires have localized consequences. Fires can be put out or contained in most cases; there are few mitigating actions one can take once a Vapour cloud gets released. Major accident hazards arise, therefore, consequent upon the release of flammable or toxic Vapours or BLEVE in case of pressurized liquefied gases. In an industry, main hazard arises due to storage and handling of hazardous chemicals. To formulate a structured approach to identification of hazards and understanding of contributory factors is essential.

2.1.3. INVENTORY

Inventory Analysis is commonly used in understanding the relative hazards and short listing of release scenarios. Inventory plays an important role in regard to the potential hazard. A practice commonly used to generate an incident list is to consider potential leaks and major releases from fractures of pipelines and vessels containing sizable inventories.

The potential Vapour release (source strength) depends upon the quantity of liquid release, the properties of the materials and the operating conditions (pressure, temperature). If all these influencing parameters are combined into a matrix and Vapour source strength computed for each release case, a ranking should become a credible exercise.

2.1.4. LOSS OF CONTAINMENT

Liquid Release may be instantaneous. Failure of a vessel leading to an instantaneous outflow assumes the sudden appearance of such a major crack that practically all of the contents above the crack shall be released in a very short time.

The more likely event is the case of liquid release from a hole in a pipe connected to the vessel. The flow rate will depend on the size of the hole as well as on the pressure head in the line, prior to the accident. Such pressure is basically dependent on the pressure in the vessel.

The vaporization of released liquid depends on the Vapour pressure and weather conditions. Such consideration and others have been kept in mind both during the initial listing as well as during the short listing procedure.

Initial listing of all significant inventories in the process plants was carried out. This ensured no emission through in advertence.

2.1.5. FACTORS CONSIDERED FOR IDENTIFICATION OF HAZARDS

In any installation, main hazard arises due to loss of containment during handling of flammable and toxic chemicals.

The Chemicals are classified according to the properties and hazard class given by National Fire Protection Association (NFPA) is responsible for 380 codes and standards that are designed to minimize the risk and effects of fire by establishing criteria for building, processing, design, service and installation.

NFPA classification (TABLE 2) for Health, Flammability & Reactivity of a chemical is on a

Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility

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scale from 0-4 least to worst. As per the NFPA Rating on the scale from 0-4 the chemicals having 3 & 4 are considered are highly hazardous and considered for analysis.

TABLE 2:NFPA CLASSIFICATION

Rating	Health	Fire
0	No hazard	will not burn
1	Can cause significant irritation	must be preheated before ignition occur
2	Can cause temporary incapacitation or residual injury	must be heated or high ambient temperature to burn
3	Can cause serious or permanent injury	can be ignited under almost all ambient
4	Can be lethal	will vaporize and readily burn at normal temperature

NFPA provides standard for the chemicals to reduce the risk of fire and other hazards. The chemicals handled by the facility, that pose health and fire hazards as identified by their NFPA ratings, are mentioned in **TABLE 3.**

Table 3:NFPA RATINGS

C N-	Raw Materials /	Boiling Point (°C)	Flash point	NFPA Rating		
S. No	Products		(°C)	Health	Fire	Reactivity
1	Sodium Hydroxide	>130	-	3	0	1
2	Ethanol	78.3	14	0	3	0
3	Hydrochloric acid	50.5	-	3	0	0

2.2. TYPES OF OUTCOME EVENTS

In this section of the report we describe the probabilities associated with the sequence of occurrences which must take place for the incident scenarios to produce hazardous effects and the modeling of their effects.

Considering the present case, the outcomes expected are

- Jet fire
- > Flash Fire

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- Vapour Cloud
- Pool Fire

2.2.1. JET FIRE

Jet fire occurs when a pressurized release (of a flammable gas or Vapour) is ignited by any source. They tend to be localized in effect and are mainly of concern in establishing the potential for domino effects and employee safety zones rather than for community risks.

2.2.2. FLASH FIRE

A flash fire is the non-explosive combustion of a Vapour cloud resulting from a release of flammable material into the open air, which after mixing with air, ignites. A flash fire results from the ignition of a released flammable cloud in which there is essentially no increase in combustion rate. The ignition source could be electric spark, a hot surface, and friction between moving parts of a machine or an open fire. Part of the reason for flash fires is that, flammable fuels have a Vapour temperature, which is less than the ambient Temperature.

Hence, as a result of a spill, they are dispersed initially by the negative buoyancy of cold Vapours and subsequently by the atmospheric turbulence. After the release and dispersion of the flammable fuel the resulting Vapour cloud is ignited and when the fuel Vapour is not mixed with sufficient air prior to ignition, it results in diffusion fire burning. Therefore, the rate at which the fuel Vapour and air are mixed together during combustion determines the rate of burning in the flash fire.

The main dangers of flash fires are radiation and direct flame contact. The size of the flammable cloud determines the area of possible direct flame contact effects. Radiation effects on a target depend on several factors including its distance from the flames, flame height, flame emissive power, local atmospheric transitivity and cloud size.

2.2.3. VAPOUR CLOUD

Vapour cloud is the result of flammable materials in the atmosphere, a subsequent dispersion phase, and after some delay an ignition of the Vapour cloud. Turbulence is the governing factor in blast generation, which could intensify combustion to the level that will result in an explosion. Obstacles in the path of Vapour cloud or when the cloud finds confined area, as under the bullets, often create turbulence. Insignificant level of confinement will result in a

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flash fire. The Vapour cloud will result in overpressures. It may be noted that Vapour cloud has been responsible for very serious accidents involving severe property damage and loss of lives.

2.2.4. POOL FIRE

This represents a situation when flammable liquid spillage forms a pool over a liquid or solid surface and gets ignited. Flammable liquids can be involved in pool fires where they are stored and transported in bulk quantities. Early pool fire was caused when the steadystate is reached between the outflow of flammable material from the container and complete combustion of the flammable material when the ignition source is available. Late pool fires are associated with the difference between the release of material and the complete combustion of the material simultaneously. Late pool fires are common when large quantity of flammable material is released within short time.

2.3. HEAT RADIATION

The effect of fire on a human being is in the form of burns. There are three categories of burn such as first degree, second degree and third degree burns. The consequences caused by exposure to heat radiation are a function of:

- The radiation energy onto the human body $\lceil kW/m^2 \rceil$;
- > The exposure duration [sec];
- The protection of the skin tissue (clothed or naked body).

The limits for 1% of the exposed people to be killed due to heat radiation, and for second-degree burns are given in **TABLE 4.**

TABLE 4:DAMAGES TO HUMAN LIFE DUE TO HEAT RADIATION

Exposure	Radiation energy	Radiation energy for	Radiation energy for
Duration (sec)	(1% lethality, kW/m ²)	2nd degree burns, kW/m ²	first degree burns, kW/m ²
10	21.2	16	12.5
30	9.3	7	4

TABLE 5:EFFECTS DUE TO INCIDENT RADIATION INTENSITY

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Radiation Intensity (kW/m ²)	TYPE OF DAMAGE
0.7	Equivalent to Solar Radiation
1.6	No discomfort for long exposure
4	Sufficient to cause pain within 20 sec. Blistering of skin (first degree burns are likely)
9.5	Pain threshold reached after 8 sec. second degree burns after 20 sec.
12.5	Minimum energy required for piloted ignition of wood, melting plastic tubing's etc.
37.5	Heavy Damage to process equipment

2.4. TYPE OF DAMAGE

The actual results would be less severe due to the various assumptions made in the models arising out of the flame geometry, emissivity, angle of incidence, view factor and others. The radiation output of the flame would be dependent upon the fire size, extent of mixing with air and the flame temperature. Some fraction of the radiation is absorbed by carbon dioxide and water Vapour in the intervening atmosphere. Finally, the incident flux at an observer location would depend upon the radiation view factor, which is a function of the distance from the flame surface, the observer's orientation and the flame geometry.

3. CONSEQUENCE ANALYSIS

TABLE 6:CONSEQUENCE ANALYSIS TABLE

S. N	CHEMICALS	SCENARIO	WEATHER	VAPOUR CLOUD DISPERSION			JET FIRE			LATE POOL FIRE			FLASH FIRE	
				UFL	LFL	1/2 LFL	4 KW/m2	12.5 KW/m2	37.5 KW/m 2	4 KW/m 2	12.5 KW/m2	37.5 KW/m2	LFL	1/2 LFL
1	HSD	Catastrophic rupture	Category 1.5/F	5.368	5.369	5.369	NA	NA	NA	71.17	85.63	52.54	5.369	5.369
			Category 5/D	4.735	4.735	4.735	NA	NA	NA	71.2	91.17	53.49	4.735	4.735
			Category 1.5/D	5.401	5.447	5.45	NA	NA	NA	71.2	85.55	52.47	5.447	5.45
		Small Leak	Category 1.5/F	NA	NA	NA	NA	NA	NA	7.424	24.02	14.83	NA	NA
			Category 5/D	NA	NA	NA	NA	NA	NA	7.415	25.66	17.65	NA	NA
			Category 1.5/D	NA	NA	NA	NA	NA	NA	7.427	24.08	14.89	NA	NA
		Medium Leak	Category 1.5/F	NA	NA	NA	NA	NA	NA	14.85	33.05	19.07	NA	NA
			Category 5/D	NA	NA	NA	NA	NA	NA	14.83	34.9	22.07	NA	NA
			Category 1.5/D	NA	NA	NA	NA	NA	NA	14.86	33.07	19.1	NA	NA
		Large Leak	Category 1.5/F	NA	NA	NA	NA	NA	NA	22.28	39.22	22.83	NA	NA
			Category 5/D	NA	NA	NA	NA	NA	NA	22.26	41.39	23.5	NA	NA
			Category 1.5/D	NA	NA	NA	NA	NA	NA	22.27	39.23	22.85	NA	NA

3.1. SUMMARY AND CONCLUSIONS

SUMMARY - VAPOUR CLOUD DISPERSION - WORST CASE SCENARIO

For HSD, LFL Fraction received at maximum distance due to Vapour Cloud Dispersion in Catastrophic Rupture scenario is 5.45 m at 1.5m/s wind speed and stability classes D. The contours of vapour cloud dispersion exceeds the site boundary.

SUMMARY - LATE POOL FIRE - WORST CASE SCENARIO

For HSD, Radiation profile (12.5 kW/m²) received at maximum distance due to Late Pool Fire in Catastrophic Rupture scenario is 91.17 m at 5m/s wind speed and stability classes D. The contours for late pool fire exceeds the site boundary.

SUMMARY - FLASH FIRE - WORST CASE SCENARIO

For HSD, Radiation profile LFL fraction received at maximum distance due to Flash Fire in Catastrophic Rupture scenario is 5.45 m at 1.5m/s wind speed and stability classes D. The contours fall inside the site boundary.

Proposed Manufacturing of Monoclonal Antibodies and Formulation Facility Risk assessment report

3.2. CONTOURS FOR ALL WORST CASE SCENARIOS

3.2.1. CONTOURS FOR VAPOUR CLOUD DIESPERSION

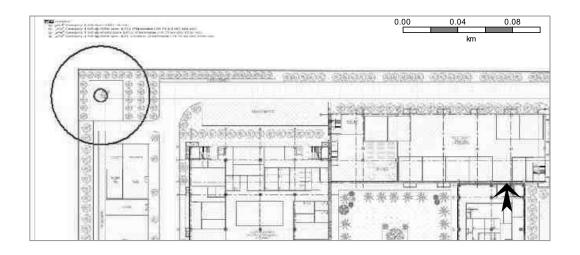


FIGURE 3: HSD -CATASTROPHIC RUPTURE-VAPOUR CLOUD DISPERSION-PROJECT LAYOUT

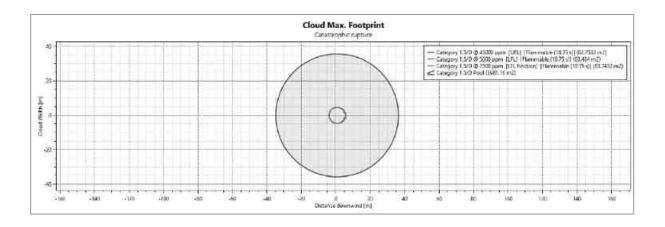


FIGURE 4: HSD -CATASTROPHIC RUPTURE-VAPOUR CLOUD DISPERSION-GRAPHICAL REPRESENTATION

3.2.2. CONTOURS FOR LATE POOL FIRE

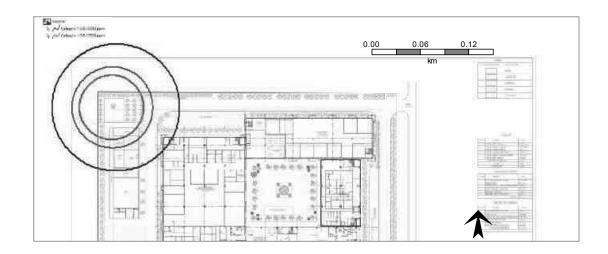


FIGURE 5: HSD-CATASTROPHIC RUPTURE-LATE POOL FIRE - PROJECT LAYOUT

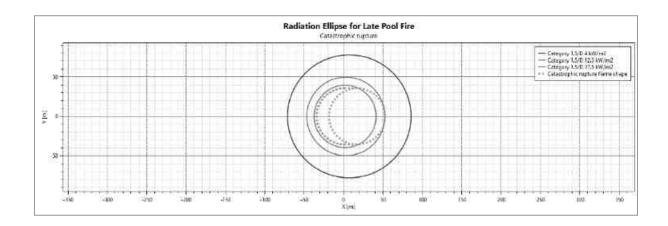


FIGURE 6: HSD - CATASTROPHIC RUPTURE-LATE POOL FIRE – GRAPHICAL REPRESENTATION

3.2.4. CONTOURS FOR FLASH FIRE

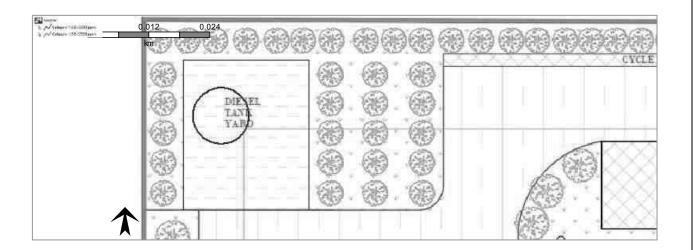


FIGURE 7: HSD -CATASTROPHIC RUPTURE-FLASH FIRE- PROJECT LAYOUT

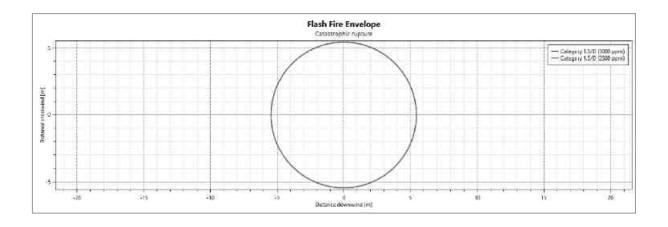


FIGURE 8: HSD -CATASTROPHIC RUPTURE-FLASH FIRE- GRAPHICAL REPRESENTATION

4. MITIGATION MEASURES

4.1. RECOMMENDATIONS FOR IMPROVING SAFETY

The following measures be considered for enhancing the safety standards at site:

- ➤ Install advanced HVAC systems to control vapour concentrations and maintain air quality, especially in indoor processing and storage areas. Ensure regular maintenance and monitoring of these systems to prevent buildup of explosive or harmful atmospheres.
- ➤ Use explosion-proof equipment and electrical systems in areas where flammable solvents or chemicals are stored and processed. Regularly inspect and maintain these systems to ensure compliance with safety standards.
- > Store all chemicals in tightly sealed containers or tanks made of non-reactive materials such as stainless steel or high-grade glass. Implement secondary containment measures to prevent leaks and spills.
- > Keep storage areas well-ventilated, cool, and away from sources of ignition, heat, or incompatible substances.
- Establish designated storage areas with clear signage, access restrictions, and spill containment measures. Use color-coded labels and safety symbols to enhance visibility and awareness.
- > Segregate the chemicals from incompatible substances such as oxidizing agents, strong acids, and alkalis to prevent accidental reactions or releases.
- ➤ Develop and implement comprehensive emergency response plans for spills, leaks, or releases of chemicals. Conduct regular drills and simulations to ensure staff are familiar with emergency procedures.
- ➤ Provide ongoing training to employees on emergency procedures, evacuation routes, and first aid measures. Include training on the specific hazards associated with monoclonal antibody production.
- Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation of ethanol, such as PESO, MSIHC Rule 1989, OSHA's Process Safety Management Standard and EPA guidelines etc.

- Train personnel on safe handling practices, including proper storage, transfer, and use of hazardous chemicals. Use Standard Operating Procedures (SOPs) and ensure they are easily accessible to all employees.
- > Implement continuous training and retraining programs for operators. Conduct regular mock drills based on identified scenarios to ensure preparedness for emergencies.
- ➤ Enforce a strict work permit system for all maintenance and operational activities. Ensure permits are not bypassed and are reviewed and approved by safety officers.
- > Strictly prohibit smoking and carrying smoking accessories in all areas of the facility.

 Implement clear signage and regular inspections to enforce this rule.
- > Safety Procedures and Do's and Don'ts should be prepared and displayed in handling, processing and storage area.
- ➤ The Plant commissioning has an important role to ensure long term safety. Proper cleaning and flushing of the system should be ensured in storage area and fire hydrant system to avoid possible hold up of welding slag's, bolts, nuts etc., which could hamper smooth operation.
- ➤ The Environment Management Team to be trained on industrial hygiene and sampling/ testing techniques.
- ➤ Keep the storage of critical chemicals to a minimum necessary for smooth plant operation. Implement a just-in-time inventory system to reduce on-site quantities.
- ➤ Even though most of the chemicals are stored in drums/barrels, the storage area will be kept effective to contain the material within and to clear the area immediately in case of any spillage in a safer way.
- > The firefighting equipment will be kept ready and tested periodically to confirm their efficiency.
- Minimum 10% of employees, in each shift, to be trained to do the needful during emergencies.
- ➤ It is suggested to consider fire detectors (with alarm/beacon) in such areas for earliest detection and response by the operator in the control room and those in the field.

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Ensure active fire protection measures as per requirement mentioned under applicable

standards/guidelines.

Automatic shutdown system shall be installed and other instrumentation system like

SCADA shall be installed.

➤ All the project premises shall be monitored by surveillance cameras.

> Proper checking of contract people for Smoking or Inflammable materials to be ensured

at entry gates to avoid presence of any unidentified source of ignition in the plant.

4.2. SAFETY MEASURES FOR HANDLING HSD

HAZARD IDENTIFICATION:

Inhalation can cause dizziness, headache and nausea, depresses central nervous system and

has an anaesthetic effect. Breathing of liquid droplets may lead to chemical pneumonia.

Ingestion can lead to nausea, diarrhoea and affect central nervous system. Skin irritant.

Prolonged contact can result in skin drying and dermatitis. Eye irritant.

POTENTIAL HAZARDS:

Inhalation: can cause dizziness, headache and nausea, depresses central nervous system and

has an anaesthetic effect. Breathing of liquid droplets may lead to chemical pneumonia.

Ingestion: can lead to nausea, diarrhoea and affect central nervous system

Skin Contact: Causes irritation to skin. Prolonged contact can result in skin drying and

dermatitis.

Eve Contact: May cause irritation

FIRST AID MEASURES

Inhalation: Remove to fresh air. Consult a physician if irritation persists. maintain

respiration and administer oxygen; enforce bed rest if liquid is in lungs

Ingestion: Do not induce vomiting. Do not give liquids. stomach should be lavaged (by

doctor) if appreciable quantity is swallowed. Get medical help at once

Skin Contact: Wash with warm water & soap.

Eye Contact: Flush with water for 15 min. Get medical attention.

FIRE FIGHTING MEASURES

Fire Extinguishing Media:

Foam, Dry Chemical Powder, CO2

HANDLING AND STORAGE

Do not use/store near heat/open flame. Use gumboots, gloves while handling the product. Do not inhale. Stay upwind while handling the product. Product should never be used to remove oil or grease from skin. It should not be siphoned by mouth. It should be stored in closed containers away from heat & source of ignition. Avoid contact with skin and eyes. Wash thoroughly after handling. Do not use/store near heat/open flame/water/acids.

5. MONOCLONAL ANTIBODIES PROCESS DESCRIPTION

The project proposes to manufacture of bulk drugs & intermediates (Monoclonal antibodies) with capacity of 520 Kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Lakh/Month. The process description is given below,

Mammalian Cell Culture Process

Mammalian Expression system is Chinese Hamster Ovary (CHO) cells and the process time considered is 20 days/batch. In the manufacturing of biopharmaceuticals from mammalian cells consists two stages those are upstream and downstream processes.

a. Upstream Process

The inoculum generation is initiated with thawing of a vial from a cell bank. The cells from the vial are expanded using shake flasks and seed bioreactors to obtain the desired amount of inoculum for starting a production bioreactor. The mode of running the bioreactor is fed batch or perfusion. The cells are allowed to grow for few days in batch mode after which feeds of nutrients like glucose, amino acids, vitamins and salts are fed in the bioreactor on different days. The bioreactor is harvested at the end of the fermentation and taken for downstream.

b. Downstream Process

Cell clarification: Continuous centrifugation followed by depth filtration is to separate the cells from the fermentation media, the supernatant of which will be clarified by depth filtration.

Capture by affinity chromatography: Target protein is among thousands of impurities will be specially retained over the affinity resin leaving impurities as unbound.

Virus inactivation: Inactivation of different viruses if any will be done in a sterile bag at a lower pH and probably at a controlled temperature between 2 and 25 deg Celsius.

Purification by ion exchange chromatography (IEC): The related impurities will be the next level of contaminants that needs to be separated from the target protein, ion exchange chromatography does the job be at an-ion or cat-ion exchange chromatography.

Virus removal by Nano-filtration: It is to remove the all forms of virus so there are no viral loads basically in the active pharmaceutical intermediate.

Concentration/ Buffer exchange by tangential flow filtration (TFF): It is critical to bring in the product to the required pre/formulation buffer which ensures the stability.

Final sterile filtration: This filtration is required to claim that the product is sterile and is qualified for fill finish requirement. Samples are collected at different stages during the batch and sent for analytical testing.

After final sterile filtration the product will be sent to formulation unit.

5.1. WHAT ARE THE RISKS?

From the experience with cytotoxic agents, the risks to healthcare workers in the preparation and administration of MABs arise from three distinct mechanisms; dermal exposure, the inhalation of aerosols, and oral intake.

- **Dermal exposure:** The skin is an effective barrier to absorption of high molecular weight proteins. The upper limit for dermal absorption of compounds is around 500 Daltons to allow penetration of the stratum corneum. Given that MABs have a much higher molecular weight (usually greater than 140kDa) the potential for dermal uptake of intact skin of unconjugated MABs or intact conjugates in the occupational setting is unlikely. As MABs are immunoglobulin based they would also have restricted access across diffusional barriers unless transport is facilitated by specific mechanisms. However, skin conditions such as dermatitis and other damage to the skin may facilitate the dermal uptake of monoclonal antibodies.
- Inhalation exposure: The greatest risk of exposure during the preparation of MABs is through inhalation. However, even this risk is low. Aerosolized cetuximab in a mouse model

has shown that the airway barriers are permeable to MABs, but its passage into the bloodstream is limited. Estimates on the bioavailability of high molecular weight substances have been at 5% by inhalation. However, given the high molecular weights of MABs, the absorption rates could be considered lower. In areas where MABs may be administered to patients via inhalation, the potential for exposure to the worker may be increased.

• Oral exposure: Oral exposure of MABs through hand-to-mouth transmission may occur. MABs are intricately folded proteins that are easily susceptible to denaturation from environmental conditions. If ingested, MABs are rapidly broken down by gut enzymes and acids resulting in denaturing of the protein and loss of biological activity. Exposure via this route would be minimal. However, there may be a theoretical risk from resultant lower molecular weight agents from conjugates which may be absorbed systemically.

5.2. CONTAMINATION RISKS

Contamination risks pose a significant challenge in monoclonal antibody manufacturing processes. Contaminants can originate from various sources, including raw materials, equipment, personnel and the environment. Common contaminants include microbial contaminants (e.g., bacteria, fungi, viruses), adventitious agents (e.g., viruses from cell lines), process-related impurities (e.g., host cell proteins, DNA) and endotoxins.

Contaminants can compromise the safety, efficacy and quality of monoclonal antibody products. They may introduce potential health risks to patients or affect the stability and function of the therapeutic antibodies. Implementing robust quality control measures, adhering to Good Manufacturing Practices (GMP) and employing stringent purification techniques are crucial to minimize contamination risks and ensure product safety.

5.3. PREVENTING CONTAMINATION IN MAB PROCESS

Bioreactors used for monoclonal antibody (mAb) production are at particular risk of contamination from adventitious agents. Contamination events interrupt manufacturing schedules, resulting in lost revenue and potential disruption of drug supply. Traditional measures to prevent upstream contamination focus on careful sourcing and selection of raw materials, comprehensive testing for the presence of viral contaminants, and implementation of technologies that prevent virus from entering production processes.

High-profile viral contamination events have led bio manufacturers to re-examine risk assessments around viral safety. As a result, many bio manufacturers are implementing additional measures upstream of the bioreactor to mitigate the risk of viral contamination.

5.4. THE PROPOSED DRUG PRODUCTS

TABLE 7: The proposed drug products list

Sl.no	Product	Kg Per annum
1	Pembrolizumab	100
2	Denosumab	20
3	Ustekinumab	20
4	Bevacizumab	10
5	Adalimumab	20
6	Aflibercept	10
7	Apixaban	50
8	Trastuzumab	20
9	Olaratumab	10
10	Omalizumab	10
11	Palivizumab	10
12	Panitumumab	10
13	Tocilizumab	10
14	Trastuzumab emtansine	10
15	Infliximab	10
16	Eculizumab	10
17	Etanercept	10
18	Ziv-aflibercept	10
19	Rituximab	10
20	Ramucirumab	10
21	Raxibacumab	10
22	Sarilumab	10
23	Inotuzumab ozogamicin	10
24	Brodalumab	10
25	Abatacept	10
26	Abciximab	10

5.5. BIOLOGICAL RISK ASSESSMENT

The use of animal cell cultures has become very beneficial for diverse applications in biotechnology. Animal cell cultures become an indispensable tool to produce a variety of products, including biopharmaceuticals, monoclonal antibodies and products for gene therapy. The use of animal cell cultures constitutes also adequate test systems for studying

biochemical pathways, virus production, pathological mechanisms or intra- and intercellular responses.

Along with the increasing importance of the contained use of animal cell cultures, biosafety concerns have pointed to the risks with respect to human health and environmental considerations. A maximal reduction of these risks necessitates a thorough biosafety risk assessment, taking account of the type of manipulation and the biological hazards inherent to the use of cell cultures.

Sources of biological contamination of biopharmaceuticals

In line with conventional pharmaceutical products, the main sources of biological contamination in biopharmaceuticals can be related to raw materials and the production environment. Indeed, the biological contaminant content of any pharmaceutical product is a representative of their starting materials and the production environment flora.

Raw materials

Animal origin materials, such as cell culture media and supplements that are extensively used in biopharmaceutical production, are of high contamination risk. These materials can be considered the main source for the contamination of biopharmaceuticals with adventitious agents such as viruses and mycoplasmas. Therefore, they should be supplied from reliable sources and special attention should be paid to their quality control procedure. It should be ensured that all raw materials, especially those of high risk, gain quality specifications for current good manufacturing practice.

Standard methods for sterilization of cell culture media and supplements should be established according to the properties of the materials. Due to the heat-liable nature of the majority of materials used in biopharmaceutical production, autoclaving is usually replaced with alternative strategies such as filter-sterilization or less frequently high-temperature, short-time treatment strategies.

Another important raw material that is used in the production of biopharmaceutical product is water, which can be considered an important source for contamination, with water-borne bacteria such as Pseudomonas spp., Alcaligenes spp., etc.

Production environment

Pharmaceutical products contamination may occur from the transformation of microorganisms from the production environment to the product. The production environment includes air, surfaces, instruments, equipment and personnel.

The critical operations in biopharmaceutical production should be performed in controlled environment or clean rooms. A clean room is a place with high control of the entrance of particles via the establishment of some air filters called High Efficiency Particulate Air (HEPA) filters. Apart from these special attentions should be paid to the position, type and texture of surfaces, floors and fixtures. They should be made from smooth and chemically stable materials. In addition, a distinct transfer lock area should exist before entry to the clean room for sanitization of materials and personnel or garment changing.

5.6. Hazards of biological contamination of biopharmaceuticals

Biological contamination of biopharmaceuticals may perhaps cause product spoilage. It may result in product metabolization by micro-organisms and therefore, lead to a decrease in biopharmaceutical potency. The product spoilage may also provide a potential health hazard to patients and lead to outbreaks of infections that may cause additional compliances. In addition, microbial-derived agents secreted in products such as endotoxins can be hazardous to a patient's health.

The biological contaminants are

- Bacteria and Fungi
- Endotoxins
- Viruses
- Mycoplasma
- Cross-contamination

Summary

Microbial quality control plays a prominent role in the manufacture of safe and effective biopharmaceuticals. The main sources of microbial contamination can be related to raw materials and the production environment. The main categories of raw materials that are involved in the manufacturing of biopharmaceuticals with a high risk of contamination are those of animal origin such as cell culture media and supplements. The production environment includes air, surfaces, instruments, equipment and personnel. All these can be considered the main source for the contamination of biopharmaceuticals with adventitious

agents such as viruses, bacteria and mycoplasma. The use of contaminated biopharmaceuticals causes product spoilage, which may lead to metabolization of therapeutic agents by microorganisms, thus bringing about a decrease in the potency of the therapeutic agent and a potential health hazard to patients as a result of either infectious diseases or microbial-derived agents such as endotoxins that are secreted into products.

Various methods are used for detecting and eliminating different biological contaminants that are used in the manufacturing of biopharmaceuticals. Generally, bacteria and fungi can be detected by standard sterility testing or microscopic characteristics, as well as biochemical tests.

The table below summarises the occupational health & safety hazards, risks associated and corresponding mitigation measures in brief.

TABLE 8:The occupational health & safety hazards, risks and mitigation measures

Sl. No.	Activity	Hazards	Risks	Mitigation Measures
1	Raw Material Handling	Chemical spills	Environmental contamination, worker exposure	Use of proper storage containers, spill containment systems, and spill response protocols
2	Cell Culture and Fermentation	Exposure to biological agents	Infections, allergic reactions	Use of biosafety cabinets, personal protective equipment (PPE), and regular health monitoring
3	Purification Processes	Chemical exposure	Toxicity, respiratory issues	Adequate ventilation, use of PPE, regular safety training, and proper handling procedures
4	Filtration and Concentration	High- pressure equipment	Equipment failure, injury to workers	Regular maintenance, pressure relief systems, and training on safe operation of equipment
5	Formulation	Exposure to hazardous chemicals	Skin and eye irritation, respiratory issues	Proper ventilation, use of PPE and adherence to safety data sheets (SDS)

Sl.	Activity	Hazards	Risks	Mitigation Measures
6	Filling and Packaging	Exposure to preservatives and solvents	Skin sensitization, respiratory issues	Closed systems, proper ventilation and use of PPEs
7	Storage and Transportation	Temperature fluctuations, chemical leaks	Product degradation, environmental contamination	Controlled storage conditions, temperature monitoring, and leak detection systems

5.7. Biosafety Recommendations and Containment Measures

The implementation of an appropriate containment level includes the following general and more specific work practices and containment measures.

- Respect good microbiological practices, especially those that are aimed at avoiding accidental contamination.
- Avoid opening of culture vessels or contact with culture fluid through a defective culture vessel, stopper or poor technique because of the ever present likelihood of contamination with airborne pathogens.
- Treat each new culture that is manipulated for the first time in the laboratory facility as potentially infectious.
- Clean up any culture fluid spills immediately with a validated disinfectant.
- Work with one cell line at a time and disinfect the work surfaces between two handlings involving cell lines.
- Aliquot growth medium so that the same vessel is not used for more than one cell line.
- Avoid pouring actions, which are a potential source of cross-contamination.
- Proceed to an adequate use of the biosafety cabinet, this is turn on for a period before
 and after use, thoroughly disinfect biosafety cabinet surfaces after each work session
 and do not clutter the biosafety cabinet with materials.
- Restrict the use of antibiotics in growth media.

- Quarantine new cell cultures to a dedicated biosafety cabinet or separate laboratory until the culture has been shown negative in appropriate tests.
- Carry out a quality control of cells demonstrating the absence of likely contaminating pathogens on a regular basis or whenever necessary.
- Handle cell cultures from undefined sources as risk group agents. If there is a reasonable likelihood of adventitious agents of higher risk class, the cell line should be handled under appropriate containment level until tests have proven safety.

The following recommendations have been adapted from the Clinical Oncology Society of Australia (COSA) and Cancer Pharmacists Group (CPG) updated position statement 2022 and the Australian Consensus Guidelines 2014. They apply to currently marketed monoclonal antibodies (MABs) *except* MABs conjugated to a cytotoxic agent, fusion protein or a radioisotope. These conjugated MABs are considered hazardous and should be prepared and administered following accepted cytotoxic safe handling precautions and regulations related to the handling of cytotoxics and radiopharmaceuticals.

- Dermal absorption of MABs across intact skin during dose preparation or administration is unlikely due to their high molecular weight; however, it should be noted that skin conditions such as dermatitis and other damage to the skin may facilitate the dermal uptake of MABs. The use of gloves and effective hand hygiene are recommended to minimise risks of contamination and infection.
- A respirator mask (P2/N95) and protective eyewear should be worn during dose preparation and administration of MABs.
- The use of gowns and/or coveralls are not warranted for either dose preparation or administration of MABs.
- Institutional guidelines should be followed in the event of a needle stick injury or a spill.
- Disposal of waste products, including waste and/or bodily fluids of patients, should be
 in accordance with the disposal of clinical biohazardous waste, i.e. not as cytotoxic
 waste, unless conjugated with a cytotoxic agent.

5.8. Personal Protective Equipment

Gloves

Glove use is essential and should be chosen to maximise protection by minimising permeability. Standard surgical gloves may not provide the required level of protection due to

drug and/or carrier permeability. Information regarding the permeability and testing of gloves can be found on their box.

Gloves:

- are disposable
- should be purpose manufactured or manufacturer-recommended for handling hazardous drugs
- must be long enough to cover wrist cuffs of gown while arm is bent or stretched
- should be changed:
 - o at the end of a procedure
 - o prior to contact with another patient
 - o at intervals of 30 minutes *OR* as recommended by the manufacturer *OR* when punctured, torn, or contaminated.

Note: ONS and NIOSH recommend that 2 pairs of gloves are worn during any activity involving hazardous drugs except during administration of intact oral drugs. However, the various state and territory Work Health Safety guidelines of Australia and New Zealand recommend wearing one pair of purpose manufactured gloves as part of standard PPE for hazardous drugs, unless attending to a hazardous spill where two pairs are recommended.

Gowns

Gowns designed for use with hazardous drugs should be made of an impermeable material and changed per the manufacturer's instructions. Non-disposable gowns should be put in an alginate bag and processed through an appropriate laundry facility. Care should be taken when removing the gown to minimise the risk of personal contamination.

The gown should:

- have a closed front and long sleeves with elastic cuffs and secure at the back of the body
- be disposed of immediately (as contaminated waste) if overt contamination occurs
- not be worn in non-clinical areas, e.g. offices, tea rooms
- not be shared
- be used for a maximum of one shift.

Protective eyewear

Protective eyewear should be worn to protect against liquid splashes to the eye's mucous membranes. A worker wearing prescription glasses must undertake a risk assessment in line with local policies and procedures to determine if additional protection is required.

Eye protection:

- can be provided by:
 - o goggles
 - o protective eyewear with side shields
 - o a transparent full face chemical splash shield
 - o full-face respiratory protective equipment
- should be cleaned with neutral detergent solution and allowed to air dry at the end of the shift or when contaminated
- if disposable should be disposed of as cytotoxic waste.

Respiratory protective equipment

Respiratory protective equipment (RPE) with a P2/N95 particulate filter is recommended to contain aerosols generated by handling hazardous drugs and related waste; surgical masks do not provide sufficient protection.

- Effective storage and maintenance for reusable RPE should be implemented as per the manufacturers' recommendations.
- Workers must be fit tested as per the manufacturers' instructions to ensure the mask is the correct size, especially for those who wear prescription glasses
 - o the positive and negative pressure seal of the respirator should be tested to ensure correct fit by gently exhaling and inhaling; if air escapes or the respirator is not drawn into the face during inhalation, the respirator needs to be adjusted.

Overshoes

- should be made of impervious material with skid-resistant plastic soles
- should be high enough to cover trouser cuffs and designed not to slip down
- should be worn when cleaning a hazardous drug or related waste spill
- disposable paper shoe covers (those used in operating rooms) do not provide sufficient protection against cytotoxic contamination.

Hair-net or head covering

• should be worn to contain exposed hair, including beards and moustaches, and minimise contamination when cleaning a hazardous drug or related waste spill.

Removing and discarding PPE

To minimise potential contamination, PPE should be removed in the following order and disposed of in cytotoxic waste.

Removing PPE if wearing one pair of gloves

- 1. Remove gloves
- 2. Perform hand hygiene with soap and water
- 3. Remove gown
- 4. Remove protective eyewear or face shield
- 5. Remove respiratory protective equipment
- 6. Perform hand hygiene with soap and water.

Removing PPE if wearing two pairs of gloves

- 1. Remove outer glove
- 2. Remove gown
- 3. Remove protective eyewear or face shield
- 4. Remove respiratory protective equipment
- 5. Remove inner gloves
- 6. Perform hand hygiene with soap and water.

Note: Perform hand hygiene between steps if hands become contaminated at any point

6. HAZARD IDENTIFICATION AND RISK ASSESSMENT (HIRA) STUDY

6.1. INTRODUCTION

Risk assessment is the systematic examination of a job intended to identify potential hazards, assess the level of risks and evaluate practical measures to control risks.

Hazard analysis involves the identification and quantification of the various hazards (unsafe conditions) that exists in the activities of Omexa during the chemical handling. On the other hand, risk analysis deals with the recognition and computation of risks, the equipment in the working area and personnel are prone to, due to accidents resulting from the hazards present in the plant.

Risk analysis follows an extensive hazard analysis. It involves the identification and assessment of risks the neighbouring populations are exposed to as a result of hazards present. This requires a thorough knowledge of failure probability, credible accident scenario, vulnerability of population etc.

6.2. RISK ASSESSMENT STEPS

There are five steps followed to assess the risks in workplace. They are;

- Step 1: Identify the hazards
- Step 2: Decide who might be harmed and how
- Step 3: Evaluate the risks and decide on precautions
 - Identify the existing control measures and recommendations, if necessary
 - > evaluate the residual risks
- Step 4: Record the findings and implement them
- Step 5: Review the assessment and update if necessary

Hazard Identification

- This step seeks to identify the hazards and risks to be managed. Comprehensive identification using a well-structured systematic process is critical, because of hazard or risk not identified at this stage may be excluded from further analysis. Identification shall include actual and potential risks, whether or not they are under the control of the entity.
- The aim is to generate a comprehensive list of risks and events that might have an impact on the achievement of each of the objectives identified in the context. These events might prevent, degrade, delay or enhance the achievement of those objectives. These are then considered in more detail to identify what can happen.
- ➤ Having identified what can happen, it is necessary to consider possible causes and scenarios. There are many ways an event can occur.

Risk Analysis and Evaluation

- ➤ Risk analysis is about developing an understanding of the risk. It involves the source of the risk, consequences and likelihood that the consequence may occur. The existing control measures shall also be identified in this section.
- The level of risk is calculated by multiplying the consequence score and probability of occurrence together.

Risk = Consequence score x probability of occurrence

> The next step is to identify and evaluate the adequacy of existing control measures and suggestion of addition recommendation, if necessary.

The matrix considered for the HIRA study are as follows:

Probability	Severity										
	1	2	3	4	5						
1	1	2	3	4	5						
2	2	4	6	8	10						
3	3	6	9	12	15						
4	4	8	12	16	20						
5	5	10	15	20	25						

In mathematical term, risk can be calculated by the equation:

Risk= Likelihood \times Severity

> The probability and consequence is assigned in terms of risk matrix defines by

Risk assessment report

aparticular organization.

- ➤ Generally, most companies use risk matrix scale from 1-25 on a matrix scale
- > Whereas in the matrix scale 1 represents low level risk and 25 refers to high level risks.

RISK	CATEGORY	ACTION PLAN
16-25	Extreme Risk (E)	Activity should not proceed in current form without adequate control measures.
08-15	High Risk (H)	Activity should be modified to include remedial planning and action
04-07	Moderate Risk (M)	Activity can operate subject to management and/or modification
01-03	Low Risk (L)	No action required, unless escalation of risk is possible.

6.3. HAZARD IDENTIFICATION AND RISK ASSESSMENT MATRIX

TABLE 9: HIRA MATRIX

S.No	Activity	Sub-Activity	Hazard	Consequence	Existing risk		risk		risk		risk		risk		risk		Existing /Required Controls	R	esid risk		C
			The drum can slip during manual handling	High chances of getting fire as the outer temperature will be very high	P S R 4 5 20 E		E	Proper SOP's should be defined for handling of hazardous and inflammable substances.	1	5	R 5	M									
Transporting and storage of hazardous and 1 highly inflammable	Loading/unloading of the chemicals in drums	The chemical can splash over the worker's body whomsoever handling it.	Can cause irritation and burn injuries based on the concentration of the chemicals.	4	5	20	E	Competent and trained personnel should be allowed to carry out the operation. Special work permits shall be issued by safety officer for handling bulk quantity of chemicals. Adequate and necessary PPE's should be provided by the organization.	1	5	5	M									
	chemicals on trucks	Storage of chemicals in the warehouse/facility	Exposure of chemicals into the environment due to improper storage	May lead to acute and chronic health effects to the workers who are in direct/indirect contact with the chemicals	4	5	20	E	Proper storage facilities with adequate ventilation has been provided. MSDS for all chemicals has been made available in the site. The MSDS should be written in a common language that should be understood by all the workers in the facility for effective results.	1	5	5	M								

S.No	Activity		_	С	Existing /Required		esid risl		\mathbf{C}				
				1	P	S	R		Controls		S	R	
		Reactor & Research development section.	Direct exposure to fumes and other poisonous dust	Can lead to respiratory disorders on continuous exposure	4	4	16	E	Proper SOP's should be defined for handling of hazardous. Training should be provided to the workers.	1	4	4	M
	Processing of		Release of emissions in the surrounding atmosphere	Can lead to air contamination, resulting in respiratory problems	5	4	20	E	Engineering control measures should be employed to minimize the particulate matter and other harmful gases. Continuous monitoring of	1	4	4	M
		nonoclonal Handling of		in the surrounding					the stack emissions should be available.				
2	chemicals & monoclonal			Dermal exposure can					Proper PPE's to be provided to the workers.				
	antibodies		Dermal exposure	result from skin contact with contaminated environmental media	4	5	20	E	Employers should provide training programs that educate workers about hazards that they may be exposed to and ways to protect themselves.	1	5	5	M
		MAb's Process	Biological Hazards (Biological hazards are a major source of risk that may result in emergencies and disasters.)	Biological hazards are of organic origin or conveyed by biological vectors, including pathogenic microorganisms, toxins and bioactive substances.	4	5	20		PPE like gloves, gowns, and respirators are used to protect workers. Proper use and decontamination of equipment minimizes exposure risks from biological hazards in laboratories.	2	5	10	Н
3	Diesel Generator	Working on the diesel generator	Exposure to high voltage electricity	Electrocution	4	5	20	E	Grounding to be provided to generator.	1	5	5	M

S.No	Activity	Sub-Activity	Hazard	Consequence	E	xisti risl		С	Existing /Required	R	esid risk		C
Si 10	riccivicy	Sub Helling	111121111	consequence	P		R	O	Controls	P		R	Ü
									Proper PPE's to be provided to the workers.				
		Environmental exposure		damage to wildlife and surrounding, greenhouse effect	4	5	20	E	Use proper containment measures to reduce the fumes exposures to environment	1	5	5	M
			Presence of high amount of scales in the combustion chamber of boiler	may tend to reduce the performance and efficiency will reduce. Also leads to explosion	3	5	15	E	Periodical maintenance should be carried out and ensure that the scale formation is in the prescribed level.	1	5	5	M
		Starting the ignition of boiler	Starting the boiler without desired	Walls of the boiler		5			Proper training should be provided to the operator to check the water levels before operating the boiler.				
				of the equipment and	4		20	E	Water level indicator should be installed and maintained properly	1	5	5	M
4	4 Boiler operation		quantity of water inside the chamber/ dry running the boiler	may blast creating a explosion.					Pre start up inspection should be carried out and the water level should be ensured by the operator before starting the operation.				
				Water tube inside the boiler may get damage due to insufficient amount of water	5	3	15	Н	Pre start-up inspection should be carried out and the water level should be ensured by the operator before starting the operation.	1	3	3	L
		Working near the boilers	Exposure to High temperature and contact with hot	Development of heat stroke to boiler operator	3	5	15	E	The workers shall be provided with necessary PPEs like heat resistant	1	5	5	M

S.No	Activity	Sub-Activity	Hazard	Consequence		xisti risk	τ	C	Existing /Required Controls	R	Residual risk		C
			surface	Injury to body if exposed to the heat directly	P	S	R		body suit, face shields, goggles to prevent radiation, gloves, helmet, shoes etc availability of shelter with drinking water and cool air near to the boiler area. Periodical health checks should be carried out. availability of First Aid Boxes and trained first aiders in all shifts Suitable clothing should be provided to withstand the huge heat generated in the boiler room Provision of cool air and drinking water facility should be provided near to the boiler area	P	S	R	
			Exposure to high level of noise near the boiler chamber	Can lead to hearing impairment	4	3	12	Н	Periodical & proper maintenance of the boiler should be carried out Proper PPE's must be provided to operators engaged in the operation.	1	3	3	L
			Generation of huge amount of pressure than the rated capacity.	Boiler may lead to huge explosion	5	4	20	E	safety valves with easing gears should be installed in the boiler and should be calibrated. Continuous monitoring of pressure level should be	1	4	4	M

S.No	Activity Sub-Activity	Hazard	Consequence		xisti risl		С	Existing /Required		esid risk		C			
5.110	rectivity	Sub receivity	Hazaru	Consequence	P	S	R		Controls	P	S	R	C		
									done during operation						
			Exposure to								Proper stacks should be provided for boilers.				
			combustion gases	Respiratory problem could occur and may					Complete combustion of fuel must be ensured.						
			and other gaseous pollutants due to improper sealing or	to lead to serious health g or issues.	3	4	12	2 H	Smoke detector should be installed.	1	4	4	L		
			fugitive emissions	issues.					Proper & periodic maintenance should be carried out						
		Maintenance activity	Opening the manhole chamber without releasing the steam completely	Can lead to explosion due to sudden pressure drop and cause death	4	5	20	E	Pressure regulators should be checked before carrying out maintenance. Work permits should be issued before entering the confined space.	- 1	5	5	M		
			Improper closing of the manhole after carrying out the maintenance activity	Can lead to explosion when the boiler is started again after maintenance	3	5	15	E	Pre inspection should be carried out before starting the boiler.	1	5	5	M		
		Housekeeping activity	Opening of the vents of the boiler to remove the scale formed	Can lead to explosion if opened before the complete release of pressure inside the boiler	3	5	15	E	Only well trained and authorised person should be allowed to carry-out the housekeeping activity. Proper SOP should be available in place and should be followed.	1	5	5	M		
			Exposure to hot surface of the boiler	In case of direct contact, can cause burn injuries.	4	3	12	Н	Provision to measure temperature before starting the maintenance	1	3	3	L		

S.No	Activity	Sub-Activity	Hazard	Consequence	risk _		Existing risk		risk _		risk		risk		Existing /Required		esid risl		C
	·	·		•	P	S	R		Controls		S	R							
			Trapping inside the boiler drum while entering the boiler for cleaning.	Can lead to death	2	5	10	Н	Only well trained and authorised person should be allowed to carry-out the housekeeping activity. Permit to work should be issued.	1	5	5	M						

P: Probability

S: Severity

R: Risk Rating

C: Category

6.4. RISK IDENTIFICATION AND CONTROL MEASURES FOR MONOCLONAL ANTIBODIES

The below Monoclonal Antibody Risk Rating and Handling Precautions Guide, provides information on the risk level and handling precautions.

TABLE 10: Risk Identification and control measures for proposed drug products

Monoclonal Antibody	Risk Level (Likelihood/consequence)	Potential Response	Risk Level (LDH Consensus)	Preparation Handling Precautions	Storage and Handling Precautions
Pembrolizumab	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to pembrolizumab is not known. Skin contact may result in irritation, rash and dermatitis. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear PVC or latex gloves. Body protection: wear a PVC apron and impervious coveralls Respiratory protection: wear a N95/P2 mask	Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. Conditions for safe storage: Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Denosumab	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate	The occupational hazard of intermittent low dose exposure to Denosumab infliximab is not known. Moderate to severe irritant to the skin and eyes.	Moderate	Eye and face protection: Wear safety glasses with side shields, chemical splash goggles, or safety	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands,

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(administration) Mucosal – possible/moderate (preparation), unlikely/moderat (administration)			glasses with side shields and a full-face shield to prevent contact with eyes. Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact. Respiratory protection: no PPE specified	face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.
Ustekinumab Dermal – No data available Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderat (administration) Mucosal – possible/moderate (preparation), unlikely/moderat (administration)		Low	No Preparation Handling required	Advice on safe handling: To avoid thermal decomposition, do not overheat. Wear personal protection equipment. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Conditions for safe storage: To maintain product quality, do not store in heat or direct sunlight. Store in

		_			
					original container. Keep containers
					tightly closed in a dry, cool and
					wellventilated place. Keep away from
					heat
Bevacizumab	Dermal – likely/none	The occupational hazard of intermittent	Moderate	Eye and face protection:	Precautions for Safe Handling:
	Oral – unlikely/low	low dose exposure to bevacizumab is not		wear splash-proof	Restrict access to work area. Avoid
	Inhalation – unlikely/moderate	known. Not classified as a skin irritant.		goggles	open handling. Minimize generating
	Mucosal – possible/moderate	Contact may result in mild irritation. Not			airborne mists and vapors. Use
	(preparation), unlikely/moderate	classified as an eye irritant. Contact may		Hand protection: wear	appropriate engineering controls to
	(administration)	cause discomfort, lacrimation and		PVC or latex gloves	maintain exposures below the B-OEF
		redness.			taking all applicable routes of
				Body protection: wear a	exposure into consideration. A chang
				laboratory coat or other	area to facilitate 'good
				protective garment if	laboratory/manufacturing'
				splashing is possible	decontamination practices is
					recommended. Avoid inhalation and
				Respiratory protection:	contact with skin, eye, and clothing.
				where an inhalation risk	When handling, use appropriate
				exists, wear a Class P1	personal protective equipment Wash
				(Particulate) respirator	hands and any exposed skin after
					removal of PPE. Releases to the
					environment should be avoided.
					Review and implement appropriate
					technical and procedural waste water
					and waste disposal measures to
					prevent occupational exposure or
					environmental releases. Potential
					points of process emissions of this
					material to the atmosphere should be
					controlled with dust collectors, HEPA
					filtration systems or other equivalent
					controls.

Adalimumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	Available as pre-filled syringe, pen, and auto- injector. Occupation exposure unlikely.	Low	No Preparation Handling required.	No additional precautions
Aflibercept	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	Available as pre-filled syringe. Occupation exposure unlikely.	Low	No Preparation Handling required.	No additional precautions
Apixaban	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	The occupational hazard of intermittent low dose exposure to Apixaban is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European StandardEN166. Hand Protection: Wear appropriate protective gloves. Respiratory protection: wear a N95/P2 mask	Handling: Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation. Storage: Keep container tightly closed in a dry and well-ventilated place. Incompatible Materials. Strong oxidizing agents
Trastuzumab	Dermal – likely/high Oral – unlikely/high Inhalation – possible/high Mucosal – unlikely/high	Cytotoxic drug. If used therapeutically under controlled clinical conditions, the potential for adverse health effects is minimised. Adverse health effects via occupational exposure are not anticipated, however, should over exposure occur, possible effects may be hair loss, bone marrow damage and allergic skin reactions. Refer to medical doctor/specialist for advice regarding adverse side effects.	High	Use cytotoxic precautions	Advice on safe handling: Wear appropriate personal protection, Smoking, eating and drinking should be prohibited in the application area. Conditions for safe storage: Store between +2°C and +8C. Store protected from light Electrical installations / working materials must comply with the technological safety standards.

Olaratumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	Available as pre-filled syringe and vials. Occupation exposure unlikely.	Moderate	Eye/Face Protection: Safety glasses with side shields recommended. Hand protection: Chemical resistant gloves. Respiratory protection: wear a N95/P2 mask	No additional precautions
Omalizumab	Dermal – likely/none Oral – unlikely/low Inhalation – possible/moderate (preparation), unlikely/moderate (administration) Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to omalizumab is not known. May cause allergic respiratory reactions.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear neoprene, nitrile or butyl rubber gloves Body protection: no PPE specified Respiratory protection: wear a N95/P2 mask	Advice on safe handling: wear appropriate personal protective equipment. Smoking, eating and drinking should be prohibited in the application area. Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.
Palivizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – unlikely/moderate	Not classified as a skin or eye irritant. May result in mild irritation.	Low	No Preparation Handling required.	Put on appropriate personal protective equipment. Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Conditions for safe storage, including

Tocilizumab Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate (preparation), unlikely/moderate (administration) The occupational hazard of intermittent low dose exposure to tocilizumab is not known. Not classified as a skin or eye irritant. May result in mild irritation. The occupational hazard of intermittent low dose exposure to tocilizumab is not known. Not classified as a skin or eye irritant. May result in mild irritation. Moderate Moderate Moderate Moderate Moderate Eye and face protection: wear aust-proof goggles Wear appropriate personal protective equipments. Smoking, eating and drinking should be prohibited in the application area. Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.	Panitumumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to panitumumab is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified	any incompatibilities Store in accordance with the datasheets recommendations. Keep away from food and drink. Use appropriate containment to avoid environmental contamination. Proper storage temperature is indicated on original container and in the product datasheet. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Useadequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment
If using pre-filled syringe	Tocilizumab	Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate	low dose exposure to tocilizumab is not known. Not classified as a skin or eye	Moderate	Respiratory protection: wear a N95/P2 mask Eye and face protection: wear dust-proof goggles Hand protection: wear butyl or nitrile or neoprene or rubber or latex gloves Body protection: no PPE specified Respiratory protection: wear a N95/P2 mask	thoroughly after each use. Store in a well ventilated area. Advice on safe handling: Wear appropriate personal protective equipments. Smoking, eating and drinking should be prohibited in the application area. Conditions for safe storage: Electrical installations / working materials must comply with the technological safety

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				or pen no Preparation	
				Handling required.	
Trastuzumab emtansine	Dermal – likely/high	Cytotoxic drug. If used therapeutically	High	Use cytotoxic precautions	Advice on safe handling Do not
	Oral – unlikely/high	under controlled clinical conditions, the			breathe vapors/dust. Smoking, eating
	Inhalation – possible/high	potential for adverse health effects is			and drinking should be prohibited in
	Mucosal – unlikely/high	minimised. Adverse health effects via			the application area. Dispose of rinse
	, ,	occupational exposure are not			water in accordance with local and
		anticipated, however, should over			national regulations.
		exposure occur, possible effects may be			8
		-			Conditions for safe storage: Protected
		hair loss, bone marrow damage and			from heat and light Keep container
		allergic skin reactions. Refer to medical			tightly closed in a dry and well-
		doctor/specialist for advice regarding			ventilated place. Electrical
		adverse side effects.			installations / working materials must
					_
					comply with the technological safety
7 0: 1	D 1 17 1 /			T 10	standards.
Infliximab	Dermal – likely/none	The occupational hazard of intermittent	Moderate	Eye and face protection:	Advice on safe handling:
	Oral – unlikely/low	low dose exposure to infliximab is not		wear dust-proof goggles	Do not breathe dust. Handle in
	Inhalation – possible/moderate	known. Skin contact may result in		Hand protection: wear	accordance with good industrial
	(preparation), unlikely/moderate	irritation, rash and dermatitis. Eye		PVC or rubber gloves	hygiene and safety practice, based on
	(administration)	contact may result in irritation,		Body protection: when	the results of the workplace exposure
	Mucosal – possible/moderate	lacrimation and redness. May cause an		using large quantities or	assessment Minimize dust generation
	(preparation), unlikely/moderate	allergic skin reaction.		where heavy	and accumulation. Keep container
	(administration)			contamination is likely,	closed when not in use. Keep away
				wear coveralls	from heat and sources of ignition.
				Respiratory protection:	Take precautionary measures against
				wear a N95/P2 mask	static discharges. Take care to prevent
					spills, waste and minimize release to
					the environment.
					Conditions for safe storage : Keep in
					properly labelled containers. Store in
					property labelled containers. Store in
					accordance with the particular national

					regulations.
Eculizumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to eculizumab is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear nitrile or latex gloves Body protection: no PPE specified Respiratory protection: wear a N95/P2 mask	Precautions for safe handling: Handling advice: Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid prolonged or repeated exposure. Remove contaminated clothing and wash before reuse. Wash thoroughly after handling. Conditions for safe storage, including any incompatibilities Storage temperature: store at <-15°C Storage Requirements: Warm to Room Temperature before use. Keep away from incompatible substances. Keep container tightly closed when not in use.
Etanercept	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal -unlikely/moderate	The occupational hazard of intermittent low dose exposure to Etanercept is not known. May cause mechanical eye irritation	Moderate	Eye and face protection: wear safety glasses Hand Protection: Wear nitrile or latex gloves. Wear protective garment. Respiratory protection: wear a N95/P2 mask	Handling: Wear personal protection equipments. Handle in accordance with good industrial hygiene and safety practice. Skin should be washe after contact. Avoid formation of dus and aerosols. Storage: No special safety precaution required. Keep container tightly closed.
Ziv-aflibercept	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal -unlikely/none	Available as pre-filled syringe and vials. Occupation exposure unlikely.	Low	No Preparation Handling required.	Precautions for Safe Handling: Product should be used in a controlle work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable

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Rituximab Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration) The occupational hazard of intermittent low dose exposure to rituximab is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: wear a laboratory coat Respiratory protection: wear a N95/P2 mask	absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling. Conditions for Safe Storage Store vials in a refrigerator at 2 to 8°C (36 to 46°F). Keep the vials in the original outer carton to protect from light. Avoid breathing vapor or mist. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls

Ramucirumab De	ermal – likely/none	The occupational hazard of intermittent	N/L-1	T 1.0	
	ermai – nkery/none	*	Moderate	Eye and face protection:	Precautions for safe handling:
Or	ral – unlikely/low	low dose exposure to ramucirumab is not		wear splash-proof	Use all reagents in accordance with
	halation – unlikely/moderate	known. Not classified as a skin or eye		goggles	the relevant package insert provided
	[ucosal – possible/moderate	irritant. May result in mild irritation.			with the product.
	reparation), unlikely/moderate			Hand protection: wear	with the product.
	dministration)			rubber or latex gloves	Do not smoke, eat, drink or apply
					cosmetics in areas where kit reagents
				Body protection: no PPE	are handled.
				specified	W
					Wear disposable latex gloves when handling reagents.
				Respiratory protection:	nanding reagents.
				wear a N95/P2 mask	Never pipet by mouth and avoid
					contact of reagents and specimens
					with skin and mucous membranes.
					Handling should be done in
					accordance with the procedures
					defined by an appropriate national
					biohazard safety guideline or
					regulation.
					Use all reagents in accordance with
					the relevant package insert provided
					with the product.
					Conditions for safe storage, including
					any incompatibilities
					Store in tightly closed original
					packages or appropriately labelled
					alternate vessels. Store in dry, bunded
					areas. Keep away from direct sunlight
					and heat sources. Recommended
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					storage temperature: 10-30°C
					(shipment), 2-8°C (long term storage).
					Protect from freezing. Keep away
					from food and drinks. Keep away
					from acids and heavy metals. Keep out
					of the reach of children.
Raxibacumab	Dermal – likely/none	Available as pre-filled syringe and vials.	Low	Eye and face protection:	Precautions for safe handling: Avoid
	Oral – unlikely/low	Occupation exposure unlikely.		Safety goggles with side-	inhalation, contact with eyes and skin.
	Inhalation – unlikely/moderate	c coupuiten emperato animionj.		shields.	Avoid dust and aerosol formation. Use
	Mucosal -unlikely/moderate				only in areas with appropriate exhaust
	Wideosai annikery/moderate			Hand protection:	ventilation.
				Protective gloves.	
					Conditions for safe storage, including
				Respiratory protection:	any incompatibilities Keep container
				wear a N95/P2 mask	tightly sealed in cool, well-ventilated
					area. Keep away from direct sunlight
					and sources of ignition.
Sarilumab	Dermal – likely/none	Available as pre-filled syringe and vials.	Low	Eye protection: Safety	Precautions for safe handling: Avoid
	Oral – unlikely/low	Occupation exposure unlikely.		goggles with side-	inhalation, contact with eyes and skin.
	Inhalation – unlikely/moderate	c coupuiten emperato animiony.		shields.	Avoid dust and aerosol formation. Use
	Mucosal -unlikely/moderate				only in areas with appropriate exhaust
				Hand protection:	ventilation.
				Protective gloves.	
					Conditions for safe storage, including
				Skin and body	any incompatibilities Keep container
				protection: Impervious	tightly sealed in cool, well-ventilated
				clothing	area. Keep away from direct sunlight
					and sources of ignition
Inotuzumab ozogamicin	Dermal – likely/moderate	May cause eye and skin irritation, as	Moderate	Eye protection: Wear	Avoid breathing dust. Avoid contact
	Oral – unlikely/moderate	with any protein, the possibility of		safety glasses as	with eyes, skin and clothing. When
	Inhalation – likely/moderate	allergic reactions exists.		minimum protection	handling, use appropriate personal
	Mucosal – possible/moderate			(goggles recommended)	protective equipment (see Section 8).
	(preparation), unlikely/moderate				Wash thoroughly after handling.

	Hand protection: Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.) Skin protection: Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.) Respiratory protection: wear a N95/P2 mask	Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls
Moderate	Eye protection: Wear safety glasses as minimum protection (goggles recommended) Hand Protection: Wear	Put on appropriate personal protective equipment. Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty
	Moderate	gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.) Skin protection: Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.) Respiratory protection: wear a N95/P2 mask Moderate Eye protection: Wear safety glasses as minimum protection (goggles recommended)

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		May be harmful if inhaled and		nitrile or latex gloves.	containers retain product residue and
		swallowed.		Wear protective garment.	can be hazardous.
				Respiratory protection:	Conditions for safe storage, including
				wear a N95/P2 mask	any incompatibilities Store in
					accordance with the datasheets
					recommendations. Keep away from
					food and drink. Use appropriate
					containment to avoid environmental
					contamination. Proper storage
					1
					temperature is indicated on original
**					container and in the product datasheet.
Abatacept	Dermal – likely/none	Available as pre-filled syringe and vials.	Low	Eye protection: Wear	Precautions for safe handling; Avoid
	Oral – unlikely/none	Occupation exposure unlikely		safety glasses as	inhalation, contact with eyes and skin.
	Inhalation – unlikely/moderate			minimum protection	Avoid dust and aerosol formation. Use
	Mucosal -unlikely/low			(goggles recommended)	only in areas with appropriate exhaust
					ventilation.
				Hand Protection: Wear	
					Conditions for safe storage, including
				nitrile or latex gloves.	any incompatibilities Keep container
				Wear protective garment.	tightly sealed in cool, well-ventilated
					area. Keep away from direct sunlight
				Respiratory protection:	and sources of ignition
				wear a N95/P2 mask	-
Abciximab	Dermal – unlikely/none	Available as pre-filled syringe and vials.	Low	Eye protection: Safety	Precautions for safe handling;
	Oral – unlikely/none	Occupation exposure unlikely		goggles with side-shields	Avoid inhalation, contact with eyes
	Inhalation – unlikely/moderate				and skin. Avoid dust and aerosol
	Mucosal -unlikely/low				formation. Use only in areas with
				Hand protection:	appropriate exhaust ventilation.
				Protective gloves.	
					Conditions for safe storage,
					Keep container tightly sealed in cool,
				Skin and body	well-ventilated area. Keep away from
		1			··

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				protection: Impervious clothing. Respiratory protection: Suitable respirator.	direct sunlight and sources of ignition. Recommended storage temperature: Please store the product under the recommended conditions in the Certificate of Analysis.
Alemtuzumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to alemtuzumab is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Moderate	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves Body protection: no PPE specified Respiratory protection: no PPE specified	WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing mists or sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately. STORAGE AND HANDLING PRACTICES: Store product in properly labelled, closed containers at temperatures between 2-8°C. Protect from physical damage. Keep containers closed when not in use.
Alirocumab	Dermal – unlikely/none Oral – unlikely/none Inhalation – unlikely/moderate Mucosal -unlikely/low	The occupational hazard of intermittent low dose exposure to Alirocumab is not known. Not classified as a skin or eye irritant. May result in mild irritation.	Low	Eye and face protection: wear splash-proof goggles Hand protection: wear rubber or latex gloves	Precautions for safe handling Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

				Body protection: Impervious clothing Respiratory protection: suitable respirator.	Conditions for safe storage, including any incompatibilities Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition. Recommended storage.
Cetuximab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to cetuximab is not known. Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness. Cetuximab may cause sensitisation by inhalation.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: wear a N95/P2 mask	Precautions for safe handling Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation. Conditions for safe storage, Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition. Recommended storage temperature: -80°C for long term.
Pertuzumab	Dermal – likely/none Oral – unlikely/low Inhalation – unlikely/moderate Mucosal – possible/moderate (preparation), unlikely/moderate (administration)	The occupational hazard of intermittent low dose exposure to pertuzumab is not known. Skin contact may result in irritation, redness, pain and rash. Eye contact may result in irritation, lacrimation, pain and redness.	Moderate	Eye and face protection: wear safety glasses Hand protection: wear PVC or rubber gloves Body protection: when using large quantities or where heavy contamination is likely, wear coveralls Respiratory protection: wear a N95/P2 mask	Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

-					
Somatropin	Dermal – likely/low	Available as pre-filled syringe and vials.	Moderate	Eye and face protection:	Minimize dust generation and
	Oral – unlikely/low	May cause sensitization by skin contact.		wear splash-proof	accumulation. Avoid breathing dust.
	Inhalation – unlikely/moderate	Harmful if swallowed.		goggles	Avoid contact with eyes, skin and
	_				clothing. When handling, use
	Mucosal – possible/moderate			Hand protection: wear	appropriate personal protective
	(preparation), unlikely/moderate			rubber or latex gloves	equipment. Wash thoroughly after
	(administration)				handling. Releases to the environment
				Body protection:	should be avoided. Review and
				Impervious clothing	implement appropriate technical and
					procedural waste water and waste
				Respiratory protection:	disposal measures to prevent
				suitable respirator.	occupational exposure or
					environmental releases. Potential
					points of process emissions of this
					material to the atmosphere should be
					controlled with dust collectors, HEPA
					filtration systems or other equivalent
					controls.
					controls.

6.5. HAZARDOUS CHEMICALS STORED AND THEIR HAZARDS, RISKS AND MITIGATION MEASURE MATRIX

TABLE 11: hazardous chemicals stored and their hazards, risks and mitigation measure matrix

S.NO	CHEMICALS		A HAZA SSIFICA F		QUANTITY STORED (Kgs per annum)	HANDLING	HAZARDS	RISKS	MITIGATION MEASURES
1.	Acetic acid	3	2	0	Corrosives area. Keep away from heat, sparks and flame. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong oxidizing agents.	Do not get in eyes, on skin, or on clothing. Wear personal protective equipment/face protection. Use only under a chemical fume hood. Do not breathe mist/vapor/spray. Do not ingest. If swallowed, then seek immediate medical assistance.	Corrosive Nature: Concentrated acetic acid is highly corrosive to skin, eyes, and mucous membranes upon contact. It can cause severe burns and irritation. Flammability: Acetic acid is flammable, and its vapours can form explosive mixtures with air. Reactivity: It may react violently with incompatible substances such as strong bases, oxidizing agents, and certain metals, releasing hazardous gases or causing fires.	Exposure Risks: Workers handling acetic acid may face risks of skin burns, eye damage, and respiratory irritation if proper safety precautions are not observed. Fire and Explosion Risks: Improper storage or handling of acetic acid can lead to fires or explosions, especially in confined spaces or areas with inadequate ventilation. Environmental Risks: Spills or leaks of acetic acid	Engineering Controls: Use ventilation systems to control vapor concentrations and prevent the build-up of flammable or hazardous atmospheres. Segregate acetic acid storage areas from incompatible substances. Safe Handling Procedures: Train personnel on safe handling practices, including proper storage, transfer, and use of acetic acid. Implement spill containment measures and emergency response protocols. Storage Requirements: Store acetic acid in compatible containers made of materials such as polyethylene, polypropylene, or stainless steel. Keep containers

can contaminate soil, water bodies, and air, posing risks to the environment and wildlife and sources of ignition. And sou	Proposed Manufacturing of Monoclonal Antibodies a	nd Formulation Facility	H/01/2024/CON/065-R0 Risk asses	sment report	
Regulatory Compliance: Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation of ethanol, such as PESO,				soil, water bodies, and air, posing risks to the environment	from heat, direct sunlight, and sources of ignition. Emergency Preparedness: Maintain spill kits, eyewash stations, and safety showers in areas where acetic acid is handled. Conduct regular safety inspections and drills to ensure readiness for emergencies. Chemical Compatibility: Clearly label containers and storage areas to indicate the presence of acetic acid and its hazards. Ensure compatibility with other chemicals stored nearby to prevent accidental reactions. Personal Protective Equipment (PPE): Provide workers with appropriate PPE such as gloves, goggles, and protective clothing to minimize direct contact with acetic acid. Regulatory Compliance: Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation

								MSIHC Rule 1989, OSHA's Process Safety Management Standard and EPA guidelines etc.
2. Ethonal	0	3	0	Keep away from heat, sparks, and flame. Keep away from sources of ignition. Store in a tightly closed container. Keep from contact with oxidizing materials. Store in a cool, dry, well-ventilated area away from incompatible substances. Flammables-area. Do not store near perchlorates, peroxides, chromic acid or nitric acid	Wash thoroughly after handling. Use only in a well-ventilated area. Ground and bond containers when transferring material. Use spark-proof tools and explosion proof equipment. Avoid contact with eyes, skin, and clothing. Empty containers retain product residue, (liquid and/or vapor), and can be dangerous. Keep container tightly closed. Keep away from heat, sparks and flame. Avoid ingestion and inhalation. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose empty containers to heat, sparks or open flames.	Flammability: Ethyl alcohol is highly flammable and can form explosive vapor-air mixtures at concentrations above its lower explosive limit (LEL), posing fire and explosion hazards. Health Effects: Inhalation or ingestion of ethanol vapors or liquid can cause central nervous system depression, dizziness, headaches, and nausea. Prolonged or high-level exposure may lead to respiratory depression, unconsciousness, and even death. Skin and Eye Irritation: Contact with ethanol can cause irritation to the skin and eyes. Prolonged or repeated exposure may lead to dermatitis or eye damage.	Exposure Risks: Workers handling ethanol may face risks of inhalation exposure, skin contact, or ingestion if proper safety precautions are not observed. Acute exposure can cause irritation or intoxication, while chronic exposure may lead to health effects. Fire and Explosion Risks: Improper handling or storage of ethanol can lead to fires or explosions, especially in the presence of ignition sources, heat, or oxidizing agents.	Engineering Controls: Implement ventilation systems to control vapor concentrations and preve the build-up of explosive atmospheres. Use explosion-proof equipme and electrical systems in areas where ethanol is handled or stored. Safe Handling Procedu Train personnel on safe handling practices, including proper storage, transfer, and use of ethan Establish designated stor areas with clear signage, access restrictions, and s containment measures. Storage Requirements: Store ethanol in tightly sealed containers or tank made of non-reactive materials such as steel or glass. Keep storage areas well-ventilated, cool, and away from sources of ignition, heat, or incompatible substances.

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			Chemical Compatibility: Segregate ethanol from incompatible substances such as oxidizing agents, strong acids, and alkalis to prevent accidental reactions or releases. Emergency Response: Develop and implement emergency response plans for spills, leaks, or releases of ethanol. Provide training to employees on emergency procedures, evacuation routes, and first aid measures. Personal Protective Equipment (PPE): Provide workers with appropriate PPE such as respirators, gloves, goggles, and protective clothing to minimize direct contact and inhalation exposure to ethanol. Regulatory Compliance:
			Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation of ethanol, such as PESO, MSIHC Rule 1989, OSHA's Process Safety

Propos	sed Manufactu	ring of N	Ionoclo	nal Ant	ibodies and Formulation Fac	ility H/01/202	24/CON/065-R0 Risk asses	Exposure Risks:	Management Standard and EPA guidelines etc. Engineering Controls:
3.	hydroxide				container. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep away from metals. Corrosives area. Keep away from acids. Store protected from moisture. Containers must be tightly closed to prevent the conversion of NaOH to sodium carbonate by the CO2 in air.	handling. Do not allow water to get into the container because of violent reaction. Minimize dust generation and accumulation. Do not get in eyes, on skin, or on clothing. Keep container tightly closed. Avoid ingestion and inhalation. Discard contaminated shoes. Use only with adequate ventilation.	hydroxide is highly corrosive to skin, eyes, and mucous membranes upon contact. It can cause severe burns, tissue damage, and eye injury. Reactivity: NaOH reacts exothermically with water, acids, and certain metals, releasing heat and hydrogen gas. It may also react violently with organic materials, leading to combustion or fire. Toxicity: Ingestion or inhalation of sodium hydroxide dust or mist can cause irritation to the respiratory system, gastrointestinal tract, and lungs. Prolonged exposure may lead to	Workers handling sodium hydroxide may face risks of skin contact, inhalation exposure, or ingestion if proper safety precautions are not observed. Acute exposure can cause burns and irritation, while chronic exposure may lead to more severe health effects. Fire and Explosion Risks: NaOH is not flammable on its own, but it can react with combustible materials, releasing heat and potentially causing fires or	Implement ventilation systems to control vapor concentrations and prevent the build-up of explosive atmospheres. Use explosion-proof equipment and electrical systems in areas where ethanol is handled or stored. Safe Handling Procedures: Train personnel on safe handling practices, including proper storage, transfer, and use of ethanol. Establish designated storage areas with clear signage, access restrictions, and spill containment measures. Storage Requirements: Store ethanol in tightly sealed containers or tanks made of non-reactive

sealed containers or tanks made of non-reactive materials such as steel or glass. Keep storage areas well-ventilated, cool, and away from sources of ignition, heat, or

explosions.

more severe health

effects.

Chemical Compatibility: Segregate ethanol from

incompatible substances.

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			incompatible substances such as oxidizing agents, strong acids, and alkalis to prevent accidental reactions or releases. Emergency Response: Develop and implement
			emergency response plans for spills, leaks, or releases of ethanol. Provide training to employees on emergency procedures, evacuation routes, and first aid measures.
			Personal Protective Equipment (PPE): Provide workers with appropriate PPE such as respirators, gloves, goggles, and protective clothing to minimize direct contact and inhalation exposure to ethanol.
			Regulatory Compliance: Adhere to relevant National and International regulations and guidelines governing the storage, handling, and transportation of ethanol, such as PESO, MSIHC Rule 1989, OSHA's Process Safety Management Standard and
		,	

									EPA guidelines etc.
4.	acid	3	0	0	Keep containers tightly closed in a dry, cool and well-ventilated place. Corrosives area. Incompatible Materials. Metals. Strong oxidizing agents. Bases. Sodium hypochlorite. Amines. Fluorine. Cyanides. Alkaline.	Wear personal protective equipment/face protection. Do not breathe mist/vapors/ spray. Do not get in eyes, on skin, or on clothing. Do not ingest. If swallowed, then seek immediate medical assistance.	Corrosivity: Corrosive material. Causes burns by all exposure routes. Thermal decomposition can lead to release of irritating gases and vapors. Use only outdoors or in a well-ventilated area Keep only in original container. Toxicity: Hydrochloric acid are toxic if ingested, inhaled, or absorbed through the skin. Causes severe skin burns, eye damage and respiratory irritation	Exposure Risks: Causes burns by all exposure routes. Workers handling acetic acid may face risks of skin burns, eye damage, and respiratory irritation if proper safety precautions are not observed.	Engineering Controls: Measures Ensure that eyewash stations and safety showers are close to the workstation location. Safe Handling Procedures: Train personnel on safe handling practices, including proper storage, transfer, and use of benzene. Establish designated storage areas with clear signage, access restrictions, and spill containment measures. Storage Requirements: Keep containers tightly closed in a dry, cool and well-ventilated place. Corrosives area. Incompatible Materials. Metals. Strong oxidizing agents. Bases. Sodium hypochlorite. Amines. Fluorine. Cyanides. Alkaline.
	H. Haalth								

H: Health

F: Fire

R: Reactivity

7. DISASTER MANAGEMENT PLAN

7.1. OBJECTIVES

- > To establish a method of systematic, safe and orderly evacuation in the least possible time, to a safe area or by the nearest safe means of way out.
- > Control the accidents.
- Rapid control and containment of hazardous situation.
- > Rescue and treatment of casualties.
- Safeguard people (both at site and neighborhood).
- Minimize damage to property and environment.
- ➤ Identify casualties, notify their relatives and render necessary help to them.
- > Proper training of the concerned person.
- > Prevent recurrence.
- ➤ Be capable of dealing with largest incident that can reasonably be foreseen.
- ➤ Have sufficient flexibility with a view to handling the emergency efficiently and avoiding unnecessary calling external agencies like fire brigade services.

7.2. BASIC FORMS OF EMERGENCY

- > Fire
- Explosions
- > Toxic release
- Natural disaster (earth quake, flooding, tsunami etc.)

7.3. ACTION PLAN TO VARIOUS EMERGENCIES

> FIRE

In case of any fire incident the following steps are to be followed by the site occupants:

- ➤ Be concerned about your own safety as well as that of others.
- ➤ Inform others by verbal signal: "FIRE, FIRE, FIRE".
- ➤ If the fire is controllable by nearby fire extinguishing equipment and you know firefighting, control the fire without undue personal risk.
- > Shut off the electrical supply quickly.
- ➤ Use fire hydrant system point located nearer to the affected area.

- ➤ If you can't extinguish it alone, activate the fire alarm/MCP and get help.
- ➤ Inform to Safety and security team-nearest helpdesk
- Inform to manager and site controller
- Make certain you know your escape route and assembly point/safe place.
- Do not panic.
- ➤ People not involved in firefighting operation directly, should quickly move through emergency exit routes & assemble at nearest emergency assembly point/safe place.
- ➤ For any other assistance Call emergency number.

> Toxic release:

- Cover your nose with wet hand kerchief/ cloth and breathe through it.
- Come out in open, check the wind direction and move away quickly in perpendicular direction of wind. (cross wind direction).
- Immediately try to get to a higher elevation, if gas is heavier than air (like chlorine, as it settles in low lying area).
- Follow the instruction and reach safe shelter as instructed notified by Government Authority or Public authority.

> NATURAL CALAMITIES

In case any natural disaster like earthquake the following procedure should be followed by the occupants:

a) When earthquake is felt:

- ➤ Take a safe position (e.g. Under the table, concrete wooden beam, concrete column, door bracket)
- > Do not use lift. Do not stand near doors, gate
- ➤ If you are driving, or on road, go to open space
- > Keep away from walls, building, and electric pole/wires.
- > Keep away from building, sheds, electric wires
- ➤ Keep cool & keep others cool.

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b) After the earthquake:

- There can be more such jerks immediately hence go to open space.
- ➤ Close connections of LPG, Electricity, water.
- ➤ Do not smoke, ignite matchstick, or put on main switches.
- > Do not touch electric wires.
- > Drink clean water.
- > Do not go near partially collapsed buildings.
- > Keep roads clear for traffic.

c) In case of flood:

- ➤ Be ready to evacuate as directed by the Emergency Coordinator.
- ➤ Follow the recommended primary or secondary evacuation routes.
- > Climb to high ground and stay there.
- Avoid walking or driving through flood water.
- > Avoid walking or driving through flood water.
- > For further help, contact emergency.

d) Post cyclone measures:

- You should remain in the shelter until informed that you can return to your home.
- ➤ You must get inoculated against diseases immediately.
- > Strictly avoid any loose and dangling wires from lamp posts.
- ➤ If you have to drive, do drive carefully.
- ➤ Clear debris from your premises immediately.
- > Report the correct losses to appropriate authorities

> STRUCTURAL COLLAPSE

- > Raising the emergency signal.
- Evacuate the site immediately and assemble at Assembly point/safe place
- ➤ Isolate & Barricade if necessary.
- ➤ Head count to be taken by the security or emergency response team.
- Rescue Operation to be carried out in case of missing personals.
- Hospitalize the victims in case of injury.

> MEDICAL EMERGENCY

- ➤ Provide information to Emergency Response Team immediately.
- > Provide the necessary first aid treatment.
- ➤ In case of critical emergency, move injured person to hospital
- Local legal requirement to be carried out.
- ➤ Information to be given to branch manager.

7.4. TYPES OF EMERGENCY

> ON-SITE EMERGENCY

An accident/ incident that take place in a factory, with effects being confined to the factory premises, involving only the persons working in the factory and the property inside the factory is called On-site Emergency. It can further be classified as minor and major emergency based on severity of the incident.

> MINOR EMERGENCY (EVACUATION IS NOT REQUIRED)

In the case of minor emergency there is no need for an evacuation siren and the respective department personnel will handle the same with assistance of Safety Squad.

> MAJOR EMERGENCY (EVACUATION IS REQUIRED)

In case of major emergency, there must be an emergency siren and situation is tackled as per the plan.

> OFF-SITE EMERGENCY

If the accident is such that it affects inside the factory uncontrolled and it may spread outside the factory premises, it is called as Off-site Emergency.

Assessment reveals that an Off-site emergency is a very remote possibility in the factory. If situation dictates, local police may be availed to warn and advice the local public on mitigation in an emergency situation.

7.5. ON SITE EMERGENCY PLAN IN PLACE WITH SITE LIMITED

7.5.1. PURPOSE

The main purpose of preparing "On-Site Emergency plan" is to define responsibility for individuals and teams to control and mitigate emergency situation in a systematic way without affecting adjacent building, neighbouring industry and public of the surrounding vicinity.

7.5.2. EMERGENCY ORGANIZATION

The effective control of emergency situations depends upon the way in which theindividual and team acting during emergency in an appropriate time. So this is very essential to identify key individual and teams for fixing specific responsibility as part of emergency organization to avoid confusion.

The following are the important key persons and team identified as part of emergency organization.

- Emergency Identifier.
- Incident controller
- Chief controller.
- Works Controller.
- Liaison Team.
- Fire and Safety Team.
- First aid Team.
- Environmental Team.
- Internal communication Team.
- Task force team.

7.5.3. INDIVIDUAL AND TEAMS ROLES AND RESPONSIBILITIES

The following are the individual and team responsibility of emergency organization. M\S Omexa formulary Pvt Ltd. may assign the following roles to their responsible employees as applicable. Some suggested responsibility bearers may be Plant Manager, Head-MAINTENANCE, Head-QC, Head-E&I, Head-OPERATION, Head-HSE, etc.

INCIDENT IDENTIFIER

The person who is noticing an incident is called "Incident Identifier". After noticing the incident he has to take the following action immediately.

In case of major incident, to inform the shift in charge about the incident. While informing, he has to tell his,

Name : ------Location : ------

And nature of Incidents like Fire, Solvent leakage and Gas leak, etc.

Shout about the Incident like "Fire! Fire or "Leak! Leak" to gather people for help.

Shift in charge /manager

After receiving the information from Incident Identifier, the following are the action to be taken by Shift in Charge or Manager of the particular location:

- 1. Assess the situation and inform the Works controller.
- 2. Try to evacuate the people in that area including contract workers.
- 3. Act as the incident controller till works controller reaches the spot.
- 4. After handing over the charge to works controller, he should take the lead of controlling the situation with the available resource.

Note: In the absence of shift in charge the next responsible person should act as shift in charge.

Chief Controller

The following are the roles and responsibility of Chief controller during an emergency:

- 1. After receiving the communication about the emergency he should reach the emergency control centre and take the control actions to control the overall incident.
- 2. Keep communicating to works controller about the action to be taken to control the emergency either directly or through internal communication team.
- 3. Send the required team to the emergency site to attend the emergency as per the requirement of works controller.

- 4. Inform external agencies like fire brigade, ambulance or other vehicles through coordinator for liaison team.
- 5. Arranging additional protective equipment through mutual help scheme through liaison coordinator.
- 6. Instruct security department to close the gate and stop loading and unloading activities inside the plant and move the vehicles to safe location.
- 7. Keep inform higher authorities either through liaison coordinator or by himself. Keep inform to kith and skin of the affected victims through liaison coordinator.
- 8. Keep inform all the necessary statutory authorities through liaison coordinator.
- 9. Keep inform to respective hospitals for arranging treatment for victims through liaison coordinator.
- 10. Instruct liaison coordinator to receive press and media and keep them in conference hall.

Works controller

After receiving the communication from incident controller and ensuring the incident to be a major one, he has to report to the chief controller about the incident and ask him todeclare an emergency.

- 1. Arrange for the evacuation of the people.
- 2. Instruct shift in charges of respective plant and adjacent plant to stop theoperation if needed.
- 3. Instruct electrical department to isolate the power.
- 4. Guiding the people to control and content incident.
- 5. Directing the team leader to take action according to their responsibility.
- 6. Communicating various actions taken to control the incident to Chief controller either directly by phone or through internal communication coordinator.
- 7. Informing to Chief controller about the external help as per mutual agreement.
- 8. Informing to Chief controller about help of external fire brigades.
- 9. Instruct environmental team to contain the effluent water without gettingmixed with storm water gutter.
- 10. Instruct safety and firefighting team to use right type of extinguishers and use hydrant system for fighting fire.
- 11. Instruct safety and firefighting team to supply sufficient numbers of personal

protective equipment to meet the emergency.

Liaison Team

Immediately after receiving the communication about emergency, he should reach the emergency control centre and act as follows:

- 1. Carefully receive the instruction from Chief controller and act accordingly.
- 2. Instruct security to regularize the manpower at the assembling point.
- 3. Instruct security to close the gate and restrict unwanted movement.
- 4. Inform kith and skin of the affected victim as per the instruction of Chief controller.
- 5. Receive representative from Press and Media and ask them to stay in conference hall and inform to chief controller.
- 6. Inform all the statutory authorities as per the instruction from Chief controller.
- 7. Arrange additional transport including ambulance as per the instruction of Chief Controller.
- 8. Arranging food and other facilities for emergency team members and others.
- 9. Keep informed hospital authorities for necessary arrangements for treating the victims.
- 10. Make way for moving ambulance.
- 11. Instruct security guards to move lorry/ tankers to safe location.
- 12. Instruct security guards to evacuate contractor workers available inside theplant to assembling Point I or II depending upon the wind direction.
- 13. Receive statutory authorities and inform to chief controller.

Fire and Safety Team

After receiving the communication about the emergency, he should reach the Emergency control centre along with Fire Squad and Fire Guards and report to the chief controller and act as follows:

- 1. Try to extinguish the fire using suitable type of fire extinguishers or fire hydrant system or foam (AFFF) depending upon the material involved.
- 2. Instruct fire guard to barricade the area.
- 3. Ensure supply of necessary personal protective equipment and inform works controller to get additional equipment as per the mutual scheme.
- 4. In case of leakage of chemicals, instruct people to contain the leakage by provide

barricade using sand without mixing into storm water gutter by using necessary personal protective equipment.

- 5. Helping first aid team to shift the victims.
- 6. Instruct one of the fire squad to ensure fire water pump is running.
- 7. Inform different action taken to control the emergency to works controller.
- 8. Note: In the absence of Head safety, the person next to him will act as the coordinator.

First Aid Team

After receiving the communication about the emergency, he should reach the Emergency control centre along with first aid team and report to the Chief controller and act as follows:

- 1. Organize the first aid team and arrange first aid treatment to the affected persons.
- 2. To arrange for immediate medical attention.
- 3. After getting head count details search for missing person.
- 4. Coordinate with Liaison coordinator for transporting the victims to the hospital.
- 5. To arrange for required medicines.

Environment Team

After receiving information about the emergency, he should reach the spot of emergency along with his team and report to chief controller and take the following action.

- 1. Contain the effluent generated during emergency and divert it to ETP without getting mixing up with storm water.
- 2. Monitor the surrounding area and inform to works controller in case of any deviation.
- 3. Mobilize suitable neutralizing agent through raw material stores.
- 4. Ensure ETP collection tank is empty.

Note: In the absence of Head environment, the person next to him will act as the coordinator.

Internal communication team

After receiving the communication about the emergency, he should reach the spot of emergency and report to Incident controller and act as follows:

- 1. Communicate the information given by Chief controller then and there to works controller by nearby intercom or by person and vice a versa.
- 2. Make all the necessary arrangements for communication system in case of failure of any system Note: In the absence of Head Instrumentation, the person next to him will act as the internal communication team coordinator.

Task Force Team

After receiving the communication about the emergency, he should reach the spot of emergency and report to Incident controller and act as follows:

- 1. Ensure evacuation of peoples and inform to Works controller.
- 2. Inform chief controller about the stoppage of loading and unloading of lorry tanker and safe parking the same.
- 3. Helping other teams like First aid and Liaison for arranging infrastructure forshifting victims.
- 4. Arranging critical equipment as per the instruction of chief/works controller.
- 5. Use appropriate personal protective equipment and arrange for transferring of chemicals either into spare tank or suitable container.
- 6. Action to be taken for arranging sufficient number of barrels for transferring of chemicals. Use appropriate personal protective equipment and arrests the leak.
- 7. Communicating works/chief controller about the additional facility needed forcontrolling either Toxic chemical leak or Gas leak.
- 8. Cut off the power as per the instruction of works Controller.
- 9. Ensure running condition of the DG.

Note: In the absence of Head Maintenance, the person next to him will act ascoordinator.

7.5.4. EMERGENCY COMMUNICATION FACILITY

The effective communication is must to alert both people and emergency action teams to take action in controlling emergency in a stipulated time.

The following are the communication system, limited to communicating emergency situation, may be considered:

• Siren System for common evacuation.

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- Siren system for Toxic release.
- Public Announcement System.
- Local alarm for fire.
- Megaphone
- Walkie Talkie

Siren System

The following are the two different types of siren used for communicating emergency.

> Wailing siren.

Wailing siren is used for declaring emergency. This is the type of siren having high and low frequency for the duration of 90 seconds.

> Continuous siren.

This is the type of siren used for declaring all clear about the emergency. This is the continuous siren of high frequency for a period of 90 seconds.

> "Beep" sound for Toxic gas release.

Public Announcement system

The Public Announcement System via megaphone, etc., is provided for the effective communication about the Nature of emergency and its location so as to mobilize the individuals and action team to take timely action to control emergency without damaging men, property and environment.

This system is also used for communicating to the general public in the surroundings, about the emergency and various actions taken to control.

Declaration of Emergency

Both emergency siren and announcement will be operated from emergency control centre.

After receiving the information about emergency, the Security who is available inemergency control centre will note down,

- 1. Name of the person intimated about emergency.
- 2. Nature of Incident.
- 3. Location.

After getting the instruction from chief controller, he actuates the wiling Siren for

around 90 Seconds followed by Announcement given by using public announcement system and inform about the Nature of emergency and location.

Declaration of All clear

After controlling an emergency, based on the environment team report, works controller will inform Chief controller to declare all clear siren to allow people to resume their jobs. Based on the report from both works controller and Head count from HR, chief controller will instruct emergency control centre operator to declare "All Clear" using both siren and public announcement.

The security guard will actuate the "All Clear" siren of continuous high frequency for 90 Seconds and then inform through public announcement system stating" Emergency is cleared! All should resume their work".

7.5.5. OFFSITE EMERGENCY PLAN

7.5.5.1. PREAMBLE

An offsite emergency, arising out of chemical hazards is one which has potential to cause serious damage or loss of life beyond the plant boundary. In addition, Accidents during transportation of hazardous chemicals by road, rail, etc., can cause offsiteemergencies. Emergency services such as Police, Fire, Medical etc., need to be prepared to handle such situations promptly and effectively. It is mandatory under Rule 16 of the Hazardous Chemical Rules for District authorities to prepare an off-site emergency plan in respect of clusters of hazardous chemical industries or at locations where accidents are likely to have an off-site adverse effect. In order to be in a state of preparedness to respond to the accidents and minimize their adverse impacts on the offsite population, requires an offsite emergency plan to be prepared by the District Controller for every District or Industrial Areas as applicable.

7.5.5.2. OBJECTIVE

The objective of the present assignment is to prepare an area specific Offsite Emergency Action Plan for the district which can be practically implemented / activated at a short notice to ensure minimal impact on life and property due to emergencies arising out of Chemical

Accidents or during Transportation of Hazardous Chemicals in the district.

The plan should be regularly updated when there are changes occurring in the Industrial set up, Transportation Aspects, Key Manpower and Administrative Changes etc., Regular drills, Training of key persons, increasing safety awareness etc. is extremely important areas that must be looked into for sound preparedness.

7.5.5.3. OFFSITE EMERGENCY CONTROL

After the "Bhopal Gas Tragedy" (Methyl Isocyanides- MIC Poisonous and toxic gas release Accident at Union Carbide, 1984) the Government felt an immediate need to be more conscious about handling of Hazardous Chemicals. Central control room Centre or Offsite Industrial Emergency Control Room "OIECR" should be established by company. It should work under the Governing Council. The Governing Council should be headed under the chairmanship by District Collector & Magistrate.

The Governing Council Members are the permanent Ex. Officio Members to manage the affairs of the Emergency Control Room.

7.5.5.4. EMERGENCY INSTRUCTION TO THE GENERAL PUBLIC

The Notification of Emergency

The emergency can be declared by following media to alert or alarm the public;

- > Public address system
- Blow horns/Bells
- > Sirens / Hooters
- > Telephone message / Fax Messages / Hot lines/ Pager / E-mail / Mobile Phone / Satellite system.
- > Sending messages through a messenger.
- Rushing personally to the Central Control Room or to the nearest Police Department or Fire Department for declaration of emergency.
- Raising of Flag for denoting the level of natural calamities.
- > By any other source by which information can reach to the public in time

Risk assessment report

Category of Alarm Systems

The following alarm system may be considered which will identify the various levels of emergency.

First Level Warning (Fire Alarm)

- For an accident / incident within the unit.
- ➤ Siren Short, intermittent.

Second Level Warning

- When the District Authority receives information that a toxic or flammable gas has leaked then the siren has to be sounded in order to facilitate early evacuations from the unit.
- ➤ Siren A wailing short and long intermittent siren notification of emergency.

Third Level Warning (All Clear)

- ➤ When the District Authority considers that the accident / incident is undercontrol, emergency is withdrawing and it is safe for re-entry.
- ➤ Siren A wailing, long and continues, intermittent siren.

Fire Fighting System

In order to tackle great risk of fire explosion, spillage of hazardous liquid or releaseof toxic gases, firefighting system should be mobilized under chief fire officesr. The operational response will be coordinated from the Central Control Room.

General Instruction to the Public

A major emergency may affect areas outside the worksite. The surrounding public must be alerted with public address system by Police or Government Authorities or nearby industrial concerns. The siren must blow to indicate the emergency situation aroused.

The type of emergency aroused, must be communicated via telecommunication sources (Television, Radio, etc.). The public may accordingly take prompt action to protect themselves in their then location or rush to the safe shelters, as instructed by the authority.

Public action must be to investigate the type of emergency aroused.

- Fire
- Explosion
- Gas Leakage / Release

- Collapse of Building, Bursting of Vessel etc.
- Natural Calamities.

If gas leakage emergency aroused, ascertain probability of gas whether flammable, toxic or poisonous. The following actions are suggested as per prevailing situation: Otherwise follow the instruction as issued by the authority.

Flammable Gas:

- Be calm.
- Do not light Cigarette etc.
- Shut down open flame, gas and electrical instruments or any source of ignition.
- Do not move any vehicle in the area.
- Do not go near the incident & don't allow anyone else either.
- > Shut down the windows, doors etc. & seal open ground or terrace.
- Follow the instruction as directed by the authority.

Toxic Poisonous Gas

- Cover your nose with wet hand kerchief/ cloth and breathe through it.
- Come out in open, check the wind direction and move away quickly in perpendicular direction of wind. (cross wind direction).
- Immediately try to get to a higher elevation, if gas is heavier than air (likechlorine, as it settles in low lying area).
- Follow the instruction and reach safe shelter as instructed notified by Government Authority or Public authority.

General Instructions:

DON'T

- 1. Do not get panicky, be calm.
- 2. Do not approach the site of incident as a spectator.
- 3. Do not approach unnecessarily for information or more enquires.
- 4. Do not allow unnecessarily crowd nearby incident place.
- 5. Do not believe in rumors unnecessarily.

DO'S

- 1. Listen radio, TV or Public Addressing System.
- 2. Emergency will be communicated by public addressing system / TV / Radio orsiren (Siren-code wailing sound for one minute).
- 3. Follow the instruction & convey to others accordingly.
- 4. On announcement of withdrawal of emergency or clearance Siren, start yourroutine work.
- 5. On enquiry, deposit your statement as required by authority at the time of investigating the incident
- 6. Co-operate, help and assist the person(s) / authority handling the emergency andrescue operation.

7.5.6. SECURITY & POLICE

Security, protection of life & property and traffic control & maintenance of law and order should be taken care of by police. During an emergency duties and responsibilities of the police may be:

- Cordoning of the incident area.
- Warning public about the hazards.
- Traffic Control, Assist firefighting.
- Services Assist first-aid medical teams.
- Assist evacuation and ensure protection of property in evacuated areas.

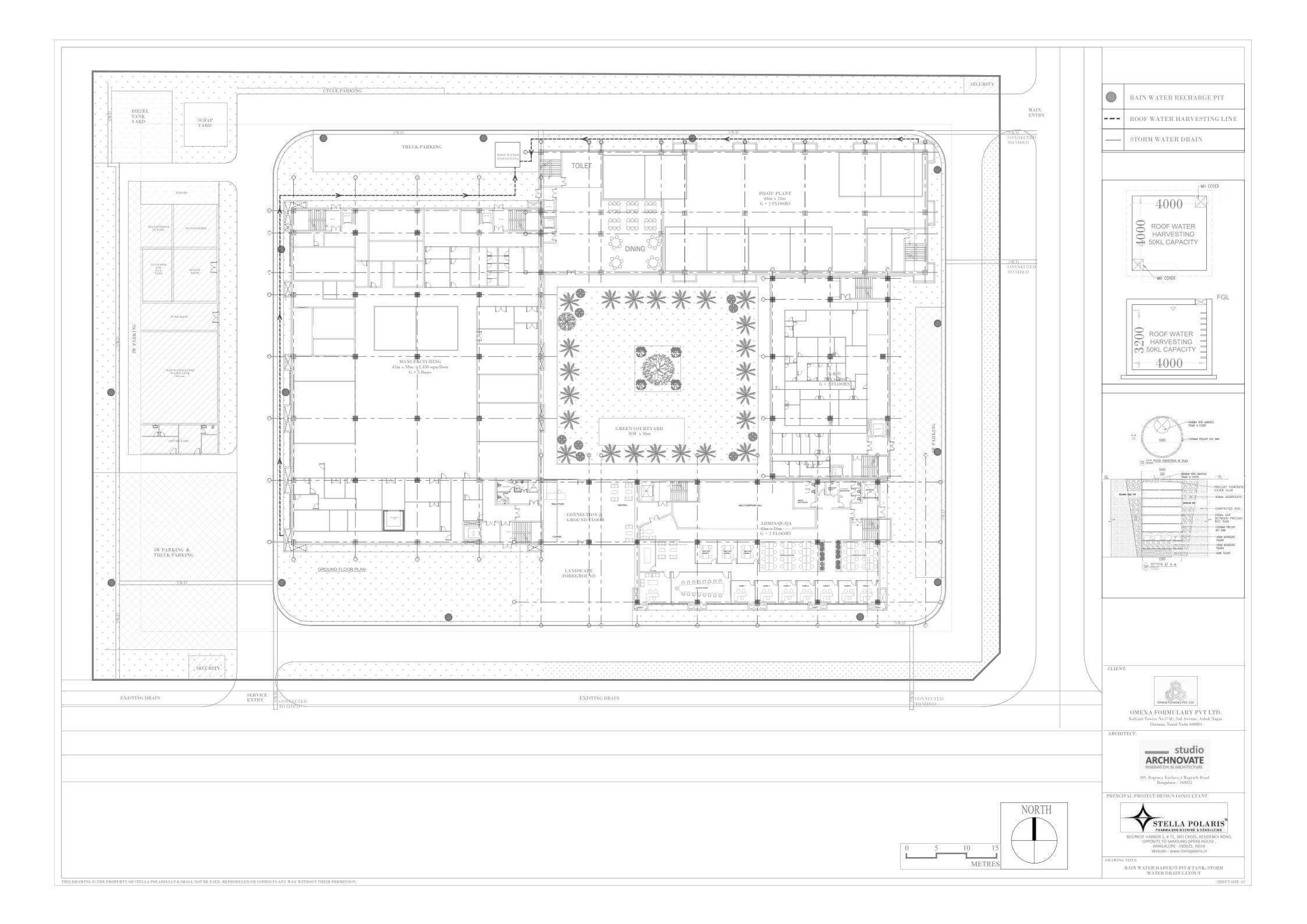
Before the Crisis

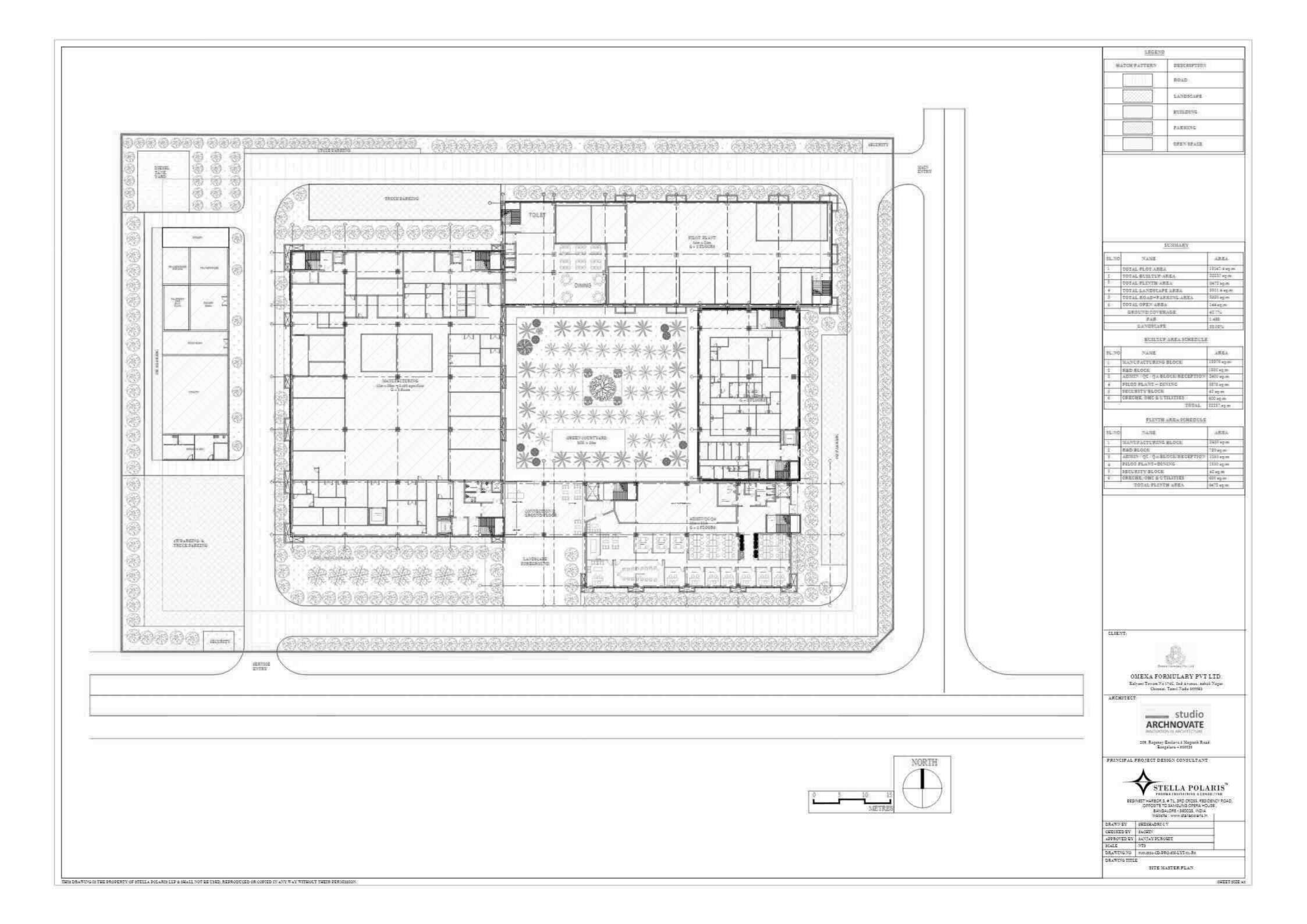
Proper planning of manpower, transport and communication network to coordinate possible incident areas and regulation of traffic should be made for each industry in the area.

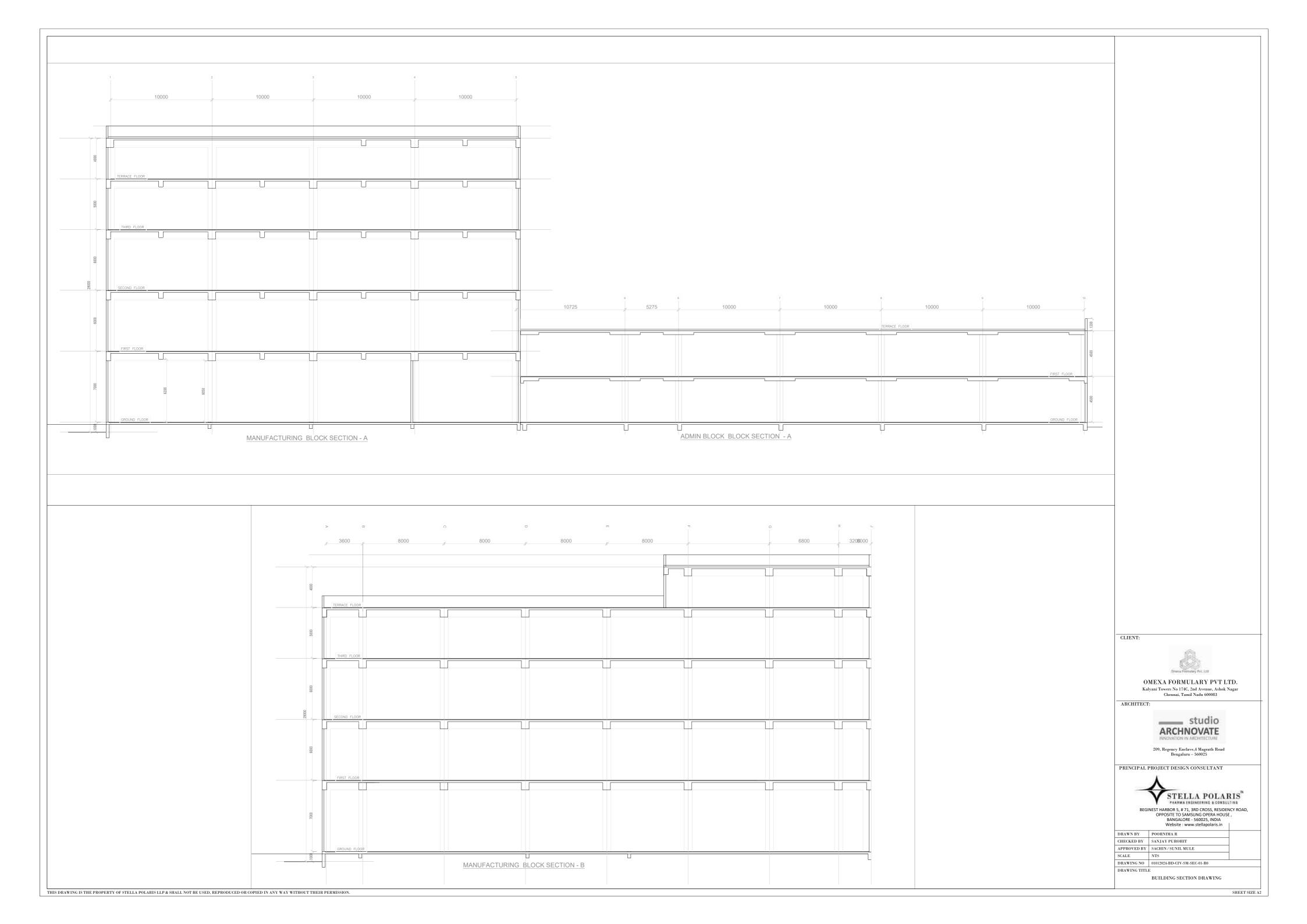
During the Crisis

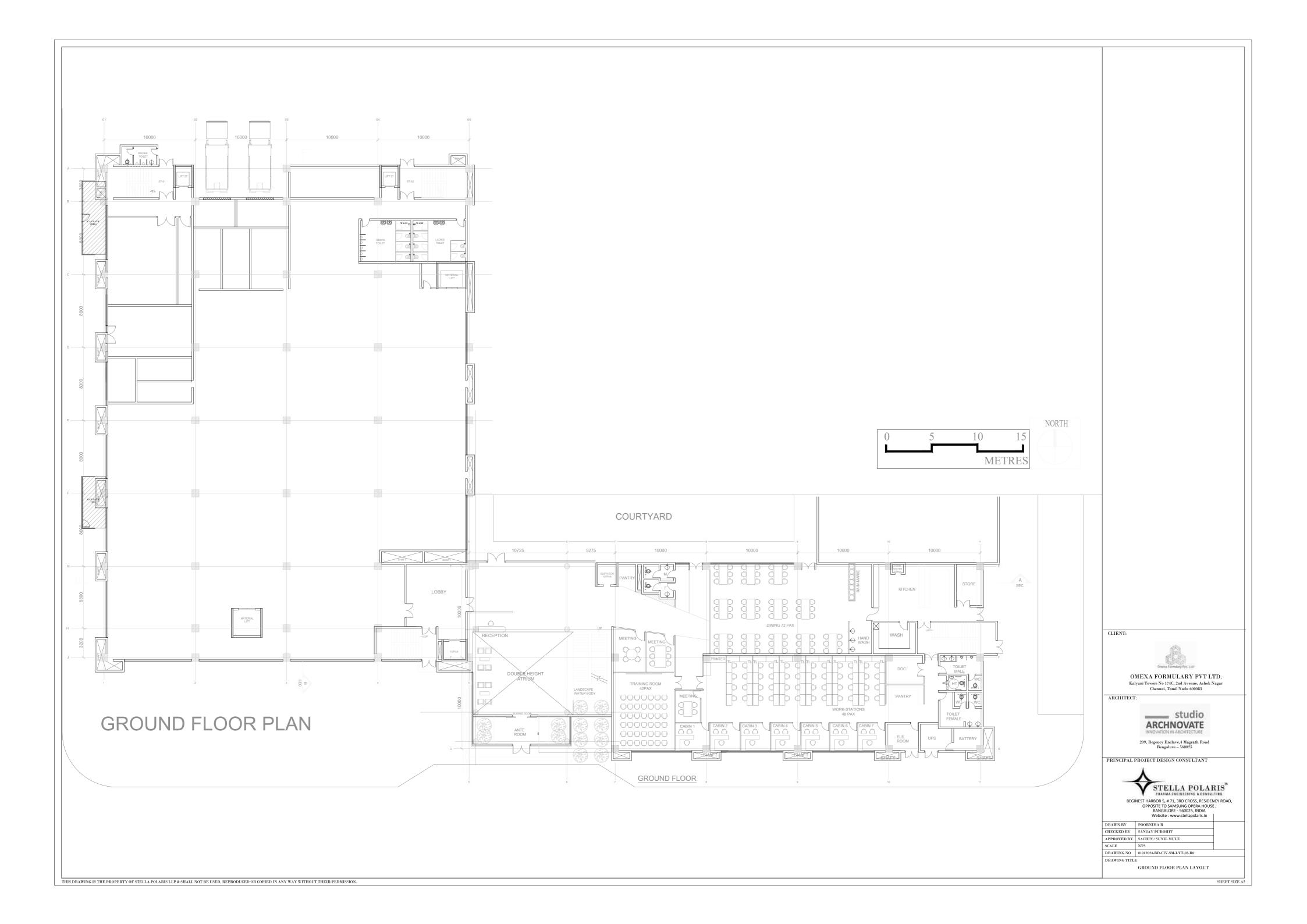
The Security Commander of the area will set in motion the relevant contingency planto control the operation.

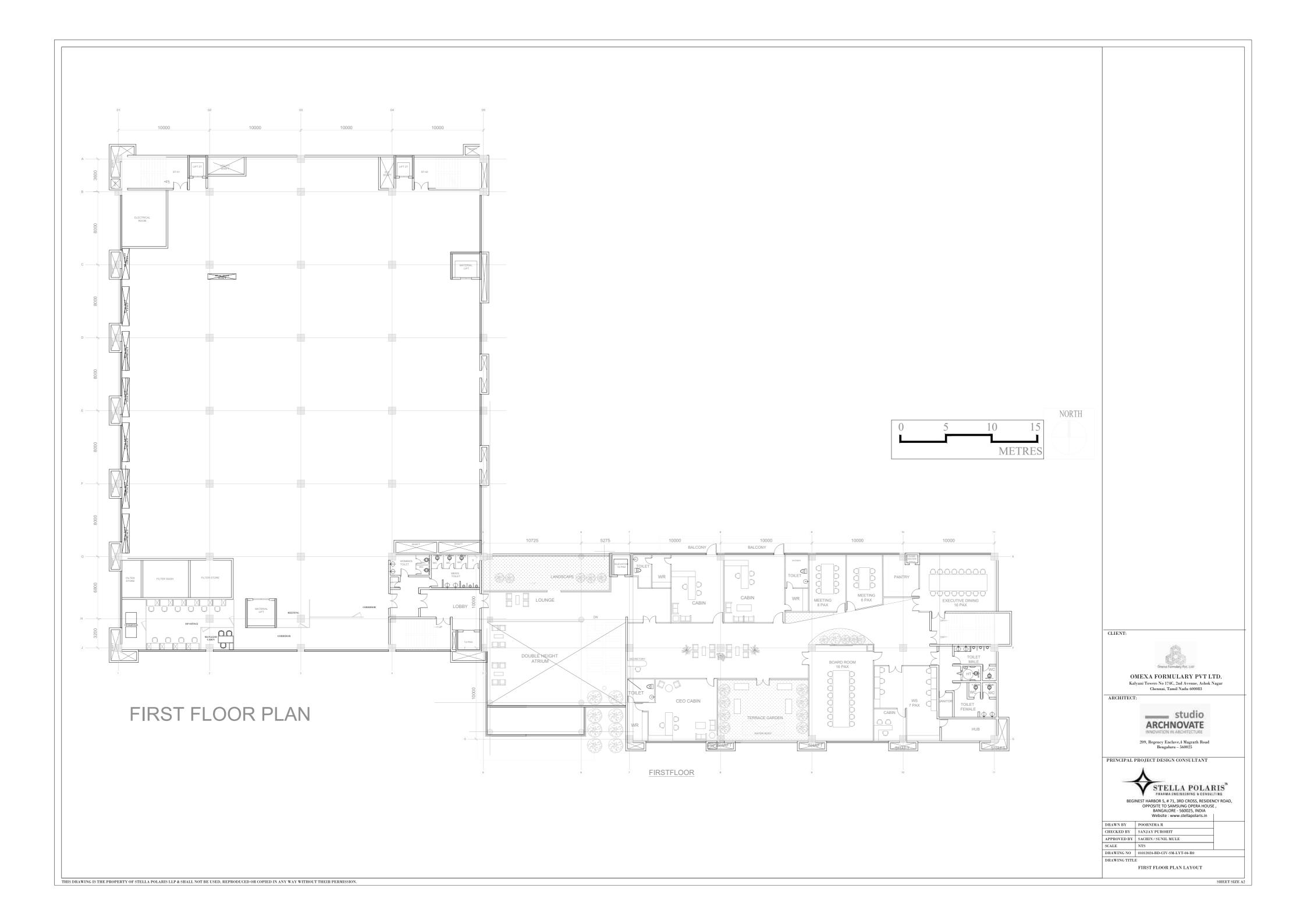
Proposed Manufacturing of Monoclonal Antibodies and Formulation	Facility H/01/2024/CON/065-R0
Risk assessment report	
After the Crisis	
Protect property in the evacuated area.	
Media	
The Control Room should release up-to-date informat	ion through the media to the
People.	
r	

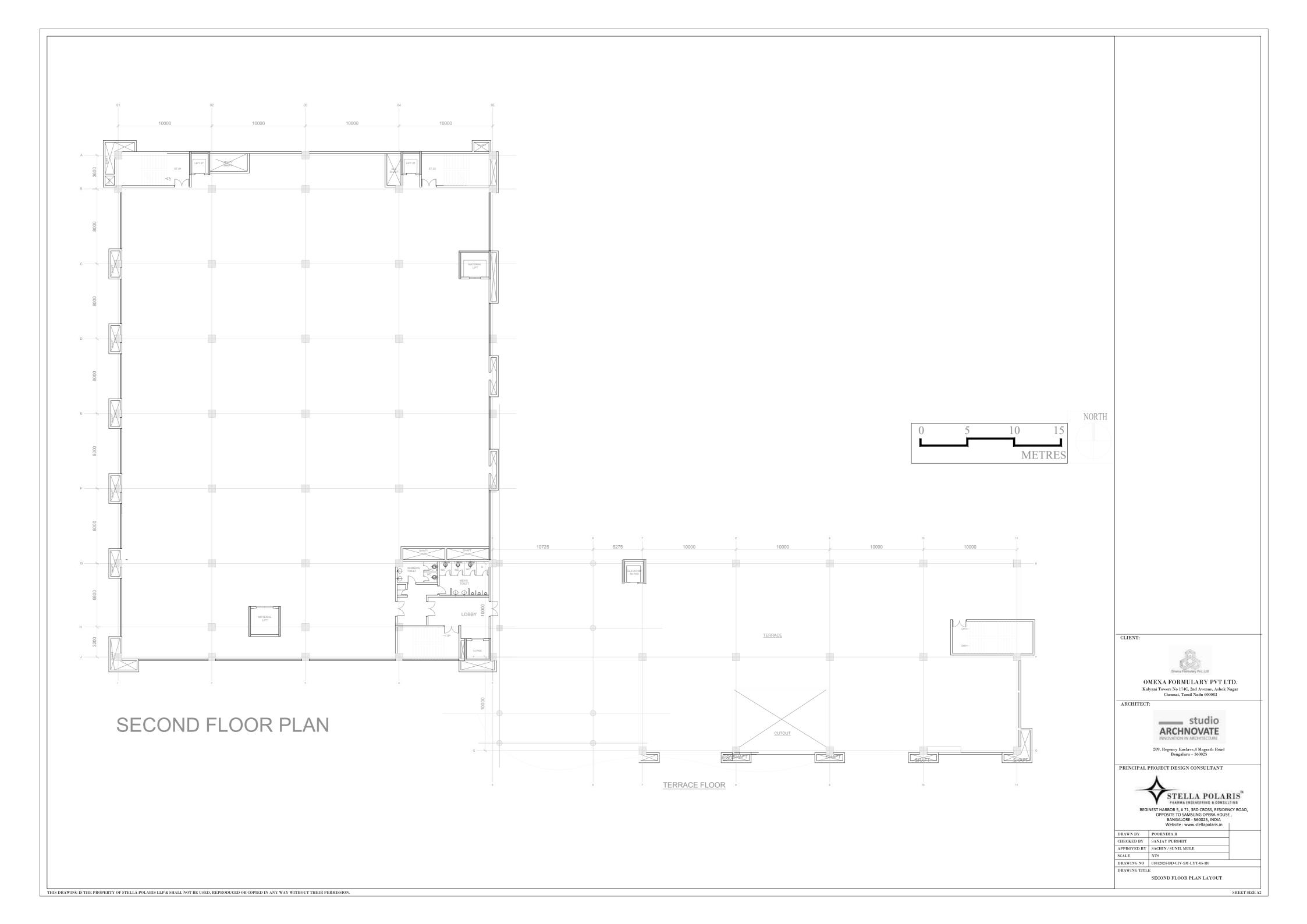


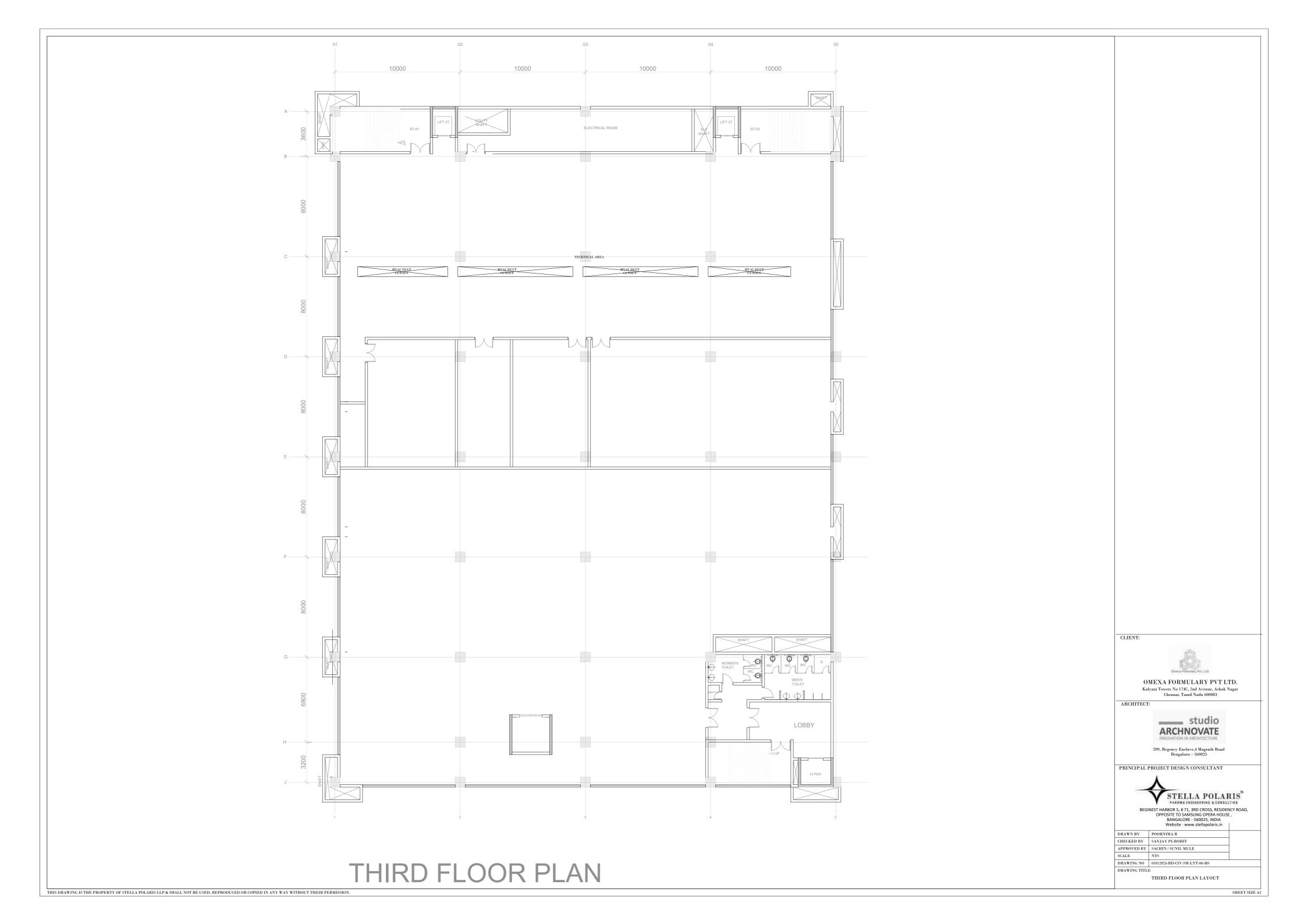


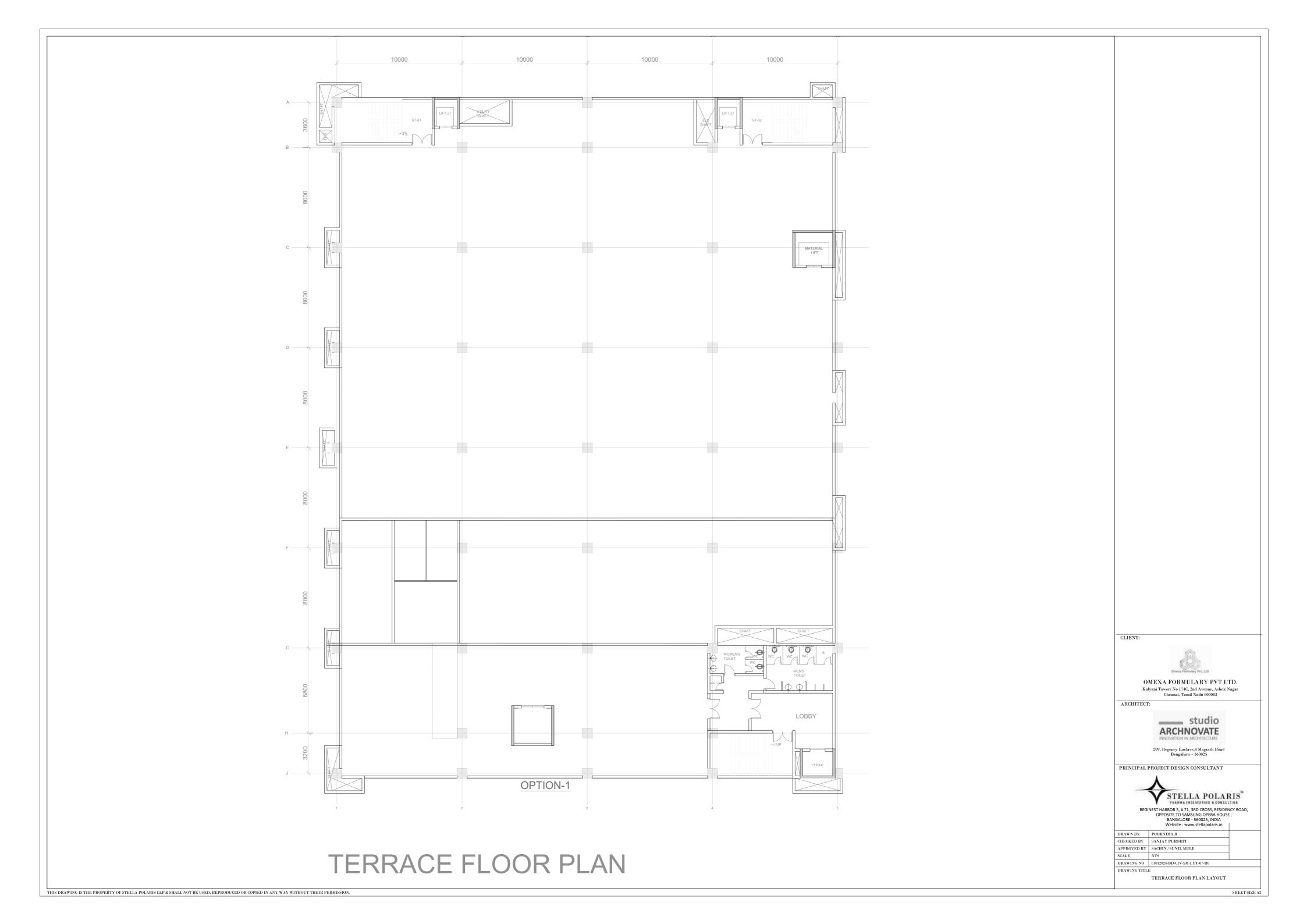


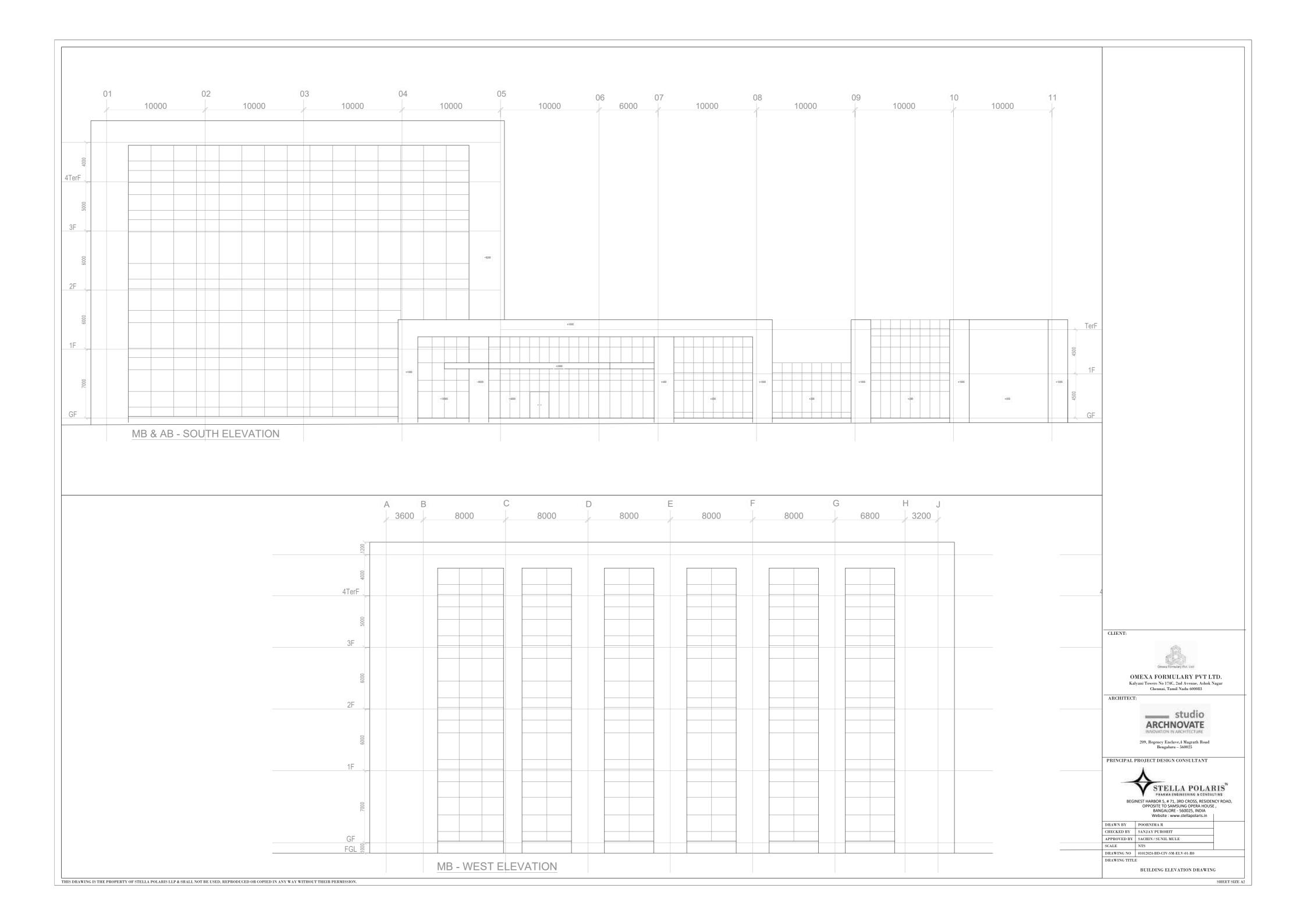












OMEXA FORMULARY	for the		OPERATION PROCEDURE clonal Antibodies and Formulation Fa	cility	Product Code:-
Effective Date: xx/xx/xxx Based on: Version 01 Page 1 of 7					

OBJECTIVE

To establish the procedure for an appropriate knowledge of the ranges of the main parameters of the up-stream stage for Monoclonal antibody production.

RESPONSIBILITY

It is responsibility of the technical personnel of the fermentation area, controlled by the Supervisor.

SECURITY CONSIDERATIONS

- *Any failure or problem during the fermentation will be informed in urgently to the supervisor.
- *Before to performing any bioreactor inoculation and fermentation operation the personnel need to be trained and evaluated properly.
- *Take special precautions during the operation with the steam and electrical supply lines.
- *Take special precautions with the caustic soda solutions manipulations, and its supply lines.
- *Take special precautions to avoid mistake in the management of the operation control system.

PROCEDURE

Expansion in the Seed Bioreactor (10 L)

- Prior to inoculation, the bioreactor has to be cleaned and sterilized.
- Inoculate "10 L Seed Bioreactor". The inoculum for this bioreactor should have cell viability higher or equal to 85 % and a cell concentration higher than $0.30~\rm X$ 10^6 cells per ml
- The culture conditions are: controlled temperature at 37.0 ± 0.5 °C, Impeller tip speed 0.6 to 1.0 m/s, gas flow to the head space between 0.1 to 0.6 vvm and to the sparger 0.005 to 0.02 vvm, dissolved oxygen concentration 20 to 100 % saturation relative to air and controlled pH 6.50 to 7.0
- The process lasts up to 6 days to reach the cell concentration of 0.30 X 10⁶ cells per mL, Corresponding to the required cell concentration for the next bioreactor, and cell viability higher or equal to 85 %
- No bioburden levels are accepted, determinate by optical microscopy.

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OMEXA STANDARD OPERATION PROCEDURE FORMULARY for the Production of Monoclonal Antibodies and Formulation Facility				cility	Product Code:-	
Effective Date: xx/xx/xxx Based on: Version 01					Page2of 7	

• Process main parameters

Parameter	Specification
Cell viability to inoculate the 10 L seed	Higher or equal to 85 %
bioreactor	
Initial cell concentration in the seed bioreactor	Higher than 0.30 X 10 ⁶ cells per mL
Temperature	$37.0 \pm 0.5 ^{\circ}\text{C}$
Impeller tip speed	0.6 to 1.0 m/s
Gas flow to the head space	0.1 to 0.6 vvm
Gas flow to the sparger	0.005 to 0.02 vvm
Dissolved oxygen concentration	20 to 100 % saturation relative to air
Ph	6.50 to 7.20
Time	Up to 6 days
Cell concentration corresponding to the concentration in the next bioreactor	0.30 X 10 ⁶ cells per mL

During all the above described steps, the operations have to be performed in a time frame that will assure that the cells will not be more than 60 days old at the moment they will be inoculated in the 50 L bioreactor

Expansion in the Intermediate Bioreactor (50 L).

- Prior to inoculation, the intermediate bioreactor has to be cleaned and sterilized
- Sterilize the transfer line from the seed bioreactor to the intermediated bioreactor.
- Seed the Intermediate bioreactor". The inoculum for this bioreactor should have cell viability higher or equal to 85 % and a cell concentration higher than 0.30 X
 10⁶ cells per ml
- The cell culture conditions are the following: culture media, impeller tip speed of 0.6 to 1.0 m/s, working temperature 37.0 ± 0.5 °C; gas flow to the head space 0.1 to 0.6 vvm and to the sparger 0.005 to 0.1 vvm, dissolved oxygen concentration 20 to 100 % saturation relative to air and pH initially controlled in the range pH 6.50 to 7.20

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OMEXA FORMULARY	STANDARD OPERATION PROCEDURE for the Production of Monoclonal Antibodies and Formulation Facility			cility	Product Code:-
Effective Date: xx/xx/xxx Based on: Version 01 Page3of 7					

- Once a cell concentration of 1.0 X 10⁶ cells per mL is reached start perfusion at 0.25vessel volume per day. This is done after proper sterilization and setup of the perfusion lines and hardware.
- The spin filter tip speed is 0.45 to 3.0 m/s. As the cell concentration increases inside the bioreactor, the spin filter tip speed is increased to improve the cell retention
- Step the perfusion rate to 0.5 vessel volume per day after 24 hours.
- Step the perfusion rate to 1.0 vessel volume per day after 24 hours.
- The process in this bioreactor can last up to 20 days, in which up to five days are used to grow the cells in batch phase and the rest of this time is run in perfusion mode, until to reach an appropriated cell mass to fulfill the criteria for inoculation of the production bioreactor i.e. 0.30 X 10⁶ cells per mL.
- If appropriated cell mass to fulfill the criteria for the inoculation of the production bioreactor i.e. 0.30×10^6 cells per mL is achieved in batch phase, there is no necessary to the batch in perfusion mode.
- No bioburden levels are accepted, determinate by optical microscopy.

Process main parameters

1 rocess main parameters					
Parameter	Specification				
Initial cell viability to inoculate the pilot	Higher or equal to 85 %				
scales bioreactor					
Initial cell concentration in the pilot scales	Higher 0.30 X 106 cells per mL				
bioreactor					
Temperature	$ 37.0 \pm 0.5 $ °C				
Impeller tip speed	0.6 to 1.0 m/s				
Gas flow to the head space	0.1 to 0.6 vvm				
Gas flow to the sparger	0.005 to 0.1 vvm				
Dissolved oxygen concentration	20 to 100 % saturation relative to air				
Ph	6.50 to 7.20				
Time	Up to 15 days				
Cell concentration corresponding to the	0.30 X 10 ⁶ cells per mL				
concentration in the next bioreactor	1				

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OMEXA FORMULARY	STANDARD OPERATION PROCEDURE for the Production of Monoclonal Antibodies and Formulation Facility			cility	Product Code:-	
Effective Date: xx	Effective Date: xx/xx/xxx Based on: Version 01 Page4of 7					

Production Bioreactor (500 L)

- Prior to inoculation, the intermediate bioreactor has to be cleaned and sterilized
- Sterilize the transfer line from the seed bioreactor to the intermediated bioreactor.
- Seed the Production bioreactor". The inoculum for this bioreactor should have cell viability higher or equal to 85 % and a cell concentration higher than 0.30 X 10⁶ cells per mL
- The cell culture conditions are the following: culture media, impeller tip speed of 0.6 to 1.0 m/s, and as the cell concentration increases inside the bioreactor, the impeller tip speed will also be increased, working temperature 37.0 ± 0.5 °C; gas flow to the head space 0.1 to 0.6 vvm and to the sparger 0.005 to 0.1 vvm, dissolved oxygen concentration 20 to 100 % saturation relative to air and pH initially controlled in the range pH 6.50 to 7.20
- Once a cell concentration of 15.0 X 10⁶ cells per mL is reached Harvest the batch

The fermentation can be stopped when

- When the results of microbial contamination in the microscope observation is out of specification.
- ·· The cell viability falls below 70 % cell viability for a period of more than three days consecutively
- When the concentration of antibody in the final stage is lower than 25 μ g/mL.
- When the age of cells in culture achieves 90days.

• Process main parameters

Parameter	Specification
Initial cell viability to inoculate the	Higher or equal to 85 %
500 L scales bioreactor	
Initial cell concentration in the 500 L	Higher 0.30 X 10 ⁶ cells per mL
scale bioreactor	
Temperature	$ 37.0 \pm 0.5 ^{\circ}\text{C} $
Impeller tip speed	0.6 to 1.0 m/s
Gas flow to the head space	0.1 to 0.6 vvm
Gas flow to the sparger	0.005 to 0.1 vvm
Dissolved oxygen concentration	20 to 100 % saturation relative to air
Ph	6.50 to 7.20

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OMEXA FORMULARY	STANDARD OPERATION PROCEDURE for the Production of Monoclonal Antibodies and Formulation Facility			cility	Product Code:-
Effective Date: xx/xx/xxx Based on: Version 01 Page 5 of 7					

- Cell clarification: Continuous centrifugation followed by depth filtration is to separate the cells from the fermentation media, the supernatant of which will be clarified by depth filtration.
- Capture by affinity chromatography: Target protein is among thousands of impurities will be specially retained over the affinity resin leaving impurities as unbound.
- Virus inactivation: Inactivation of different viruses if any will be done in a sterile bag at a lower pH and probably at a controlled temperature between 2 and 25 degC.
- Purification by ion exchange chromatography (IEC): The related impurities will be the next level of contaminants that needs to be separated from the target protein, ion exchange chromatography does the job be at an-ion or cat-ion exchange chromatography.
- Virus removal by Nano-filtration: It is to remove the all forms of virus so there are no viral loads basically in the active pharmaceutical intermediate.
- Concentration/ Buffer exchange by tangential flow filtration (TFF): It is critical to bring in the product to the required pre/formulation buffer which ensures the stability.
- Final sterile filtration: This filtration is required to claim that the product is sterile and is qualified for fill finish requirement. Samples are collected at different stages during the batch and sent for analytical testing.
- After final sterile filtration the product will be sent to formulation unit.

PROCEDURE

Generalities

- Verify that the Formulation Solution is in the range of established pH to perform the formulation process.
- Clean the laminar flow, the palletank and the High Scale Balance and turn on the light UV, according to POP-T4005 "Laminar Flow Working Procedure", and put all the materials to use inside it

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OMEXA FORMULARY	cility	Product Code:-						
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- Verify that all the plastic bags that contain the Active Pharmaceutical Ingredients (APIs) to conform the API Pool are in the area, where, will be carried out the product formulation.
- Check the volumes of each plastic bag that contain the APIs (have to be written in the corresponding GMP label) write the values in the BMR- "Batch Record for hR3 Formulation Process".

Process Formulation.

- Record in the BMR- "Batch Record for hR3 Formulation Process" different volumes of the selected bags containing the API bulk.
- Clean the exterior surfaces of bags with the selected API bulk to be formulated.
- Introduce in to the ceiling laminar flow the bags with the selected API bulk to be formulated. Stay them in the auxiliary table.
- Clean the exterior surfaces of the package with the formulation system with recirculation.
- Introduce in to the ceiling laminar flow the package with the formulation system with recirculation.
- Open the package of formulation system with recirculation and positioned it inside the 200 L palletank. Check that all bag's corners are correctly positioned.
- Connect the male and female MPX connections to establish the recirculation loop.
- Introduce the pumping segment of recirculation loop in the head of peristaltic recirculation pump
- Connect the first bag containing the selected API bulk in one of the two free entrances.
- Connect the bag containing the Formulation Solution in the second entrance. (See diagram # 2)
- Introduce the pumping segment of connection pipe in the head of peristaltic transfer pump. (See diagram # 2)
- Switch on the high scale balance and set "zero".
- Transfer the API bulk from the firs 50 L bag to the 200 L formulation bag. (See diagram # 2)
- Record this operation in the BMR- "Batch Record for hR3 Formulation Process"
- Repeat this operation so many times as necessary.
- Make a sum of all volumes collected in the 200 L formulation bag and compare with the current weight in the balance. Record this operation in the "Batch Record for hR3 Formulation Process". The sum of all API bulk volumes can be called Total Initial API Volume. (TIAPIV).

TIAPIV = \sum Volumes of all used API bags_(mL)

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OMEXA FORMULARY	cility	Product Code:-							
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- Check the weight in the balance and record this operation in the BMR- "Batch Record for hR3 Formulation Process".
- Compare the values obtained from the sum of volumes from the bags label and the value of the weight in the high scale balance.
- If the difference between them is less them 5 mL, continue the operation using the value of the high scale balance as the TIAPIV.

|(∑ Volumes of all used API bags_(mL)) - weight in the high scale balance_(g)| ≤10 mL

Consider the weight of 1 mL as 1 q

- If the difference is higher, those 10.0 mL claim for the supervisor presence. At this discrepancies point he will take the final decision for the TIAPIV value.
- When the TIAPIV value is defined, open the clamps of the recirculation loop and close the clamps in the 200 L bag inlet lines and in the filtration line.
- Switch on the recirculation peristaltic pump in medium speed and in the correct sense. (taking out API bulk from the bottom and reincorporating them on the top).
- Homogenize the API Pool during 5 minutes.
- With a sterile and disposable syringe, in the sampling port, take a sample of 1 mL of the API bulk and measure the protein concentration by optic density according to the SOP- "Protein Concentration by Spectrophotometryc Method"

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Omexa Formulary Pvt. Ltd.

Empowering Health, Elevating Ufe

To

Date: 11.07.2024

Principal Chief Conservator of Forest (PCCF) and Chief wildlife Warden (CWLW)

Office of the Principal Chief Conservator of Forest (PCCF)

Velachery Road, Guindy,

Chennai,

Tamil Nadu-600032

Sub: M/s. Omexa Formulary Private Limited - Request letter to approval for "Proposed Manufacturing of Monocional antibodies and formulations facility" at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State-Reg

Reference:

1. ToR Copy issued by SEIAA vide F.No: 10894 dated: 29.06.2024

Respected Sir,

With reference to the above project and reference, we have received the Terms of Reference (ToR) for the preparation of EIA report for "Proposed Manufacturing of Monoclonal antibodies and formulations facility" at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State from TNSEIAA vide Ref No: 1.

In that Terms of Reference (ToR), we have following condition prescribed by SEAC as a Site Specific ToR Condition (SI. No: 59, Page No: 6):

*59. Proponent shall furnish the letter received from DFO concerned stating the proximity details of Reserve Forests, Protected Areas, Sanctuaries, Tiger reserve etc., up to a radius of 25 km from the proposed site."

We request you kind self to accept this letter and enable us to obtain the letter from DFO concern about the details of Reserve Forests, Protected Areas, Sanctuaries, Tiger reserve etc., up to a radius of 25 km from the proposed site. Based on above only, we will able to get the Environmental Clearance from TNSEIAA.

Thanking You.

E. Ramanathan Director

Kalyani tower, 174C 2nd Avenue, Ashok nagar Chennal - 600083 Contact No. +91 8428424699. E-mall - Contact@Omexa.in www.omexa.in

Baseline Period-march 2024 to May 2024

PM 10

S. No.	Date	AAQ1	AAQ2	AAQ3	AAQ4	AAQ5	AAQ6	AAQ7	AAQ8
Loca	ntion Name	Near Project Site	Ural	Tindivanam	Pelakuppam	Vempundi	Kollar	Kattusiviri	Pudur
1	04-03-24	46.77	49.04	56.58	42.18	44.25	43.71	41.00	44.71
2	08-03-24	35.54	37.26	42.98	32.04	33.62	33.20	31.15	33.97
3	11-03-24	47.10	49.38	56.98	42.48	44.56	44.02	41.29	45.03
4	15-03-24	36.69	38.47	44.38	33.09	34.71	34.29	32.16	35.08
5	18-03-24	37.73	39.55	45.63	34.02	35.69	35.25	33.07	36.06
6	22-03-24	35.95	37.69	43.48	32.42	34.01	33.59	31.51	34.37
7	25-03-24	48.01	50.34	58.08	43.30	45.42	44.86	42.09	45.90
8	29-03-24	35.87	37.60	43.38	32.34	33.93	33.51	31.44	34.29
9	02-04-24	36.77	38.55	44.48	33.16	34.79	34.36	32.24	35.16
10	05-04-24	38.01	39.85	45.98	34.28	35.96	35.52	33.32	36.34
11	08-04-24	36.24	37.99	43.83	32.68	34.28	33.86	31.76	34.64
12	12-04-24	48.34	50.68	58.48	43.59	45.74	45.17	42.38	46.22
13	16-04-24	37.24	39.04	45.05	33.58	35.23	34.80	32.65	35.60
14	19-04-24	46.88	49.15	56.70	42.27	44.35	43.80	41.09	44.81
15	22-04-24	37.19	38.99	44.98	33.53	35.18	34.75	32.60	35.55
16	03-05-24	34.50	36.17	41.73	31.11	32.64	32.24	30.24	32.98
17	06-05-24	48.14	50.47	58.23	43.41	45.54	44.98	42.20	46.02
18	10-05-24	49.17	51.55	59.48	44.34	46.52	45.95	43.10	47.01
19	14-05-24	41.46	43.46	50.12	37.40	39.23	38.75	36.36	39.64
20	17-05-24	47.68	49.99	57.68	43.00	45.11	44.56	41.80	45.58

21	20-05-24	36.36	38.12	43.98	32.79	34.40	33.98	31.87	34.76
22	23-05-24	47.31	49.60	57.23	42.66	44.76	44.21	41.47	45.23
23	27-05-24	35.54	37.26	42.98	32.04	33.62	33.20	31.15	33.97
24	30-05-24	48.55	50.90	58.73	43.78	45.93	45.37	42.56	46.41
	N	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
	Min	34.50	36.17	41.73	31.11	32.64	32.24	30.24	32.98
	Max	49.17	51.55	59.48	44.34	46.52	45.95	43.10	47.01
	Mean	41.38	43.38	50.05	37.31	39.14	38.66	36.27	39.55
]	Median	37.87	39.70	45.81	34.15	35.83	35.39	33.20	36.20
	SD	5.70	5.97	6.89	5.14	5.39	5.33	5.00	5.45
	C V %	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
98	Percentile	48.89	51.25	59.13	44.08	46.25	45.68	42.85	46.73
ľ	NAAQS	100	100	100	100	100	100	100	100

Baseline Period-march 2024 to May 2024

PM 2.5

S. No.	Date	AAQ1	AAQ2	AAQ3	AAQ4	AAQ5	AAQ6	AAQ7	AAQ8
Loca	ation Name	Near Project Site	Ural	Tindivanam	Pelakuppam	Vempundi	Kollar	Kattusiviri	Pudur
1	04-03-24	27.09	26.57	31.51	25.97	26.08	24.77	24.64	24.21
2	08-03-24	20.58	20.18	23.94	19.73	19.81	18.82	18.72	18.40
3	11-03-24	27.28	26.76	31.74	26.15	26.27	24.94	24.82	24.38
4	15-03-24	21.25	20.84	24.72	20.37	20.46	19.43	19.33	18.99
5	18-03-24	21.85	21.43	25.42	20.94	21.04	19.98	19.88	19.53
6	22-03-24	20.82	20.42	24.22	19.96	20.04	19.04	18.94	18.61
7	25-03-24	27.81	27.27	32.35	26.66	26.77	25.42	25.30	24.86
8	29-03-24	20.77	20.37	24.17	19.91	20.00	18.99	18.90	18.57
9	02-04-24	21.30	20.89	24.78	20.42	20.51	19.47	19.38	19.04
10	05-04-24	22.02	21.59	25.61	21.10	21.20	20.13	20.03	19.68
11	08-04-24	20.99	20.58	24.42	20.12	20.21	19.19	19.09	18.76
12	12-04-24	28.00	27.46	32.57	26.84	26.96	25.60	25.47	25.03
13	16-04-24	21.57	21.15	25.09	20.68	20.77	19.72	19.62	19.28
14	19-04-24	27.15	26.63	31.58	26.03	26.14	24.82	24.70	24.27
15	22-04-24	21.54	21.12	25.06	20.65	20.74	19.69	19.59	19.25
16	03-05-24	19.98	19.60	23.25	19.15	19.24	18.27	18.18	17.86
17	06-05-24	27.88	27.34	32.43	26.73	26.84	25.49	25.36	24.92
18	10-05-24	28.48	27.93	33.13	27.30	27.42	26.04	25.91	25.45
19	14-05-24	24.07	23.61	27.98	23.08	23.18	22.02	21.91	21.53
20	17-05-24	27.62	27.08	32.13	26.47	26.59	25.25	25.12	24.68

21	20-05-24	21.06	20.65	24.50	20.19	20.28	19.25	19.16	18.82
22	23-05-24	27.40	26.87	31.88	26.27	26.38	25.05	24.93	24.49
23	27-05-24	20.58	20.18	23.94	19.73	19.81	18.82	18.72	18.40
24	30-05-24	28.12	27.58	32.71	26.95	27.07	25.71	25.58	25.13
	N	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
	Min	19.98	19.60	23.25	19.15	19.24	18.27	18.18	17.86
	Max	28.48	27.93	33.13	27.30	27.42	26.04	25.91	25.45
	Mean	23.97	23.50	27.88	22.97	23.07	21.91	21.80	21.42
	Median	21.93	21.51	25.52	21.02	21.12	20.05	19.95	19.60
	SD	3.30	3.24	3.84	3.16	3.18	3.02	3.00	2.95
	C V %	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
98	3 Percentile	28.31	27.77	32.94	27.14	27.26	25.89	25.76	25.31
	NAAQS	60	60	60	60	60	60	60	60

Baseline Period-march 2024 to May 2024

 SO_2

S. No.	Date	AAQ1	AAQ2	AAQ3	AAQ4	AAQ5	AAQ6	AAQ7	AAQ8
Loc	cation Name	Near Project Site	Ural	Tindivanam	Pelakuppam	Vempundi	Kollar	Kattusiviri	Pudur
1	04-03-24	9.96	10.30	11.85	9.93	10.63	9.60	10.84	11.32
2	08-03-24	7.57	7.83	9.00	7.54	8.08	7.29	8.24	8.60
3	11-03-24	10.03	10.37	11.94	10.00	10.70	9.67	10.92	11.40
4	15-03-24	7.81	8.08	9.30	7.79	8.34	7.53	8.51	8.88
5	18-03-24	8.03	8.31	9.56	8.01	8.57	7.74	8.75	9.13
6	22-03-24	7.66	7.92	9.11	7.63	8.17	7.38	8.33	8.70
7	25-03-24	10.23	10.57	12.17	10.19	10.91	9.85	11.13	11.62
8	29-03-24	7.64	7.90	9.09	7.61	8.15	7.36	8.32	8.68
9	02-04-24	7.83	8.10	9.32	7.81	8.36	7.55	8.53	8.90
10	05-04-24	8.10	8.37	9.63	8.07	8.64	7.80	8.81	9.20
11	08-04-24	7.72	7.98	9.18	7.69	8.24	7.44	8.40	8.77
12	12-04-24	10.30	10.65	12.25	10.26	10.99	9.92	11.21	11.70
13	16-04-24	7.93	8.20	9.44	7.90	8.46	7.64	8.63	9.01
14	19-04-24	9.98	10.32	11.88	9.95	10.65	9.62	10.87	11.35
15	22-04-24	7.92	8.19	9.42	7.89	8.45	7.63	8.62	9.00
16	03-05-24	7.35	7.60	8.74	7.32	7.84	7.08	8.00	8.35
17	06-05-24	10.25	10.60	12.20	10.22	10.94	9.88	11.16	11.65
18	10-05-24	10.47	10.83	12.46	10.44	11.17	10.09	11.40	11.90
19	14-05-24	8.94	9.24	10.61	8.91	9.53	8.62	9.72	10.14
20	17-05-24	10.16	10.50	12.08	10.12	10.84	9.79	11.06	11.54

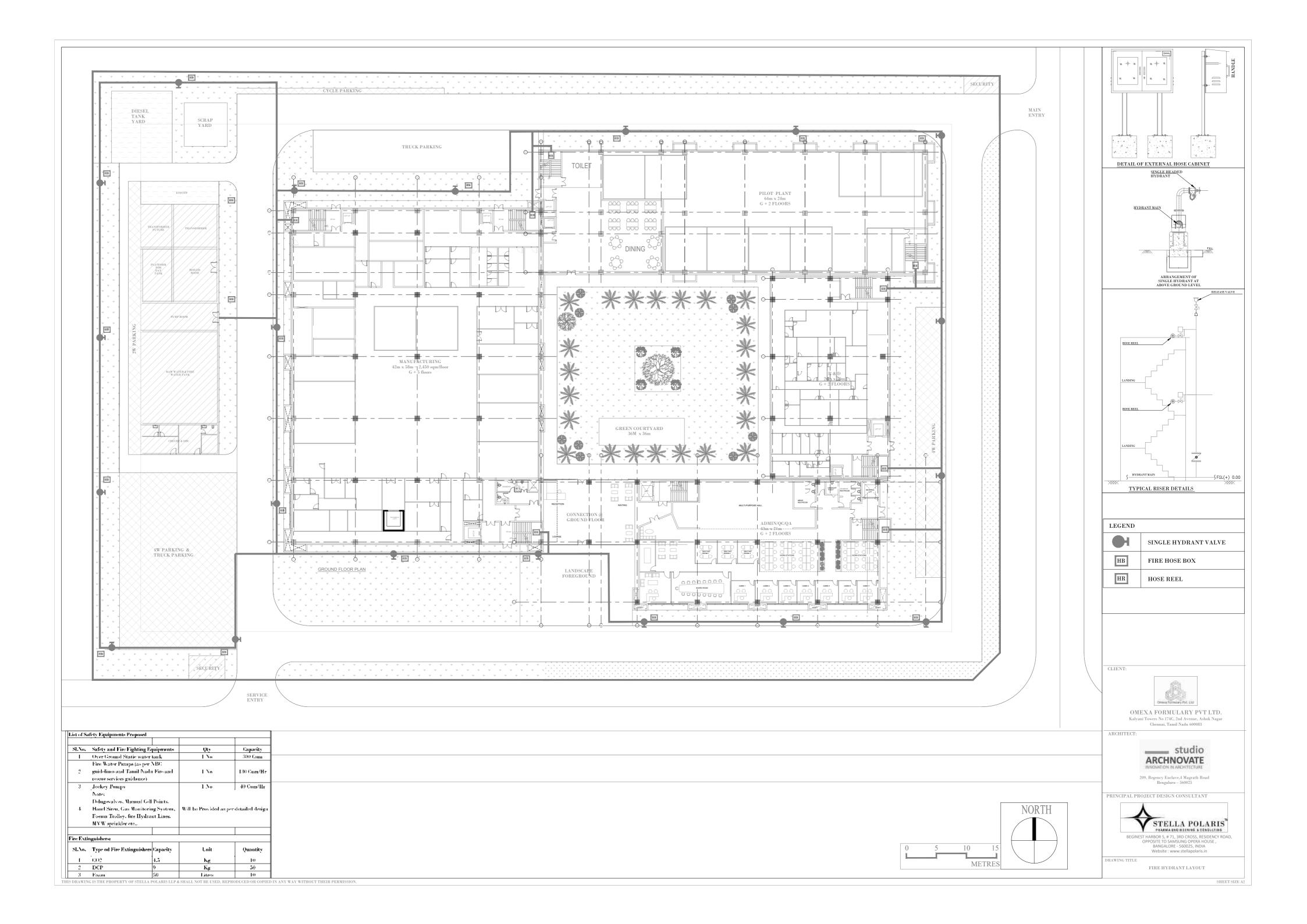
i		1	ı	1	ı	1	1	1	1
21	20-05-24	7.74	8.01	9.21	7.72	8.26	7.46	8.43	8.80
22	23-05-24	10.08	10.42	11.99	10.04	10.75	9.71	10.97	11.45
23	27-05-24	7.57	7.83	9.00	7.54	8.08	7.29	8.24	8.60
24	30-05-24	10.34	10.69	12.30	10.30	11.03	9.96	11.26	11.75
	N	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
	Min	7.35	7.60	8.74	7.32	7.84	7.08	8.00	8.35
	Max	10.47	10.83	12.46	10.44	11.17	10.09	11.40	11.90
	Mean	8.82	9.12	10.49	8.79	9.41	8.50	9.60	10.02
	Median	8.07	8.34	9.60	8.04	8.61	7.77	8.78	9.17
	SD	1.21	1.26	1.44	1.21	1.30	1.17	1.32	1.38
	C V %	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
98	3 Percentile	10.41	10.77	12.39	10.38	11.11	10.03	11.33	11.83
	NAAQS	80	80	80	80	80	80	80	80

Baseline Period-march 2024 to May 2024

 NO_2

S. No.	Date	AAQ1	AAQ2	AAQ3	AAQ4	AAQ5	AAQ6	AAQ7	AAQ8
Loca	ation Name	Near Project Site	Ural	Tindivanam	Pelakuppam	Vempundi	Kollar	Kattusiviri	Pudur
1	04-03-24	23.27	22.65	24.65	22.40	23.16	22.41	21.95	22.29
2	08-03-24	17.68	17.21	18.73	17.02	17.60	17.03	16.68	16.93
3	11-03-24	23.44	22.81	24.83	22.56	23.32	22.57	22.10	22.45
4	15-03-24	18.26	17.77	19.34	17.57	18.17	17.58	17.22	17.48
5	18-03-24	18.77	18.27	19.89	18.07	18.68	18.08	17.70	17.98
6	22-03-24	17.89	17.41	18.95	17.22	17.80	17.23	16.87	17.13
7	25-03-24	23.89	23.25	25.31	23.00	23.77	23.01	22.53	22.88
8	29-03-24	17.85	17.37	18.91	17.18	17.76	17.19	16.83	17.09
9	02-04-24	18.30	17.81	19.38	17.61	18.21	17.62	17.26	17.52
10	05-04-24	18.92	18.41	20.04	18.21	18.82	18.22	17.84	18.11
11	08-04-24	18.03	17.55	19.10	17.36	17.94	17.36	17.01	17.27
12	12-04-24	24.06	23.41	25.48	23.15	23.94	23.17	22.69	23.04
13	16-04-24	18.53	18.04	19.63	17.84	18.44	17.85	17.48	17.75
14	19-04-24	23.33	22.70	24.71	22.45	23.21	22.46	22.00	22.34
15	22-04-24	18.50	18.01	19.60	17.81	18.41	17.82	17.45	17.72
16	03-05-24	17.17	16.71	18.19	16.52	17.08	16.53	16.19	16.44
17	06-05-24	23.95	23.31	25.37	23.06	23.84	23.07	22.59	22.94
18	10-05-24	24.47	23.81	25.92	23.55	24.35	23.56	23.07	23.43

19	14-05-24	20.70	20.15	21.92	19.93	20.60	19.94	19.53	19.83
20	17-05-24	23.73	23.09	25.13	22.84	23.61	22.85	22.38	22.72
21	20-05-24	18.09	17.61	19.17	17.42	18.00	17.42	17.06	17.33
22	23-05-24	23.54	22.91	24.94	22.66	23.43	22.67	22.20	22.55
23	27-05-24	17.68	17.21	18.73	17.02	17.60	17.03	16.68	16.93
24	30-05-24	24.16	23.51	25.59	23.25	24.04	23.27	22.78	23.14
	N	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
Min		17.17	16.71	18.19	16.52	17.08	16.53	16.19	16.44
Max		24.47	23.81	25.92	23.55	24.35	23.56	23.07	23.43
Mean		20.59	20.04	21.81	19.82	20.49	19.83	19.42	19.72
	Median	18.84	18.34	19.96	18.14	18.75	18.15	17.77	18.05
	SD	2.84	2.76	3.00	2.73	2.82	2.73	2.67	2.72
C V %		13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
98 Percentile		24.32	23.67	25.77	23.41	24.21	23.43	22.94	23.30
NAAQS		80	80	80	80	80	80	80	80





SAFETY, HEALTH & ENVIRONMENT POLICY

HEALTH AND SAFETY POLICY:

- Provided and maintain so far as is reasonably, practicable, plant, equipment, systems
 and working conditions which are safe and without risk to the health of all employees,
 visitors, contactors, and public and which avoid damage to property and adverse impact on
 the environment.
- Protect all employees from exposure to any substance or activity which may be hazardous to health by providing suitable control measures based on assessment of the risks and recommendations made through periodical safety audits.
- Provide information, instruction, training and supervision for all employees to enable them to carry out their duties and responsibilities in a safe and effective way.
- Develop and maintain appropriate emergency response procedures, contingency plans and resources, commensurate with the risks to business activities.
- Provide n effective occupational heath programme.
- Take full account of health, safety and loss prevention considerations in projects, planning and decision making.
- Treat local laws and regulations on health and safety as minimum standards to be improved upon wherever reasonably practicable.
- Actively encourage the involvement of employees in the promotion of health and safety.
- Encourage employees to accept individual responsibility for their own health and safety and for that their colleagues and to coordinate fully with company management in maintaining and improving health and safety standards.

For Omexa Formulary Pvt. Ltd.

E. Ramanathan Director



ENVIRONMENT POLICY:

- To take account of environmental consideration in planning and decision making.
- To monitor the impact of all the company activities upon the environment and to ensure that it is maintained.
- To pay special regards to the environment protection of the communities in which its operations are located.
- To conduct periodical audits to ensure implementations of the company's environmental policy.
- That environmental regulations laid down by the government and public authorities are treated as minimum standard to be improved upon wherever practicable.
- That the company works closely with appropriate authorities in seeking to improve its
 environmental performance.

For Omexa Formulary Pvt. Ltd.

Ramanathan Director



तमिलनाडु TAMILNADU

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S.CHANDRASEKARAN STAMP VENDOR LIC. No.13832 / 3/93 No.22 ! 6. SAIDAPET ROAD, YADAPALANI, CHENNAI - 600 02

SWORN AFFIDAVIT

I, (Mr.) E. RAMANATHAN, Director, Authorized Signatory, representing the M/s. Omexa Formulary Pvt. Ltd., having its Registered Office at Kalyani Towers, No. 174C, 2nd Avenue, Ashok Nagar, Chennai-600083 for the "Proposed manufacturing of Monoclonal antibodies with Capacity of 520 kg/Annum & formulation products (Syringes & vials) with Capacity of 1,64,000 Lakh/Month" at Plot No. 27 & 28, TANSIDCO Industrial Park, Pellakuppam Village, Tindivanam Taluk, Villupuram District and Tamil Nadu State, hereby take oath and state as under in this affidavit:

I hereby declare that:

- 1. There is no any Court Cases pending against the project and/or land in which the project is
- 2. There is no any Direction issued under EPA Act/Air Act/Water Act from MoEF&CC/ CPCB/TNCPB

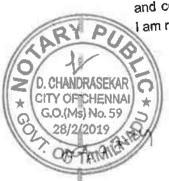
DECLARATION

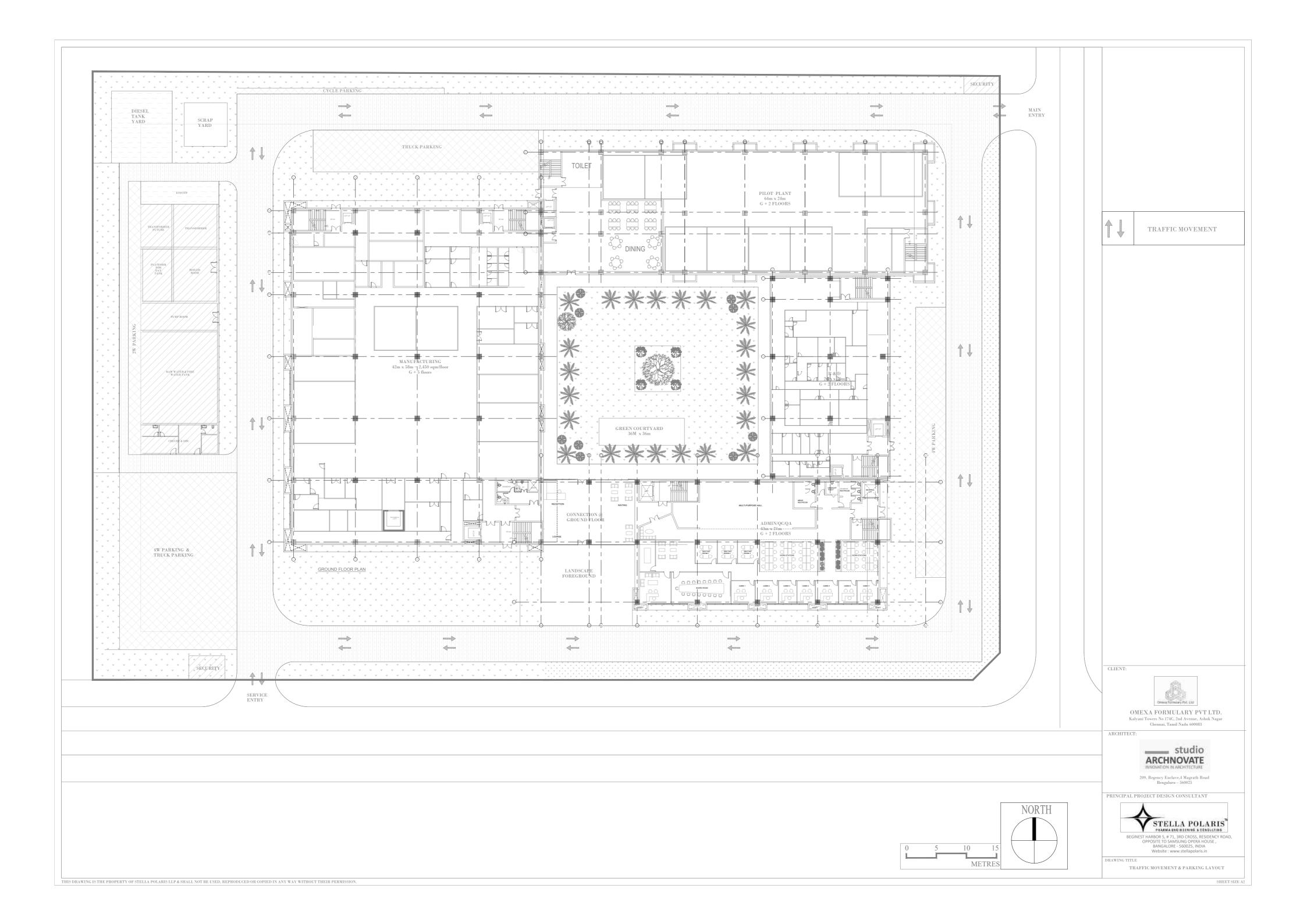
The above-named deponent to hereby verify that the statement made by me under para (1 & 2) is true and correct to the best of my knowledge and belief. Nothing is false and nothing is concealed in it. For Omexa Formulary Pvt. Ltd I am responsible for any misrepresentation of facts.

SIGNED BEFORE ME

Signature of the Affidavimatha Director

09-07-M D. CHANDRASEKAR ADVOCATE & NOTARY PUBLIC COMMISSIONER OF OATHS No.1, Jeevanandam Salai, K.K.Nagar, Chennai - 600 078. Mob: 94444 90972, 97102 03933







S V T V P & Associates LLP Chartered Accountants

Certificate on Projected Value of Fixed Assets

We have examined the below mentioned investment of Biotech Manufacturing unit at TANSIDCO Pharma Industrial Park, Pellakuppam village, Tindivanam Taluk of Omexa Formulary Private Limited for the period from March 2024 to March 2025 as per the prospective project report in accordance with Standard on Assurance Engagement 3400, "The Examination of Prospective Financial Information", issued by the Institute of Chartered Accountants of India;

G N		Projected Value of		
S. No.	Assets	Fixed Assets (Rs. In Crores)		
1	Land	4.00		
2	Building	20.00		
3	Plant & Machinery	42.00		
4	ETP/STP/Utilities	20.00		
5	Other Assets	9.00		
	Total	95.00		

The. Prospective Financial Information forecast including the underlying assumptions, set out in the Prospective Financial Information, is the responsibility of the management and has been approved by the Board of directors of the company. The sources of information are set out in the prospective financial information. Our responsibility is to examine the evidence supporting the forecast. Our responsibility does not include verification of the forecasts. Therefore, we do not vouch for the accuracy of the same.

This forecast has been prepared with a set of assumptions for setting up of new unit in TANSIDCO Pharma Industrial Park Tindivanam by the Board of Directors.

We have carried out our examination of the prospective financial information on a test basis.

Based on our examination of the evidence supporting the assumptions, nothing has come to our attention, which causes us to believe that assumptions do not provide a reasonable basis for the forecast. Further, in our opinion the forecast is properly prepared on the basis of assumptions using appropriate accounting principles.

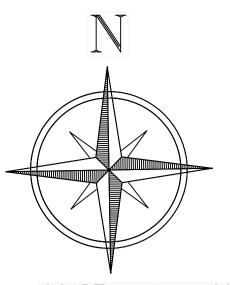
Even if the events anticipated under the hypothetical assumptions described above occur, actual results are still likely to be different from the projection since other anticipated events frequently do not occur as expected and the variation may be material.

For S V T V P & Associates LLP, Chartered Accountants, (Firm Regn No: 019007S / S000033)

Date: 08/05/2024 Place: Chennai S Venkatesh
Partner
M No. 237253

[UDIN: 24237253BKBKRB1323]





SCALE - 1 : 1600 ALL DIMENSIONS ARE IN METER

Plot Details	Area in Acres		
Plot No.1	1.47		
Plot No.2	1.659		
Plot No.3	1.712		
Plot No.4	1.712		
Plot No.5	1.696		
Plot No.6	1.698		
Plot No.7	1.71		
Plot No.7A	1.71		
Plot No.9	1.73		
Plot No.10	1.73		
Plot No.11	1.72		
Plot No.12	1.72		
Plot No.12A	1.73		
Plot No.14	1.73		
Plot No.15	1.73		
Plot No.16	1.73		
Plot No.16A	1.72		
Plot No.18	1.72		
Plot No.19	1.73		
Plot No.20	1.73		
Plot No.21	1.42		
Plot No.22	1.37		
Plot No.23	1.37		
Plot No.24	1.58		
Plot No.25	1.45		
Plot No.25A	1.45		
Plot No.27	1.88		
Plot No.28	1.86		
Plot No.29	1.80		
Plot No.30	2.32		
Plot No.31	2.92		
Plot No.32	0.66		
	3.49		
Plot No.33			
Plot No.34	2.32		
Plot No.34A	1.8		
Plot No.36	1.86		
Plot No.37	1.88		
Plot No.38	1.45		
Plot No.39	1.45		
Plot No.40	0.99		
Plot No.41	0.70		
Plot No.42	1.90		
Plot No.43	2.25		
Plot No.43A	2.36		
Plot No.45	2.36		
Plot No.46	2.36		



TAMILNADU SMALL INDUSTRIES DEVELOPMENT CORPORATION LTD., CHENNAI - 600 032

LAYOUT PLAN OF

TANSIDCO PHARMA INDUSTRIAL PARK AT PELLAKUPPAM, KOLLAR & VENMANIYATHUR VILLAGE TINDIVANAM TALUK VILUPURAM DISTRICT

GENERAL NOTES

TOTAL EXTENT : 113.00Acres D / F ROAD PORTION AREA : (-) 1.53 Acres

SIPCOT LAND A - 18

EXTENT AFTER Deduct SIPCOT Road : 111.47 Acres

ROAD AREA

: 15.70 Acres (14.08%) : 95.77 Acres

Extent After ROAD AREA

: 1.37 Acres (1.23%) PUBLIC PURPOSE (PP) : 3.73Acres (3.35%)

COMMERCIAL PURPOSE (CMP)

: 5.07 Acres (4.55%) ETP & STP PLOTS

: 1.20 Acres (1.08%) : 2.76 Acres (2.48%) **FACILITIES**

: 81.64 Acres (73.23%) SALEABLE INDUSTRIAL AREA

NUMBER OF PLOTS

INDUSTRIAL PLOTS : 46 NOS. COMMERCIAL PURPOSE PLOTS(SHOP) 12 NOS. PUBLIC PURPOSE PLOTS (PP) : 1 NO. **ETP & STP PLOTS** : 1 NO : 1 NO **FACILITIES** : 1 NO TOTAL NO OF PLOTS : 62 NOS.

OPEN SPACE RESERVATION LAND

PUBLIC PURPOSE LAND

COMMERCIAL PURPOSE LAND

SL.NO. F	PP No.	EXTENT IN ACRES	SL.NO.	CMP No.
1 F	PP - 1	1.37 AC	1	CMP - 1
TOTA	\L	1.37 AC	2	CMP - 2
			3	CMP - 3
			4	CMP - 4
			5	CMP - 5
			C	CMD C

SL.NO.	CMP No.	EXTENT IN ACRES		
1	CMP - 1	0.46 AC		
2	CMP - 2	0.40 AC		
3	CMP - 3	0.34 AC		
4	CMP - 4	0.27 AC		
5	CMP - 5	0.21 AC		
6	CMP - 6	0.15 AC		
7	CMP - 7	0.24 AC		
8	CMP - 8	0.20 AC		
9	CMP - 9	0.16 AC		
10	CMP - 10	0.42 AC		
11	CMP - 11	0.62 AC		
12	CMP - 12	0.26 AC		
TOT	AL	3.73 AC		

INDEX:	
	BOUNDARY INTERNAL ROADS
	COMMERCIAL PLOTS
	OPEN SPACE RESERVATION
	PUBLIC PURPOSE
	EXISTING VILLAGE ROAD