

RISK ASSESSMENT

(QRA)

**RISK ASSESSMENT
HAZOP STUDY
ON SITE DISASTER CONTROL PLAN
OFF SITE DISASTER CONTROL PLAN**

For

Proposed API Manufacturing Unit

At

LEVANTEX PHARMACEUTICALS

PLOT NO. A-13, MIDC CHINCHOLI INDUSTRIAL AREA,
TALUKA: MOHOL, DISTRICT: SOLAPUR, MAHARASHTRA - 413 255.

Prepared By

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SECTION 1: EXECUTIVE SUMMARY

There is proposal by M/s. Levantex Pharmaceuticals for manufacturing unit of Intermediates for API on Plot No. A-13, MIDC Chincholi Industrial Area, Taluka: Mohol, District: Solapur, Maharashtra - 413 255.

TABLE NO. 1.1: THE PROPOSED PRODUCTION CAPACITY OF PRODUCTS

SN	NAME OF PRODUCT	CAS NO.	QUANTITY (MTPA)
1	Losartan Potassium.	124750-99-8	120
2	Telmisartan.	144701-48-4	120
3	Gabapentin.	60142-96-3	120
4	Metoprolol Succinate.	98418-47-4	120
5	Paroxetine.	61869-08-7	90
6	Pregabalin.	148553-50-8	120
TOTAL			690

This QRA study towards compliance of TOR requirements for obtaining Environmental Clearance. Risk Assessment Methodology is as per “The Technical EIA Guidance Manual for Synthetic Organic Chemicals”, prepared for “The Ministry of Environment and Forests Government of India”.

Section 2 is devoted for identification of hazards. Hazardous chemicals are identified and Chemicals having the highest NFPA - hazard rating of Health, Flammability and Reactivity are identified.

Applicability of “The Manufacture Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989” and amendments; formed under “The Environment Protection Act, 1986”, checked for inventory and hazardous processes carried out at site. The site is not classified as MAH (Major Accident Hazard installation).

Relative ranking by DOW F&E Index, Fire Index as per MOND Analysis are applied for comparison of hazardous chemicals significant storage installations hazard rating. In addition hazards of any transformation, decompositions, reactivity and compatibility are identified.

HAZOP Study is carried out considering storages, and unit processes and unit operations node. The methodology used is as per “The Hazard Identification and Hazard Analysis Techniques of Hazard Identification and Risk Analysis – Code of Practice IS 15656: 2006”. As an outcome of this identification of hazards exercise worst possible events are listed and used for selection of events for carrying out consequence analysis.

In Section 3 Consequence Analysis are carried out modeling outflow, evaporating pool, burning pool, dispersion down wind, flash fire, vapor cloud explosion, jet fire, BLEVE etc. as relevant for the events under consideration. The event of Hydrogen release followed by dispersion downwind/ fire/ explosion is considered as MCA having potential for serious off site consequence and considered for further quantitative risk estimation. The potential consequences from the hazardous scenarios identified is determined and the impact zones modeled using ALOHA and PHAST software tools.

Apart from the maximum credible releases, the conservative approach appears in adoption of atmospheric conditions, used in the dispersion calculation. In general, the assumptions/ conditions will result in the largest damage distances. Hence, it must be remembered that this analysis will be pessimistic & conservative in approach & is only a planning tool. Its use should not be extended without understanding its limitations.

In Section 4 estimation of the Frequency of the event is carried out by developing the Event Tree. The assessment begins with an initiating event and work toward a final result. This approach is inductive. The method provides information on how a failure can occur and the frequency of occurrence.

In Section 5 the vulnerable zones as estimated during consequence analysis are superimposed on the satellite image of site plan termed as MARPLOT to assess the impact of the proposal on the site activities and surroundings.

Section 6 the individual risk considering employees engaged in site operations is estimated. The site is located in MIDC Industrial Zone. Population density as that of the present project site is assumed in the vulnerable zone and societal risk of fatality is estimated for constructing F-N curve. It should be noted that the risk estimation is for unmitigated risk.

RISK MITIGATION:

A series of risk mitigation measures are suggested in Section No. 8 of the report. These measures are of two types;

- 1) To reduce the probability of undesired event and
- 2) Reducing the severity of the consequences.

As a part of risk mitigation measures in order to address the residual risk after providing risk mitigation measures following disaster control plans are prepared;

- 1) Emergency Preparedness Plan,
- 2) On Site Disaster Control Plan and
- 3) Off Site Disaster Control Plan.

In essence these plans are relevant to emergency level 1, 2 and 3 respectively. The Offsite Disaster Control Plan gives fact sheet and other dove tailing data for further use.

The study reveals that the risk posed by the proposed site activities are at reasonably acceptable level. However, it should be noted it depends heavily upon the maintenance of the hardware and of the management procedures; neglect of either will lead to loss of protection and the rating will rise to the higher level.

DISCLAIMER:

Information contained in this report is believed to be reliable but no representation, guarantee or warranties of any kind are made as to its accuracy, suitability for a particular application or results to be obtained from them. It is up to the manufacturer to ensure that the information contained in the report is relevant to the product manufactured/ handled or sold by him as the case may be. We make no warranties expressed or implied in respect of the adequacy of this document for any particular purpose.

SECTION 2: IDENTIFICATION OF HAZARDS

2.1 IDENTIFICATION OF HAZARD CHECK LIST

IDENTIFICATION OF HAZARD CHECK LIST		PHASE OF THE PROJECT			
Hazard		Pre Construction	Construction	Operation	Post Operation/ Decommissioning
Natural Causes	Cyclone.		√	√	√
	Earth quake.		√	√	√
	Land slide.		√	√	√
	Flooding - heavy rain.		√	√	√
Physical Hazards	Noise.		√	√	√
	Radiation (UV, radioactive materials).	X	X	X	X
	Extreme temperatures.		√	√	√
	Vibration.		√	√	√
	Material handling operations.		√	√	√
	Steam pressure piping failure/ boiler drum failure.			√	
	Boiler explosion.			√	
Bio Hazards	Epidemics/ pandemic e.g. COVID-19/ communicable diseases by pests, insects, rodents etc.		√	√	√
	Animal/ snake bites.		√	√	√
	Occupational health hazards at industry.			√	√
Electrical Hazard	Transformer oil fire/ explosion.		√	√	√
	Lightening strike.	√	√	√	√
	Fires due to short circuit.		√	√	√
	Power outage.		√	√	√
Hazardous Substances And Wastes	Air conditioners, Refrigeration unit gas release/ explosion.		√	√	
	Diesel fire at DG set.		√	√	√
	Foul odor at dumping sites.		√	√	√
	Hazardous waste uncontrolled disposal.		√	√	√
	Hazardous waste uncontrolled disposal; e –waste batteries.		√	√	√
	Welding cutting flammable gas cylinders fire/ explosion.		√	√	√
	Fuel cylinder at canteen failure fire/ explosion.	√	√	√	√
	Release of toxic gas at cooling tower.			√	
	Site decontamination.	√	√	√	√
	Smoke in fire, acrid gases in fire, dumping yard.			√	√
	Vehicles fuel fire.	√	√	√	√
Mechanical	Failure of machinery and equipment.		√	√	√
	Lack of safety guards in machines.		√	√	√
	Poor maintenance of machinery and equipment.		√	√	√
	Power driven tools, saws, grinders, abrasive cutting wheels.		√	√	√
	Scaffolding – fixed and portable failure.		√	√	√
	Structural failure.		√	√	√
	Truck and transport vehicles.		√	√	√

IDENTIFICATION OF HAZARD CHECK LIST		PHASE OF THE PROJECT			
Hazard		Pre Construction	Construction	Operation	Post Operation/ Decommissioning
Storages & Process Operations	Spill of solvents at tank farm leading to fire/ explosion.			√	√
	Uncontrolled reaction exotherm pressurization/ explosion.			√	√
	Static charge as source of ignition leading to fire/ explosion.			√	√
	Hydrogen Chloride gas release at vent.			√	√
	Dust explosion.			√	√
	Hazardous waste spill hazard.			√	√
	Compatibility and reactivity hazard at chemical store.			√	√
Frequent Causes Of Accidents During Construction Activity	Being struck by falling object.		√	√	√
	Caught in or compressed.		√	√	√
	Cranes, winches, hoisting and hauling equipments failure.		√	√	√
	Dusting.		√	√	√
	Electricity (electrocution).		√	√	√
	Fall from height.		√	√	√
	Uncontrolled explosion during demolition/ land development.		√		√
	Hit by sharp objects.		√		√
	Injuries during handling heavy objects.		√		√
	Lack of PPE, housekeeping practices, safety signs.		√	√	√
	Oxygen deficiency in confined spaces.			√	√
	Paint/ thinner cleaners, pesticides, waste oil, flammable combustible materials fire at store.		√	√	√
	Poor illumination.		√	√	√
	Slipping on wet surfaces.		√		√
	Snapping cables, ropes, chains, slings, hooks, chains.		√	√	√
Ergonomics & Psychosocial Hazards	Struck by moving objects.	√	√	√	√
	Welding fumes and radiations.		√		√
	Repetitive, monotonous, excessive workload, strain injuries.		√	√	
	Mental stress, human relations (aggressive behavior, alcohol and drug abuse, violence).		√	√	√
	Poverty, low wages, lack of education.		√	√	√
	Long working hours, shift work, temporary employment.		√	√	√
	Security threats.				

IDENTIFICATION OF HAZARD CHECK LIST		PHASE OF THE PROJECT			
Hazard		Pre Construction	Construction	Operation	Post Operation/ Decommissioning
Occupational Health	Coal and ash dust, liquid fuels exposure.			√	√
	Injuries from rotating equipments and material handling.		√	√	√
	Fall from height.		√	√	√
	Burn from steam leakages and hot surfaces.		√	√	
	Reduced lung functioning.		√	√	
	Confined space entry.		√	√	√
	Exposure to toxic vapors, volatile toxicants.		√	√	√
	Exposures to noise.		√	√	√
	Road accidents.	√	√	√	√
Others	Escalating the designed event during Mock Drill.		√	√	√
	Power outage to emergency equipments/ cable failure.		√	√	√
	Stampede during evacuation at assembly point.		√	√	√
	Spreading rumors.	√	√	√	√
	Organic contaminated water generated during fire fighting operations, sprinkler operation, spill/ floor washing may enter storm drain.		√	√	√

FIGURE NO. 2.1: SITE PLAN



SN.	Installation	Area	SN.	Installation	Area
1	Guardhouse.	18.00	13.	Area Under Road.	3261.85
2	Office.	337.50	14.	Rain Water Harvesting Tank.	25.00
3	Work Shed 1 (Utility Block).	230.12	15.	Fire Water Storage Area.	80.00
4	Work Shed 2 (Warehouse).	240.16	16.	ETP.	140.98
5	Work Shed 3 (Production Block).	181.80	17.	Parking For Truck.	50.35
6	Work Shed 4 (Production Block).	354.60	18.	Air Pollution Control Equipment.	84.00
7	Work Shed 5 (Warehouse).	237.77	19.	Coal Storage Area.	106.00
8	Work Shed 6 (Production Block).	300.00	20.	Hazardous Waste & Ash Storage	148.51
9	Future Expansion Area.	361.22	21.	Boiler Area And Stack.	117.48
10	Parking Area.	1504.00	22.	Hydrogen Storage.	34.50
11	Green Belt.	5582.79	23.	Acid Storage Tank.	76.12
12	Pavers Area.	875.15	24.	Solvent Storage Tank.	302.10

2.2 HAZARDOUS CHEMICALS

TABLE NO. 2.1: FLAMMABILITY HAZARD MATERIAL

SN.	Name	CAS NO.	LEL	UEL	Flash Point	Boiling Point	NFPA Hazard Index
			%	%	°C	°C	N _f
1	Hydrogen.	1333-74-0	4	75	gas	gas	4
2	Methyl Tertiary Butyl Ether.	1634-04-4	2	15	-33	55	3
3	Diethylamine.	109-89-7	1.8	10.1	-28	55	3
4	Di Iso Propyl Ether.	108-20-3	1.4	7.9	-26	68.5	3
5	Hexane.	110-54-3	1.2	7.7	-23	55	3
6	Acetone.	67-64-1	2.2	13	-17.7	56.48	3
7	Tetra Hydro Furan.	109-99-9	2	11.8	-14.5	66	3
8	Ethyl Acetate.	141-78-6	2	11.5	-4	77	3
9	Acetonitrile.	75-05-8	4.4/3	16	5.6/2	82	3
10	Methanol.	67-56-1	6	36.5	11	64.7	3
11	Iso Propyl Alcohol.	67-63-0	2.3	12.7	12	82	3
12	N,N-Diisopropyl Ethylamine.	7087-68-5	3	17	12	127	3
13	Toluene.	108-88-3	1.27	7.1	12.7	110.4	3
14	Ethyl Alcohol.	64-17-5	3.3	19	13	79	3
15	Epichlorohydrin.	106-89-8	3.8	21	31	116	3
16	Xylene.	1330-20-7	1	7	32	144	3
17	Raney Nickel.	7440-02-0	NA	NA	*	-	4

* Spontaneously combustible.

NFPA 704M - Hazard Index, Scale 1 to 4 (N_f – Flammability)	
0	Materials which will not burn.
1	Slightly combustible. Materials that require considerable preheating before ignition can occur. This rating includes most ordinary combustible materials.
2	Combustible. Materials that must be moderately heated before ignition can occur. Including liquids having a flash point above 100 degrees F and solids that readily give off flammable vapors.
3	Flammable. Liquids and solids that can be ignited under almost all ambient temperature conditions. Including liquids with a flash point below 73 degrees F and a boiling point above 100 degrees F, solid materials which form coarse dusts that burn rapidly without becoming explosive, materials which burn rapidly by reason of self-contained oxygen (i.e. organic peroxides), and materials which ignite spontaneously when exposed to air.
4	Extremely flammable. Materials which will rapidly vaporize at normal pressure and temperature and will burn readily. Including gases, cryogenic materials, any liquid or gaseous material having a flash point below 73 degrees F and a boiling point below 100 degrees F, and materials which can form explosive mixtures with air.

TABLE NO. 2.1A: TOP FIVE - LOWEST BOILING POINT LIQUIDS

SN.	NAME	CAS NUMBER	BOILING POINT (°C)
1	Dichloromethane.	75-09-2	40
2	Methyl Tertiary Butyl Ether.	1634-04-4	55
3	Hexane.	110-54-3	55
4	Diethylamine.	109-89-7	55
5	Acetone.	67-64-1	56.48
6	Methanol.	67-56-1	64.7

TABLE NO. 2.1B: TOP FIVE - WIDEST FLAMMABILITY RANGE MATERIALS

SN.	NAME	CAS NUMBER	LEL (%)	UEL (%)	RANGE
1	Hydrogen.	1333-74-0	4	75	71
2	Methanol.	67-56-1	6	36.5	30.5
3	Epichlorohydrin.	106-89-8	3.8	21	17.2
4	Ethyl Alcohol.	64-17-5	3.3	19	15.7
5	Methyl Tertiary Butyl Ether.	1634-04-4	2	15	13.0
6	Acetonitrile.	75-05-8	4.4/3	16	11.6
7	Acetone.	67-64-1	2.2	13	10.8

TABLE NO. 2.2: TOXICITY HAZARD MATERIALS

SN.	Name	CAS NO.	Oral LD ₅₀	Dermal LD ₅₀	Inhal. LC ₅₀	NFPA Hazard Index
			mg/kg	mg/kg	ppm	N _h
1	Epichlorohydrin.	106-89-8	90	515	250	4
2	Phosphorous Oxy Chloride.	10025-87-3	380	NA	32	3
3	Sulphuric Acid.	7664-93-9	2140	250 µg	510 mg/m ³	3
4	Potassium Hydroxide.	1310-58-3	273	NA	NA	3
5	N,N-Diisopropyl Ethylamine.	7087-68-5	317	>2000	2.63 mg/l	3
6	Diethylamine.	109-89-7	540	820	4000	3
7	Chloroform.	67-66-3	908	NA	NA	2
8	Dichloromethane.	75-09-2	1600	NA	NA	2
9	Succinic Acid.	110-15-6	2260	NA	NA	2
10	Acetonitrile.	75-05-8	2460	NA	NA	2
11	Hydrochloric Acid.	7647-01-0	3124	900	NA	3
12	Xylene.	1330-20-7	4300	NA	5 mg/m ³	2
13	Acetic Acid.	64-19-7	5620	3310	5620	2
14	Iso Propyl Alcohol (IPA).	67-63-0	5840	NA	100 mg/l	2
15	Di Iso Propyl Ether (DIPE).	108-20-3	8470	20	162 mg/m	2

NFPA 704M - Hazard Index, Scale 1 to 4 (N _h – Health)	
0	No chemical is without some degree of toxicity.
1	Slightly toxic material. May cause irritation, but only minor residual injury even without treatment. Recognized innocuous materials when used with responsible care.
2	Moderately toxic material. Intense or continued exposure could cause temporary incapacitation or possible residual injury unless prompt medical treatment is given.
3	Seriously toxic material. Short term exposure could cause serious temporary or residual injury even though prompt medical treatment is given. Includes known or suspect small animal carcinogens, mutagens or teratogen.
4	Highly toxic material. Very limited exposure could cause death or major injury even though prompt medical treatment is given. Includes known or suspect human carcinogens, mutagens or teratogen.

TABLE NO. 2.3: TOP TEN - REACTIVITY HAZARD MATERIALS

SN.	Name	CAS NO.	NFPA Hazard Index		Material Factor
			N _f	N _r	
1	Benzoyl Peroxide.	94-36-0	4	4	40
2	Epichlorohydrin.	106-89-8	3	2	24
3	Phosphorous Oxy Chloride.	10025-87-3	0	2	24
4	Sulphuric Acid.	7664-93-9	0	2	24
5	Hydrogen.	1333-74-0	4	0	21
6	Tetra Hydro Furan.	109-99-9	3	1	16
7	Acetonitrile.	75-05-8	3	0	16
8	Ethyl Acetate.	141-78-6	3	0	16
9	Hexane.	110-54-3	3	0	16
10	Ethyl Alcohol.	64-17-5	3	0	16
11	Toluene.	108-88-3	3	0	16
12	Potassium Hydroxide.	1310-58-3	0	1	14

Material Factor Scale 1 to 40.

NFPA 704M - Hazard Index, Scale 1 to 4 (N _r – Reactivity)	
0	Materials which are normally stable, even under fire conditions, and which are not reactive with water.
1	Materials which are normally stable, but which can become unstable at elevated temperatures and pressures, or which may react with water with some release of energy, but not violently.
2	Materials which in themselves are normally unstable and readily undergo violent chemical change, but do not detonate. It includes materials which may react violently with water or which may form potentially explosive mixtures with water.
3	Materials which in themselves are capable of detonation but which require a strong initiating source, or which must be heated first. This rating includes materials which are shock sensitive at elevated temperatures, and which react explosively with water without requiring heat.
4	Materials which in themselves are readily capable of detonation or explosive decomposition at normal temperatures and pressures. Includes materials which are shock sensitive at normal temperatures and pressures.

2.3 INVENTORY ANALYSIS

TABLE NO. 2.4: INVENTORY

SN.	Name	CAS Number	Location	Mode of Storage	Max. Qty. Stored (MT)
1	1,1-Cyclohexane di acetic Acid Monoamide.	99189-60-3	Warehouse	Drum	4.00
2	4-(2-Methoxyethyl) Phenol.	56718-71-9	Warehouse	Drum	1.63
3	4-(bromomethyl) biphenyl-2 carboxylic acid methyl ester.	114772-38-2	Warehouse	Drum	1.67
4	4-Methyl-6-(1-methyl-1H-benzoimidazol -2-yl)-2-propyl-1H-benzo imidazole.	152628-02-9	Warehouse	Drum	1.67
5	Acetic Acid.	64-19-7	Acid Tank Farm	Tank	6.64
6	Acetone.	67-64-1	Solvent Godown	Drum	3.77
7	Acetonitrile.	75-05-8	Solvent Godown	Drum	0.18
8	Activated Carbon.	7440-44-0	Warehouse	Drum	1.38
9	Aq. Ammonia.	1336-21-6	Warehouse	Drum	0.83
10	Benzene Sulfonyl Chloride.	98-09-9	Warehouse	Drum	1.52
11	Benzoyl Peroxide.	94-36-0	Warehouse	Drum	3.45
12	Chloroform.	67-66-3	Warehouse	Drum	0.30
13	Citric Acid.	77-92-9	Warehouse	Bag	1.25
14	Coal (18.4 TPD).	NA	Coal yard	Open	
15	Di Methyl Malonate.	108-59-8	Warehouse	Drum	1.85
16	Di Ethyl Amine.	109-89-7	Solvent Godown	Drum	0.63
17	Diisopropyl Ether.	108-20-3	Solvent Godown	Drum	0.33
18	Dimethyl Dibromo Hydantoin.	77-48-5	Warehouse	Drum	2.28
19	Dimethyl Sulfoxide.	67-68-5	Tank farm	Tank	9.20
20	Epichlorohydrin.	106-89-8	Solvent Godown	Drum	2.03
21	Ethanol.	64-17-5	Solvent Tank Farm	Tank	20
22	Ethyl Acetate.	141-78-6	Solvent Godown	Drum	0.58
23	Heptane.	142-82-5	Solvent Godown	Drum	1.25
24	Hexane.	110-54-3	Solvent Godown	Drum	0.28
25	Hiflow.	68855-54-9	Warehouse	Drum	0.10
26	HSD for D.G Set (107.5 l/hr).	68476-34-6	Utility	Drum	
27	Hydrochloric Acid.	7647-01-0	Acid Tank Farm	Tank	5.74
28	Hydrogen.	1333-74-0	Hydrogen shed	7 m ³ Cylinder	7 nos.
29	Hyflo Super Cell.	68855-54-9	Warehouse	Drum	3.88
30	Industrial Methylated Spirit.	64-17-5 67-56-1	Solvent Godown	Drum	0.50
31	Isopropyl Alcohol.	67-63-0	Tank Farm	Tank	20
32	Isopropyl Amine.	110-91-8	Solvent Godown	Drum	2.63
33	Isovaleraldehyde.	590-86-3	Warehouse	Drum	1.03
34	L(-) di-p-Toluoyl Tartaric acid.	32634-66-5	Warehouse	Drum	3.33
35	Liq. NH ₃ .	1336-21-6	Warehouse	Drum	0.78
36	Lithium Aluminium Hydride in Tetrahydro Furan (30%).	16853-85-3 109-99-9	Solvent Godown	Drum	2.14
37	Mandelic Acid.	90-64-2	Warehouse	Drum	0.33
38	Methanol.	67-56-1	Tank Farm	Tank	20
39	Methyl Tertiary Butyl Ether.	1634-04-4	Solvent Godown	Drum	0.78
40	Methylene Dichloride.	75-09-2	Tank farm	Tank	20
41	Methylene Dichloride.	75-09-2	Warehouse	Drum	0.88

SN.	Name	CAS Number	Location	Mode of Storage	Max. Qty. Stored (MT)
42	Methyl-N-Methylamino Malonate.	71510-95-7	Warehouse	Drum	2.43
43	Morpholine.	110-91-8	Warehouse	Drum	0.20
44	N,N-Diisopropyl Ethyl Amine.	7087-68-5	Solvent Godown	Drum	0.95
45	Ortho Toly Benzonitrile.	157366-46-6	Warehouse	Drum	3.78
46	P-Fluorobenzaldehyde.	459-57-4	Warehouse	Drum	2.30
47	Phenyl Chloroformate.	1885-14-9	Warehouse	Drum	1.15
48	Potassium Hydroxide	1310-58-3	Warehouse	drum	2.81
49	2-Propanol.	67-63-0	Solvent Godown	Drum	0.78
50	Raney Nickel.	7440-02-0	Warehouse	Drum	1.03
61	Sesamol.	533-31-3	Warehouse	Drum	1.19
62	Sodium Azide.	26628-22-8	Warehouse	Drum	3.18
63	Sodium Bi Carbonate Solution.	144-55-8	Warehouse	Drum	3.10
64	Sodium Borohydride.	16940-66-2	Warehouse	Drum	0.13
65	Sodium Chloride.	7647-14-5	Warehouse	Drum	2.62
66	Sodium Cyanide.	143-33-9	Warehouse	drum	0.50
67	Sodium Hydroxide.	1310-73-2	Tank farm	Tank	8.70
68	Sodium Hypochlorite.	7681-52-9	Warehouse	Drum	1.50
69	Sodium Methoxide.	124-41-4	Warehouse	drum	1.00
70	Succinic Acid.	110-15-6	Warehouse	Drum	0.50
71	Sulphuric Acid.	7664-93-9	Warehouse	Drum	1.65
72	TBAI (Catalyst).	1643-19-2	Warehouse	Drum	0.05
73	Tetra Hydro Furan (THF).	109-99-9	Solvent Godown	Drum	0.10
74	Tetra-n-octyl Ammonium Bromide.	14866-33-2	Warehouse	Drum	0.08
75	THF.	109-99-9	Solvent Godown	Tank	13.98
76	Toluene.	108-88-3	Tank Farm	Tank	7.75
77	Tri Ethyl amine.HCl.	554-68-7	Warehouse	Drum	5.45
78	Trityl Chloride.	76-83-5	Warehouse	Drum	5.95
79	Xylene.	1330-20-7	Solvent Godown	Drum	0.63

Temperature ambient from 20 to 40 °C (annual variation) for both storage installations.

TABLE NO. 2.5: APPLICABILITY OF MSIHC RULES 1989 & AMENDMENTS

Group		Material	Max. Storage Capacity (Mt.)	*Threshold Qty. Mt. For application of Rule	
				5, 7-9 & 13-15	10 - 12
3	Highly Reactive Chemicals.	Hydrogen.	Less than threshold*	2	50
5.3	Very Highly Flammable Liquids.	Chemicals having flash point $\leq 23^{\circ}\text{C}$ & boiling point $< 35^{\circ}\text{C}$.	Less than threshold*	1500	10000
5.5	Highly Flammable Liquids.	Chemicals having $23^{\circ}\text{C} < \text{flash point} \leq 60^{\circ}\text{C}$	Less than threshold*	2500	20000
5.6	Flammable Liquids.	Chemicals having $60^{\circ}\text{C} < \text{flash point} < 90^{\circ}\text{C}$	Less than threshold*	5000	50000

The site is not Major Accident Hazards (MAH) installation.

2.4 RELATIVE RANKING

2.4.1 DOW F&E Index:

Identification of hazardous units and segments of plants and storage units based on “**relative ranking technique**”, such as Fire and Explosion Index. F & EI, is a method universally adopted for classifying/ categorizing/ indexing of chemicals based on their reactivity and instability. The more widely used hazard index is the F & EI developed by DOW Chemical Company. DOW Fire and Explosion Index (F&EI) guide (Seventh Edition) is used.

TABLE NO. 2.6: DOW F & E INDEX

SN.	Installation	DOW F&E Index	The Degree Of Hazard	Radius Of Exposure (m)	Damage Factor	Toxicity Index	Toxicity Category
1	Hydrogen.	50	Light	12.8	0.51	-	-
2	Toluene.	38	Light	9.8	0.36	4.73	I

2.4.2 MOND Index Assessment:

The MOND Index is a rapid hazard assessment method for use on chemical plant or in plant design. The use of this technique puts the hazard of a plant on a numerical scale, where the comparative pictures of all subdivisions of the plant form emerge. The assessment is carried out as per MOND INDEX Manual 1993.

TABLE NO: 2.7 MOND INDEX ASSESSMENT

SN.	Installation	Fire Index	Internal Explosion Index	Aerial Explosion Index	Over All Hazard Rating
1	Hydrogen	Light	Moderate	Low	Low
2	Toluene	Light	Moderate	Light	Moderate

The hazard indicated by this assessment depends heavily upon the maintenance of the hardware and of the management procedures.

2.5 COMPATIBILITY/ REACTIVITY HAZARD

TABLE NO. 2.8: COMPATIBILITY/ REACTIVITY HAZARD CHART

SN.	Chemical Mixed With →	1	2	3	4	5	6	7	8	9
1	Ammonium Hydroxide.									
2	Benzoyl Peroxide.	N								
3	Chloroform.	C	C							
4	Dichloromethane.	C	C	Y						
5	Phosphorus Oxychloride	N	N	Y	Y					
6	Sodium Bicarbonate.	C	N	C	C	C				
7	Sodium Hypochlorite.	N	N	N	N	N	C			
8	Sulfuric Acid.	N	N	N	N	N	N	N		
9	Water.	C	C	C	C	N	C	N	C	

CHART LEGEND:

Y	Compatible	-	No hazardous reactivity issues expected.
N	Incompatible	-	Hazardous reactivity issues expected.
C	Caution	-	May be hazardous under certain conditions.
SR	Self Reactive	-	Potentially self reactive e.g. polymerizable.

(Incompatibility implies as the equimolar mixing of two materials under ambient temperature and pressures that will produce heat (10 Kcal per mole), gases, or other real and immediate hazards).

RISK MITIGATION:

- Storage of chemicals considering the compatibility and reactivity hazards.
- Provision of smoke detector at warehouses.

2.6 DECOMPOSITION/ TRANSFORMATION PRODUCTS

TABLE NO. 2.9: TRANSFORMATION - IF ANY, WHICH COULD OCCUR

SN.	NAME	DECOMPOSITION /COMBUSTION PRODUCTS
1	Epichloro Hydrin.	The substance will polymerize due to heating or under the influence of strong acid(s), base(s). On combustion, forms toxic and corrosive fumes, Hydrogen Chloride and Chlorine fumes. Attacks steel in the presence of water.
2	Sulphuric Acid.	Contact with most metals causes formation of flammable and explosive Hydrogen gas. Toxic fumes of oxides of Sulfur when heated to decomposition. Will react with water or steam to produce toxic and corrosive fumes.
3	Benzoyl Peroxide.	May explosively decompose on shock, friction, or concussion. May explode on heating above 103-105°C. On combustion, forms irritating and toxic fumes and gases of benzoic acid and Carbon Monoxide .

2.7 SOLVENT HAZARDS

TABLE NO. 2.10: SOLVENT HAZARDS

Sr. No.	Solvent	Waste recycling incineration VOC & bio treatment issues	Environment Impact fate and effect on the environment	Health acute & chronic effect on human health and exposure potential	Flammability & Explosion Storage and handling	Reactivity Stability Factors affecting the stability of the Solvent	Life Cycle Score Environmental impact to produce the solvent
1	Acetone.	3	9	8	4	9	7
2	Acetonitrile.	2	6	6	6	10	3
3	Chloroform.	3	6	3	6	9	6
4	MDC.	3	6	4	6	9	7
5	Ethanol.	3	8	8	6	9	9
6	Ethyl Acetate.	4	8	8	4	8	6
7	Hexane.	5	3	4	2	10	7
8	IPA.	3	9	8	6	8	4
9	Methanol.	4	9	5	5	10	9
10	THF.	3	5	6	3	4	4
11	Toluene.	6	3	4	4	10	7
12	Xylene.	7	2	6	5	10	7

Scale 1 to 10	1	2	3	4	5	6	7	8	9	10
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2.8 OCCUPATIONAL HEALTH HAZARD

An occupational hazard is a hazard experienced in the workplace. Occupational hazards can encompass many types of hazards, including chemical hazards, biological hazards (biohazards), psychosocial hazards, and physical hazards. Occupational hazard as a term signifies both long-term and short-term risks associated with the workplace environment.

TABLE NO. 2.11: EXPOSURE HAZARDS

Sr. No.	NAME	CAS NUMBER	TLV	STEL	IDLH
			ppm	ppm	ppm
1	Epichlorohydrin.	106-89-8	0.5	1.5	75
2	Chloroform.	67-66-3	10	NA	NA
3	Di Ethyl Amine.	109-89-7	5	15	NA
4	Iso Propyl Amine.	110-91-8	5	NA	NA
5	Acetic Acid.	64-19-7	10	15	NA
6	Morpholine.	110-91-8	20	NA	NA
7	Dichloromethane.	75-09-2	50	125	NA
8	Toluene.	108-88-3	50	500	500
9	Xylene.	1330-20-7	100	150	-
10	Methanol.	67-56-1	200	250	-

TABLE NO. 2.12: CARCINOGENIC HAZARDS

Name	CAS	IARC International Agency for Research on Cancer	
Chloroform.	67-66-3	2B	The chemical, group of chemicals, industrial process or occupational exposure is possibly carcinogenic to humans.
Epichlorohydrin.	106-89-8	2A	The chemical, group of chemicals, industrial process or occupational exposure is probably carcinogenic to humans.

2.9 LABORATORY CHEMICALS

There is large number of laboratory chemicals. Any accidental mix up of the chemicals may lead to unsafe condition, smoldering, fire, explosion depending upon the chemicals involved.

Segregate the laboratory chemicals while storage on storage racks considering functional groups compatibility and reactivity hazards.

2.10 HAZOP STUDY

- 2.10.1 The methodology used as per Hazard Identification and Hazard Analysis Techniques of Hazard Identification and Risk Analysis – Code of Practice IS 15656: 2006.
- 2.10.2 Identification of hazards by HAZOP Study is carried out for nodes listed in Table No. 2.14. HAZOP Study report is enclosed separately.
- 2.10.3 Each identified hazards/ events/ accident scenarios are evaluated considering on severity (S) and Probability (P) of the event on the scale 1 to 5. Hazard risk rating is evaluated for each identified hazard on the scale 1 to 25 using the hazard rating matrix given in Table No. 2.13 resulting in risk (R).

TABLE NO: 2.13 HAZARD RISK RATING MATRIX

	SEVERITY						
PROBABILITY			Very High 5	High 4	Moderate 3	Slight 2	Nil 1
	Very Likely.	5	25	20	15	10	05
	Likely.	4	20	16	12	08	04
	Quite Possible.	3	15	12	09	06	03
	Possible.	2	10	08	06	04	02
	Not Likely.	1	05	04	03	02	01

TABLE NO. 2.14: NODES FOR HAZOP STUDY

NODE 1	:	Tank Farm & Ware House.
NODE 2	:	Losartan Potassium.
NODE 3	:	Telmisartan.
NODE 4	:	Gabapentin.
NODE 5	:	Metoprolol Succinate.
NODE 6	:	Paroxetine.
NODE 7	:	Pregabalin.

TABLE NO. 2.15: PRODUCT WISE - RAW MATERIALS

Type	Name Of Raw Material	Telmisartan	Losartan Potassium	Pregabalin	Metoprolol Succinate	Gabapentine	Paroxetine
Reactant	4 - (bromomethyl) biphenyl-2 Carboxylic Acid Methyl Ester.	X					
Reactant	4-Methyl-6-(1-methyl-1H-benzoimidazol-2-yl)-2-propyl-1H-benzo imidazole.	X					
Reactant	Aq. Ammonia.	X		X			
Reactant	Potassium Hydroxide.	X		X			
Reactant	Sodium Azide.		X				
Reactant	Sodium Borohydride.		X				
Reactant	Sulphuric Acid.		X				
Reactant	Benzoyl Peroxide.		X				
Reactant	Dimethyl Dibromo.		X				
Reactant	Ortho Toly Benzotrile.		X				
Reactant	Sodium Hydroxide.		X		X	X	X
Reactant	Tri Ethyl Amine.HCl.		X				
Reactant	Trityl Chloride.		X				
Reactant	Hydrochloric Acid.			X		X	X
Reactant	Hydrogen.			X			
Reactant	Sodium Cyanide.			X			
Reactant	Di Methyl Malonate.			X			
Reactant	Di Methyl Sulfonide.			X			
Reactant	Isovaleraldehyde.			X			
Reactant	Mandelic Acid.			X			
Reactant	Morpholine.			X			
Reactant	Sodium Bi Carbonate Solution.			X			
Reactant	4-(2-Methoxyethyl).				X		
Reactant	Epichlorohydrin.				X		
Reactant	Iso Propyl Amine.				X		
Reactant	Succinic Acid.				X		
Reactant	1,1-Cyclohexanediactic Acid Monoamide					X	
Reactant	Sodium Hypochlorite.					X	
Reactant	Sodium Methoxide.						X
Reactant	Tetra-n-octylammonium Bromide.						X
Reactant	Benzene Sulfonyl Chloride.						X
Reactant	Citric Acid.						X

Type	Name Of Raw Material	Telmisartan	Losartan Potassium	Pregabalin	Metoprolol Succinate	Gabapentene	Paroxetine
Reactant	Diethylamine.						X
Reactant	L(-) di-p-Toluoyl Tartaric acid.						X
Reactant	Lithium Aluminium Hydride in Tetra Hydro Furan (30%).						X
Reactant	Methyl-N-Methylamino malonate.						X
Reactant	P-Fluorobenzaldehyde.						X
Reactant	Phenyl Chloroformate.						X
Reactant	Sesamol.						X
Catalyst	Raney Nickel.			X			
Catalyst	TBAI (Catalyst).		X				
Solvent	Acetic acid.		X	X			X
Solvent	Acetone.	X			X		X
Solvent	Acetonitrile.		X				
Solvent	Chloroform.		X				
Solvent	Diisopropyl Ether.		X				
Solvent	Ethanol.			X			
Solvent	Ethyl Acetate.		X		X		X
Solvent	Heptane.						X
Solvent	Hexane.			X			
Solvent	Iso Propyl Alcohol.			X	X		X
Solvent	Methanol.	X	X	X			
Solvent	Methyl Tertiary Butyl Ether.			X			
Solvent	Methylene Di Chloride (MDC).			X		X	X
Solvent	N,N-Diisopropyl Ethylamine.						X
Solvent	2- Propanol.						X
Solvent	Tetra Hydro Furan (THF).			X			X
Solvent	Toluene.		X				X
Solvent	Xylene.		X				
Solvent	Industrial Methylated Spirit.						X
Others	Activated Carbon.			X		X	
Others	Sodium Chloride.			X			X
Others	Hyflo Super Cell.	X	X	X			
Others	Water.	X	X	X	X	X	X

2.10.4 Hazard are identified and risk evaluated for each identified hazard on the scale 1 to 25 using the hazard rating matrix given in table 2.13. Top ten identified hazards/ events / accident scenarios having risk rating in 16 to 25 ranges are as follows:

TABLE NO. 2.16: TOP TEN – IDENTIFIED HAZARDS

SN.	Hazard	Severity	Probability	Risk Level
1	Release of Hydrogen gas release followed by fire/ explosion.	5	4	20
2	Spill of Toluene followed by pool fire.	4	4	16
3	Release of Hydrogen Chloride gas in case of scrubber failure followed by dispersion downwind.	4	4	16
4	Reaction exotherm leading to run away reaction, explosion hazard.	4	4	16
5	Static charge accumulation to dangerous level in handling of flammable solvents, fire hazard.	5	4	20
6	Reactivity and compatibility hazards due to accidental spill and mixup at tank farm/ ware house.	4	4	16
7	Health hazard due to minor leaks/ fugitive emissions at work place.	4	4	16
8	Release of decomposition production during fire condition.	4	4	16
9	Hazardous waste involving Transport mishap.	4	4	16
10	Natural hazards like flood, cyclone earth quake.	5	4	16

- Estimate is before applying any risk mitigation measures.

2.10.5 RISK MITIGATION;

As a outcome of HAZOP study changes suggested in process and storage and site operations;

1. In the product Lasartan Potassium manufacturing process sodium bromide is generated. Consider recovery of sodium bromide as by product
2. In the product Gapentene manufacturing process stage 2 Hydrogen Chloride gas is generated. Provide scrubber for recovery of Hydrochloric Acid as by-product.
3. In the product Gapentene manufacturing process stage 1, Carbon Di Oxide is released at vent. Provide caustic scrubber to eliminate emission of Carbon Di Oxide to atmosphere.
4. In view of safe handling of Sodium Cyanide. Provide lock and key arrangement for storage of Sodium Cyanide storage.
5. In the product Pregabalin manufacturing process ensure that any unreacted Sodium Cyanide is completely destroyed from effluent before sending it to ETP.
6. Avoid organic contaminated water generated during fire fighting operation, sprinkler operation, floor washing entering storm water drain. Provide containment arrangement of fire water runoff, testing and safe disposal.

7. Consider storage of chemicals considering compatibility and reactivity hazards especially for storage of Benzoyl Peroxide.
8. Consider second exit for the site.
9. Relocation of fire water storage and pump house near main gate for easy access for external fire fighting agencies.
10. In the product Paroxetine manufacturing process stage 2, Oxygen is released to atmosphere through vent. At the vent at Oxygen rich atmosphere is potential for fire/ explosion hazard as the decreased MIE of materials in that area. Locate the vent to safe place.

2.10.6 Accident scenarios considered for consequence analysis.

- 1. Release of Hydrogen followed by fire/ explosion.**
- 2. Release of Hydrogen Chloride due to scrubber failure.**
- 3. Release of Toluene followed by pool fire/ explosion.**

2.11 PANDEMIC - CORONAVIRUS DISEASE (COVID-19)

Symptoms: People may experience:

- Cough.
- Fever.
- Difficulty breathing (severe cases).

In more severe cases infection can cause pneumonia, severe acute respiratory syndrome, and even death. The period within which the symptoms would appear is 2-14 days.

Using available preliminary data, the median time from onset to clinical recovery for mild cases is approximately 2 weeks and is 3-6 weeks for patients with severe or critical disease.

SECTION 3: CONSEQUENCE ANALYSIS

3.1 INTRODUCTION

The accident scenarios as identified during HAZOP study are divided in two categories considering the consequence seriousness and occurrence frequency.

- MAXIMUM CREDIBLE LOSS SCENARIO (MCLS).
- WORST POSSIBLE SCENARIO.

MAXIMUM CREDIBLE LOSS SCENARIO (MCLS)

Maximum Credible Loss Scenario (MCLS) is one of the methodologies evolved to access the events in realistic and practical way. An MCLS can be described as the worst “credible” accident or as an accident with a maximum damage distance, which is still believed to be probable. Minor Leaks from hose/ piping failure are quite probable events. Such accidental release is considered as MCLS.

WORST POSSIBLE SCENARIO

Worst Case Scenario/ MCA (Maximum Credible Accident) Accident Scenario accidental release of Chlorine release, dispersion downwind is considered as Worst Case Scenario/ MCA (Maximum Credible Accident).

3.2 RESULTS

TABLE NO. 4.1A: AFFECT DISTANCE (DISPERSION)

SN.	ACCIDENT SCENARIO	DOWNWIND AFFECT DISTANCE (M)					
		Toxic Vapor Cloud				Flammable Vapor Cloud	
		PAC 3	PAC 2	PAC 1	IDLH	60 % LEL	10 % LEL
1	Hydrogen.	<10	11	20	—	48	118
		ERP G 3	ERP G 2	ERP G 1			
2	Toluene.	32	66	210	49	<10	31
3	Hydrogen Chloride at scrubber vent.	24	72	198	45	NA	NA

TABLE NO. 4.1B: AFFECT DISTANCE (VCE & POOL FIRE SCENARIOS)

SN.	ACCIDENT SCENARIO	DOWNWIND AFFECT DISTANCE (M)					
		Blast Over Pressure (psi)			Thermal Radiation (KW/m ²)		
		8	3.5	1.0	10	5	2
1	Hydrogen.	34	36	43	<10	<10	<10
2	Toluene.	LOC was never exceeded	<10	<10	26	38	61
3	Hydrogen Chloride scrubber failure.	NA	NA	NA	NA	NA	NA

The stable atmospheric stability conditions, ambient temperature of 30 °C, wind speed was 1.5 m/s. and humidity (50%), No inversion assumed for Consequence Analysis.

SECTION 4: FREQUENCY ANALYSIS

4.1 EVENT TREE

Event trees begin with an initiating event and work toward a final result. This approach is inductive. The method provides information on how a failure can occur and the probability of occurrence. Frequency of the incident is estimated by Event Tree.

4.2 INITIATING EVENT FREQUENCY

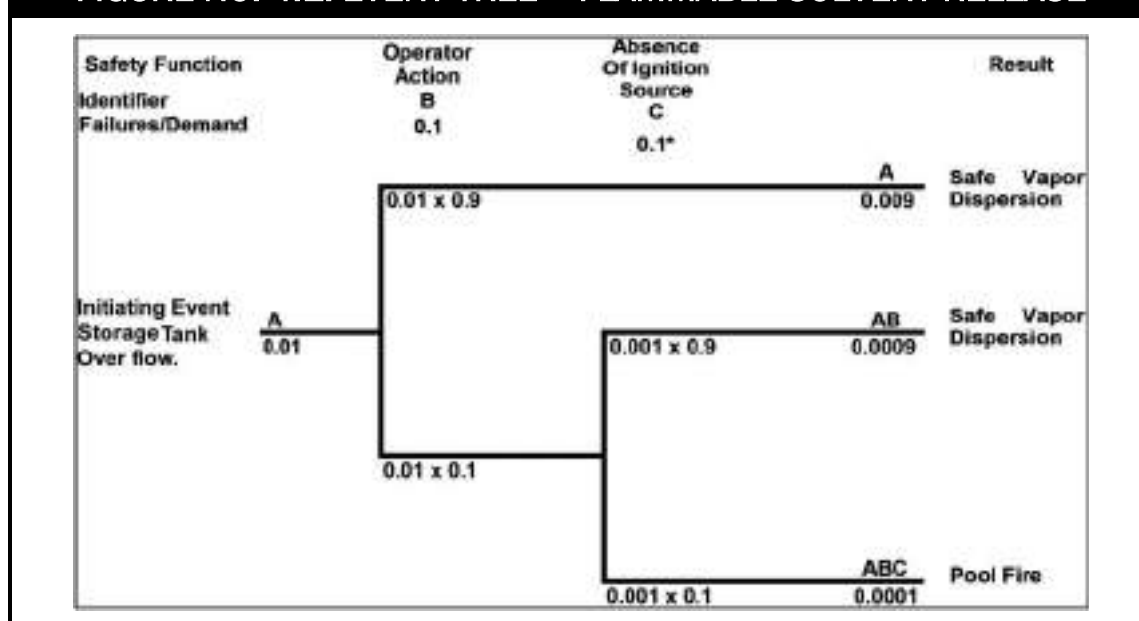
Initiating event frequency/yr range (all causes included) is 1×10^{-2} to 1×10^{-3} .

Typical frequency values assigned to initiating events;

Regular failure	=	1×10^{-1}
Gas kept/ packing blow out	=	$1 \times 10^{-2}/\text{yr}$
Piping leak (10% sections), 100 m	=	$1 \hat{=} 10^{-3}/\text{yr}$
Piping residual failure, 100 m, full breach	=	$1 \times 10^{-5}/\text{yr}$
Safety valve opens spuriously	=	$1 \times 10^{-2}/\text{yr}$
Operator failure (to execute routines procedure, well trained, unstressed, not fatigued) range	=	$1 \hat{=} 10^{-1}$ to $1 \hat{=} 10^{-3}/\text{opportunity}$

Ref: Table 11.3: Chemical Process Safety Fundamentals With Applications; Dainel A. Crowl/ Joseph L. Second Edition.

FIGURE NO. 4.1: EVENT TREE – FLAMMABLE SOLVENT RELEASE



4.3 IGNITION PROBABILITY

- *0.5 if distance to 50 % LFL falls within plant (with control of company) and
- *0.1 if distance to 50 % LFL falls inside electrically classified area.

Absence of ignition source dispersion downwind in specified direction results in safe vapor dispersion provided any person in vulnerable zone takes adequate action of escape and/or protection.

FIGURE NO. 4.2: VULNERABLE ZONE HYDROGEN RELEASE



Estimated downwind distance for 60 % LEL and 10 % LEL concentration is 48 m and 118 m respectively.

TABLE 4.1: EVENT FAILURE FREQUENCY

SN.	EVENT	EVENT FREQUENCY/ YR
1	Hydrogen gas accidental VCE.	4.5×10^{-4}
2	Hydrogen gas accidental jet fire.	5.0×10^{-4}
3	Hydrogen gas accidental flash fire.	9.5×10^{-4}
4	Flammable solvent Toluene - pool fire.	1.0×10^{-4}
5	Toxic gas release at scrubber vent.	1.0×10^{-4}

It is reasonable to assume this change, however it depends heavily upon the maintenance of the hardware and of the management procedures; neglect of either will lead to loss of protection and the rating will rise to the original estimate (a) indicated above.

SECTION 5: IMPACT ASSESSMENTS

5.1 OVER PRESSURE IMPACT

Flammable vapors cloud in flammable range finding source of ignition resulting into vapor cloud explosion is considered as Worst Case Scenario and following table indicates the over pressure impact.

TABLE NO. 5.1: EFFECT OF BLAST PRESSURE WAVE

OVER PRESSURE (bar)	EFFECTS
0.01	Shattering of glass windows. Failure of panels.
0.03	Shattering of asbestos siding.
0.1	Collapse of steel framing panels.
0.3	Shearing of brick walls (8-12 inches).

ALOHA modeling of the vulnerable zones are superimposed on satellite site maps called **MARPLOT** for estimation of impact.

FIGURE NO. 5.1: VULNERABLE ZONE - HYDROGEN RELEASE VCE



EVENT FREQUENCY: 4.5×10^{-4} per Year

IMPACT:

- Hydrogen instantaneous release from hydrogen cylinder trolley likely to rise upward and dispersed however in case the downwind drifting flammable vapor cloud finds source of ignition will lead to flash fire/ vapor cloud explosion.
- There will be direct negative impact on the persons working in the vulnerable zone. Risk of affected by pressure wave as a result of Hydrogen Vapor cloud explosion is likely. Off-Site Emergency likely.
- Depending the prevailing atmospheric conditions at the time of the event the impact will undergo change However any reduction in the crowding in this zone need attention.

5.2 THERMAL RADIATION IMPACT

Flammable solvent release followed acetone Pool fire at tank farm will result in thermal radiations likely to impact direct the personnel in vulnerable zone with burn injuries and even fatality as given in following tables;

TABLE NO. 5.2: FATAL THERMAL RADIATION EXPOSURE LEVELS

Radiation Level KW/m ²	Seconds Exposure For A (%) Fatality Levels		
	1 %	50 %	99 %
1.6	500	1300	3200
4.0	150	370	930
12.5	30	80	200
37.5	8	20	50

**TABLE NO. 5.3:
EFFECTS OF THERMAL RADIATION ON UNPROTECTED SKIN**

Radiation Level (KW/m ²)	Duration Period Seconds Before	
	Pain Is Felt	Blistering Starts
22	02.0	03.0
18	02.5	04.3
11	05.0	08.5
08	08.0	13.5
05	16.0	25.0
2.5	40.0	65.0
Below 2.5	Prolonged exposure can be tolerated.	

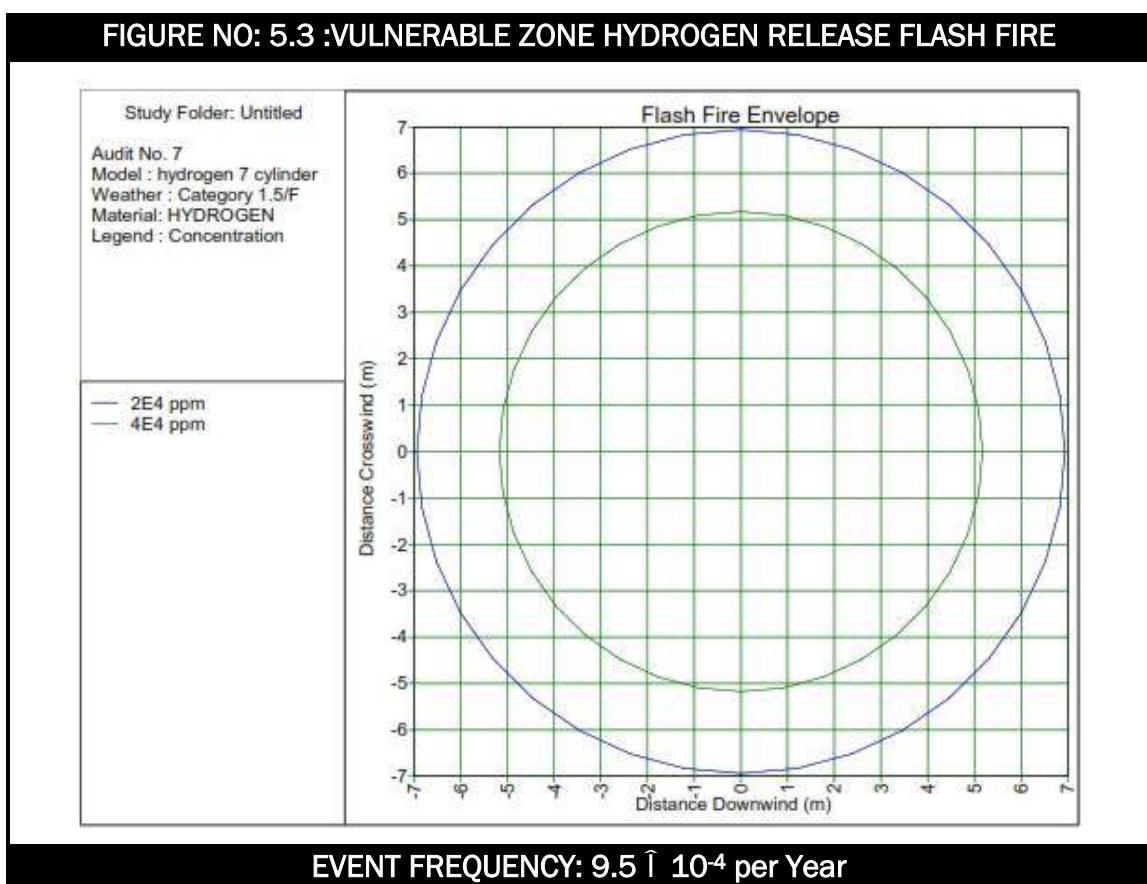
FIGURE NO. 5.2: VULNERABLE ZONE - TOLUENE POOL FIRE



IMPACT (Toluene Pool Fire):

- Thermal radiations of 10 KW/m^2 are likely within 26 m radius zone, which is mainly tank farm.
- It is reasonable to assume that well trained employees within the vulnerable zone are likely to move out of this zone within 90 seconds hence avoiding fatality.
- Continued exposure to heat flux of 4.0 KW/m^2 level of heat flux or greater is considered sufficient to cause injury. Hence, injury risk is likely up to 10 m around the pool fire.
- It may be noted that thermal effect of a pool fire is usually limited to a distance of 2 to 3 times the pool diameter.
- Toluene pool fire impact will be confined within the site.

FIGURE NO: 5.3 :VULNERABLE ZONE HYDROGEN RELEASE FLASH FIRE



JET FIRE:

Accidental release of gases from a high-pressure source usually results in a turbulent jet. This when ignited forms a torch or jet flame. Such flame on impingement virtually cuts Through equipment, piping and structures causing extensive damage. Thermal radiation due to jet flame may cause various degrees of burns on human body. The thermal effects of a jet fire are limited to a small distance and do not usually extend beyond the property line.

5.3 TOXICITY IMPACT

FIGURE NO: 5.4 :VULNERABLE ZONE HYDROGEN CHLORIDE RELEASE



EVENT FREQUENCY: 1.0×10^{-3} per Year

TABLE NO. 5.4: HEALTH EFFECTS OF HYDROGEN CHLORIDE EXPOSURE

Concentration	Concentration Symptoms Of Exposure
< 1 ppm	Odor Threshold.
10 - 50 ppm	Irritation of the eyes and mucous membranes, which can be tolerated or several hours.
50 - 100 ppm	Immediate irritation of the throat, which may be tolerated for an hour.
1000 - 1300 ppm	A dangerous health hazard, even for short periods of time.

Exposure to concentrations in excess of 1300 ppm may cause laryngeal spasms, resulting in death.

FIGURE NO: 5.5 :VULNERABLE ZONE TOLUENE EVAPORATING POOL



EVENT FREQUENCY: 1.0×10^{-3} per Year

IMPACT:

Toluene vapors inhalation may cause irritation of the upper respiratory tract. Symptoms of overexposure may include fatigue, confusion, headache, dizziness and drowsiness. Peculiar skin sensations (e. g. pins and needles) or numbness may be produced. Very high concentrations may cause unconsciousness and death.

SECTION 6: RISK ESTIMATION

6.1 INDIVIDUAL RISK

Individual risk is defined by AIChE/ CCPS as risk to a person in the vicinity of a hazard. This includes the nature of the injury to the individual, the likelihood of the injury occurring and the time period over which the injury might occur. It is estimated that at assembly point existing.

$$IR = \left(\frac{1}{N} \right) \sum I_i \times f_i$$

Where,

N	=	number of persons.
i	=	incident identification number.
I	=	impact of incident.
f _i	=	frequency of the incident.

Average individual risk (exposed hours/worked hours) to two personnel at Hydrogen handling area.

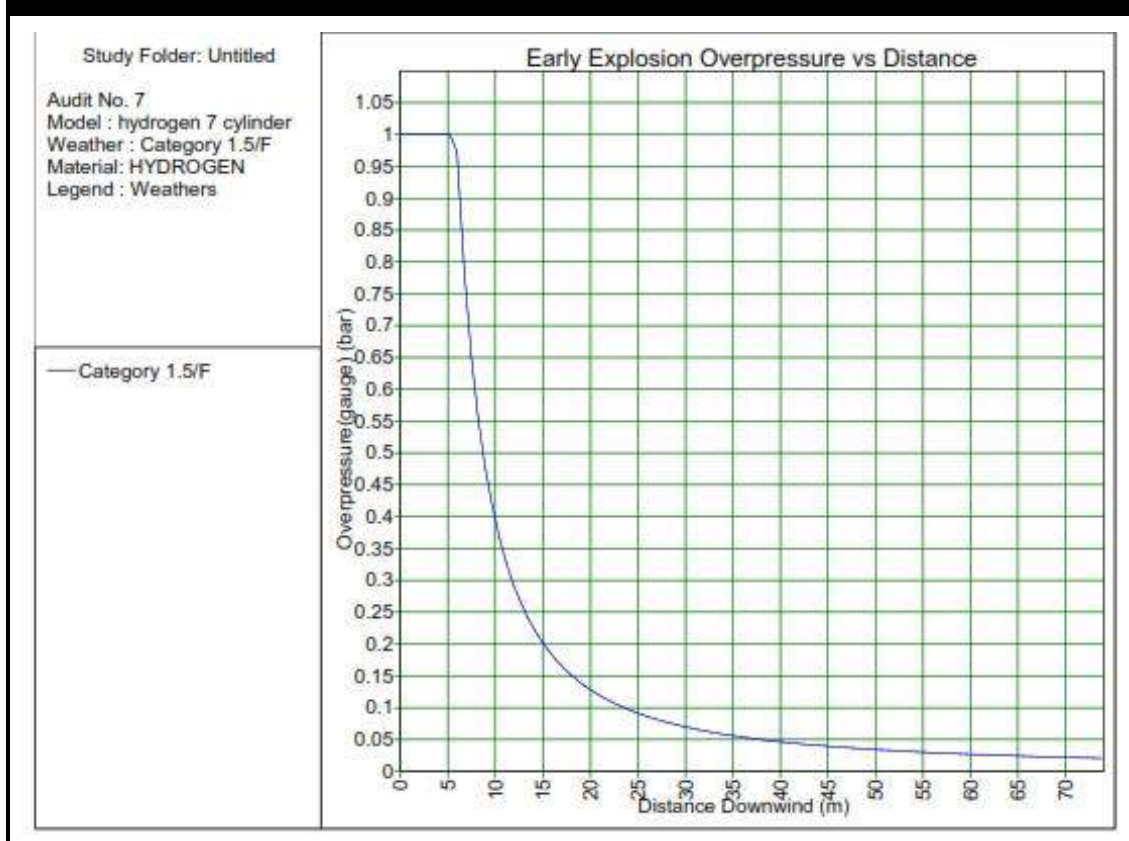
TABLE 6.1: INDIVIDUAL RISK RESULTS*

	RISK	EVALUATION
Prevailing risk from existing facilities	Insignificant (new project)	Acceptable
Perceived risk from the proposed facilities	4.6×10^{-4}	Acceptable

FIGURE NO. 6.1: VULNERABLE ZONE: HYDROGEN - VCE



FIGURE NO. 6.2: VULNERABLE ZONE: HYDROGEN - VCE



EVENT FREQUENCY: 4.5×10^{-4} per Year

TABLE 6.2: INDIVIDUAL RISK - HYDROGEN - VCE

Contour No.	Individual Fatality (IR)	Downwind Affect Distance (M)	Remarks
1	4.4×10^{-4} per year.	15	This contour remains within the site.
2	4.5×10^{-5} per year.	18	This contour remains within the site.
3	4.5×10^{-6} per year.	74	This contour extends into commercial and industrial developments only.

TABLE 6.3: INDIVIDUAL FATALITY CRITERIA

Individual Fatality (IR)	Individual Fatality Criteria
1×10^{-4} per year	This contour remains on-site.
1×10^{-5} per year	This contour extends into industrial developments only.
1×10^{-6} per year	This contour extends into commercial and industrial developments only.

6.2 SOCIETAL RISK

Societal risk measures the risk to a group of people (CCPS, 1989). Societal risk measures estimate both the potential size and likelihood of incidents with multiple adverse outcomes. In this example, the adverse outcome considered is immediate fatality resulting from fire, explosion, or exposure to toxic vapors. Societal risk measures are important for managing risk in a situation where there is a potential for accidents impacting more than one person.

F-N Curve;

Societal risk criteria are generally presented as curves on F – N plots. Mathematically, the equation for an F – N criterion curve may be presented as; [Ball 19981].

$$F = k \times N^{-a}$$

Where,

F	=	the cumulative frequency of N or more fatalities.
N	=	the number of fatalities.
a	=	aversion factor (often between 1 and 2).
k	=	constant.

When the F – N curve slope is equal to -1, the risk criterion is termed ‘risk neutral’. A risk criterion for which the curve slope is more negative than -1 is said to be more risk averse. An anchor point along the curve (e.g. N=10 fatalities, F=10⁻³/year) and a slope (e.g. -1) is usually enough information to plot a risk criterion F – N curve. if any portion of the calculated F – N curve exceeds the criterion line, the societal risk is said to exceed that risk criterion.

TABLE 6.4: SOCIETAL RISK

SN.	Release Event	Cumulative Frequency/ Yr	Fatalities
1	Hydrogen - VCE.	4.5×10^{-5}	1 No.
2	Toluene - Pool Fire.	5.5×10^{-4}	0 No.
3	Hydrogen Chloride release.	6.5×10^{-4}	0 No.

The figure illustrates that the QRA results lies well below the UK societal risk criteria line.

FIGURE NO. 6.3: F - N CURVE

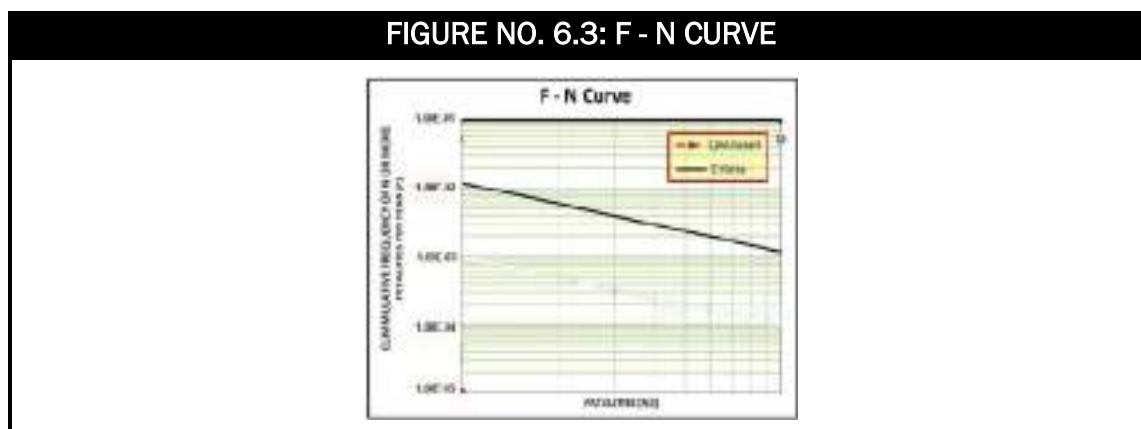


FIGURE NO. 6.4: ON SITE DISASTER CONTROL PLAN



FIGURE NO. 6.5: SITE SURROUNDINGS

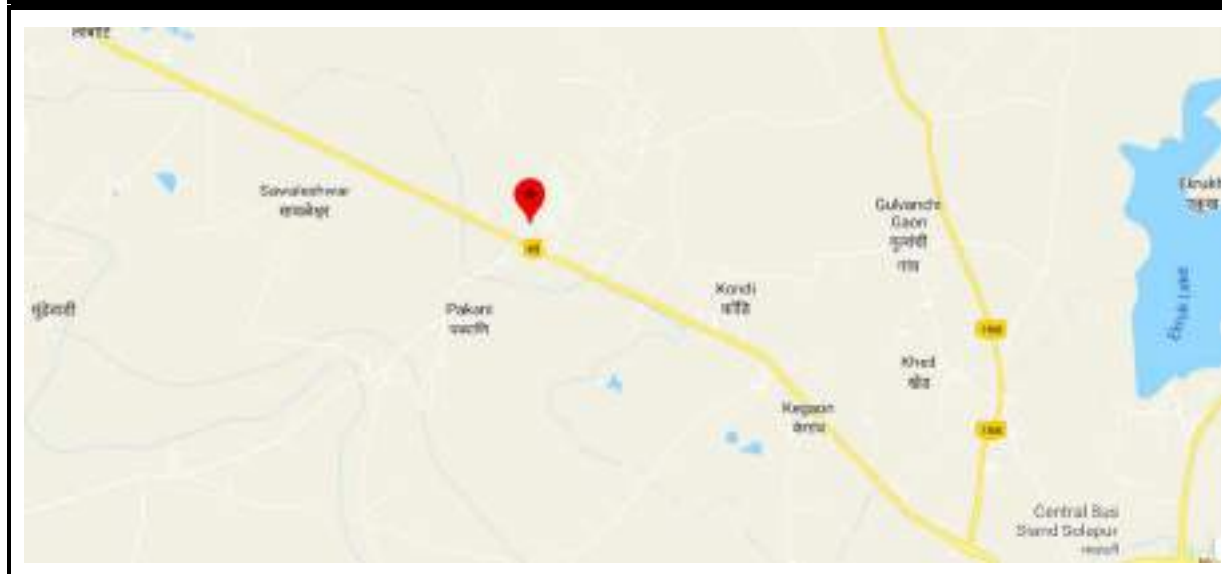
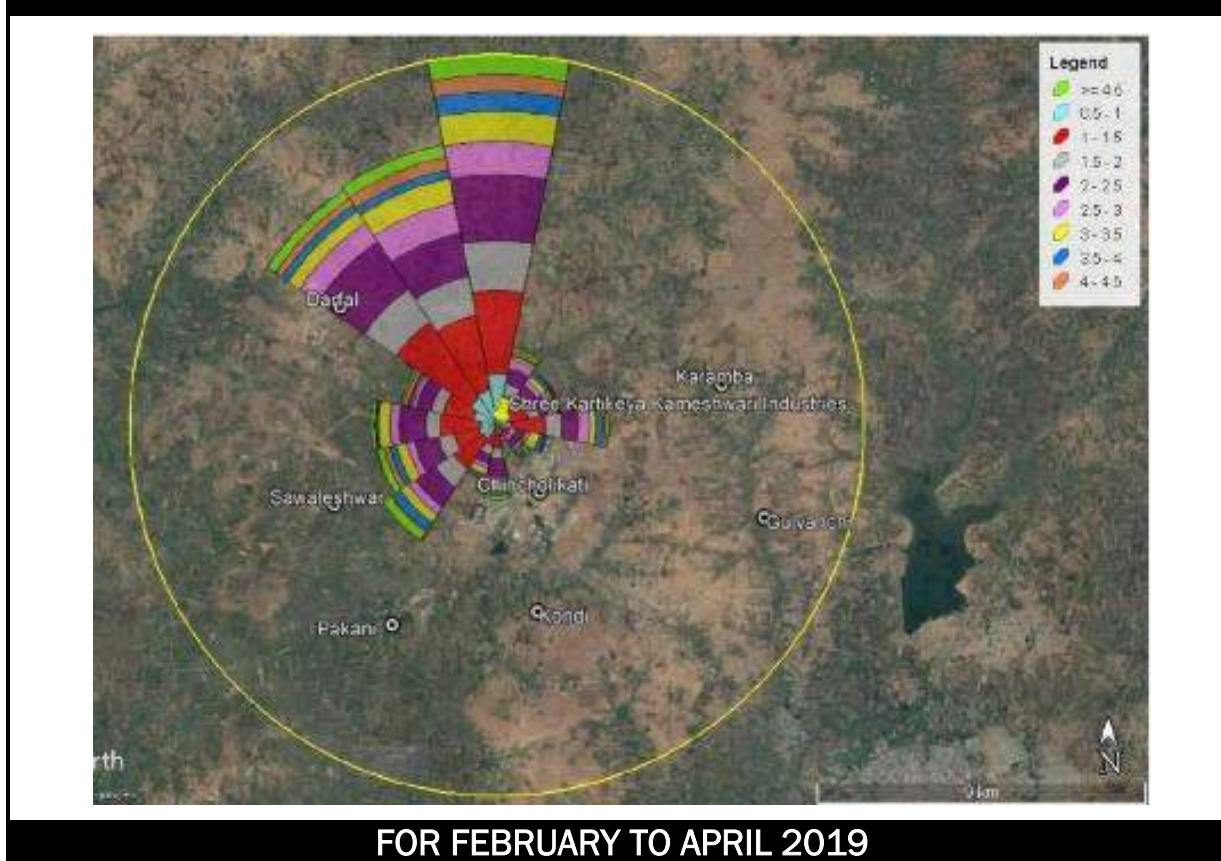


TABLE 6.5: POPULATION IN THE SITE SURROUNDING VILLAGES

Name	Distance (km)	Population	Name	Distance (km)	Population	Name	Distance (km)	Population
Morvanchi	9.89	1551	Shirapur (Mo)	6.76	714	Gulwanchi	6.35	2607
Shirapur (Solapur)	9.9	3039	Peertakali	9.66	1487	Bhogaon	9.88	2131
Lamboti	8.83	2637	Darfal	5.47	3067	Khed	7.73	1157
Chincholikati	0.85	2785	Mohitewadi	8.37	391	Kegaon Kh.	6.26	962
Sawaleswar	4.18	3948	Akolekati	6.68	3430	Kegaon Bk		1481
ArjunSond	7.42	1944	Karamba	7.6	3228	Hiraj	6.56	3136
Pophali	7.62	1432	Kondi	4.08	6819	Pakani	6.25	3905
Wirwade Kh	8.45	439	Wirwade Bk		2555	Shivani	5.72	930

FIGURE NO. 6.6: WIND ROSE



The site surroundings population data analysed. The effects of the proposed site activity are well contained within the notified industrial area and indicate insignificant societal risk. The population within the specified radius of vulnerable zone is mainly industrial.

In the present case any fatality unlikely for the industrial trained population in surroundings the site and there is no situation point above the criterion line in F-N curve indicating insignificant societal risk.

The risk posed by the proposed site activities with implementation of risk mitigation measures are at reasonably acceptable level, however it should be noted it depends heavily upon the maintenance of the hardware and of the management procedures; neglect of either will lead to loss of protection and the rating will rise to the higher level.

SECTION 7: RISK MITIGATION MEASURES

1. Provide Scrubber for Carbon Di Oxide emission in Gapentene manufacturing process stage 1.
2. Consider recovery of Sodium Bromide as by product in the Lasartan Potassium manufacturing process.
3. Provide Scrubber for Hydrogen Chloride gas emission in Gapentene manufacturing process stage 2.
4. Provide lock and key arrangement for storage of Sodium Cyanide storage.
5. Dyke for above ground storage tanks.
6. Containment arrangement of fire water runoff, testing and safe disposal.
7. Fire hydrant system.
8. Storage of chemicals considering compatibility and reactivity hazards.
9. Work area monitoring for maintaining air born concentration of chemicals within prescribed limit.
10. Develop P & I Diagram, identify hazards by HAZOP study and provide process interlocks for critical parameters and SOP's before commissioning of the plant.
11. On Site Disaster Control Plan (Refer: Figure No. 7.1 for highlights).
12. Off Site Disaster Control Plan.
13. General:
 1. Occupational Health: Good work environment. Good housekeeping. First aid facilities. Masks with suitable canisters and other Personnel protective equipments for operating personnel. Regular health check up including functioning of lungs for the personnel exposed to high levels of dust. Monitoring of air born concentration of chemicals in work environment. Work permits. Awareness program for workers. Automation in operations with an objective that physical presence of personnel at hazardous work stations all the time avoided as far as possible.
 2. Toxic Materials handling : Use of closed feed system, Equipment venting through scrubber system, Leak detection and Alarm, Monitoring of air born concentration of chemicals in work place and Periodic medical surveillance of the employees. Safety shower and Eye wash fountain, SCBA and PPE.
 3. Flammable materials handling: NO open flames, NO sparks, and NO smoking. Leak detection and Alarm, Prevent build-up of electrostatic charges to dangerous level consider earthing and bonding of equipments; Closed system, ventilation, explosion-proof electrical equipment and lighting. Ventilation, local exhaust, or breathing protection. Portable fire extinguishers, SCBA and PPE.
 4. Reactivity & compatibility hazards: Separate the bulk storage of chemicals considering the compatibility and reactivity hazards. Maintain MSDS of transformation products, Smoke detector at warehouses. Segregate drain to avoid uncontrolled mix up in drain network system. Segregate the laboratory chemicals while storage on storage racks considering functional groups compatibility and reactivity hazards.

5. Spill Hazard : Dyke for above ground storage tanks. Pipe work designed for high standard, Decontamination procedures.
6. Corrosive materials; Splash guards over flange joints in pressurized transfer lines of corrosive materials.
7. Transport of hazardous chemicals: Spark arrestor at exhaust of vehicles, Display of class labels. Specified predetermined routes. Valid registration to carry the said goods, PUC and driver Training. TREM card. PPE, First aid box, tool box, MSDS, antidotes.
8. Disaster management: Emergency power - DG set, Search and rescue Kit, Safety Signage & Symbols, wind direction sock, siren, Structural Audit, Stability checks, Preventive maintenance and regular inspection system, CCTV security system, Lightning arrestor PPE stock – SCBA, safety shoes, goggles, helmet, apron, protective dress, Medical oxygen, antidotes, first aid room, ambulance /emergency vehicle, first aid and fire fighting Trained staff, Fire extinguishers. Mock Drill and Fire Drill.

FIGURE NO. 7.1: ON SITE DISASTER CONTROL PLAN



ANNEXURE 1: GLOSSARY

Acceptance Criteria (Risk).	: Defines the level of risk to which an individual is exposed, as either tolerable (negligible risk), intolerable or within the ALARP region.
Consequence	: This is the severity associated with an event in terms of toxic doses, fire or explosion etc., i.e. the potential effects of a hazardous event.
ERPG	: The Emergency Response Planning Guidelines. ERPG 1: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor. ERPG 2: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action. ERPG 3: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.
Frequency	: This is the number of occurrences of an event expressed per unit time. It is usually expressed as the likelihood of an event occurring within one year.
Hazard	: A physical situation with the potential for human injury, damage to property, damage to the environment or some combination of these.
Hazardous Scenario	: The identified isolatable sections and/or those which have been broken down into scenarios for specific items of equipment.
IDLH	: Immediately Dangerous To Life And Health. The maximum concentration would not cause any escape imparting symptoms or irreversible health effects to a person exposed for 30 minutes.
Individual Risk	: The frequency at which an individual may be expected to sustain a given level of harm from the realization of specified hazards.
Individual Risk Contours.	: As IR (Individual Risk) is calculated at a point, calculating the IR at many points allows the plotting of IR contours, these being lines that indicate constant levels of risk. Most commonly used are the 1 chance per million-year contour and the 10 chances per million-year contour.
Individual Risk Of Fatality.	: Individual risk with "harm" measured in terms of fatality. It is calculated at a particular point for a stationary, unprotected person for 24 hours per day, 365 days per year. Normally measured in chances of fatality per million years.
Individual Risk Of Injury.	: Similar to individual risk of fatality, however with "harm" measured in terms of injury.
Isolatable Section.	: A system of pipes or vessels containing the hazardous materials that are bounded by specific isolation points.

Isolation Point.	: A point in the process, which can be used to isolate one part of the process from the rest of the system.
LEL.	: Lower Flammability Limit. Expressed as % by volume of flammable gas in air. This is the minimum concentration of gas in air mixture which can ignite. Gas air mixtures below this concentration do not ignite.
Probability.	: The expression for the likelihood of an occurrence of an event or an event sequence or the likelihood of the success or failure of an event on test or demand. By definition, probability must be expressed as a number between 0 and 1.
Quantitative Risk Assessment.	: A risk assessment undertaken by combining quantitative evaluations of event frequency and consequence.
Risk.	: The combination of frequency and consequences, the chance of an event happening that can cause specific consequences.
Risk Reduction.	: The process of risk assessment coupled to a systematic consideration of potential control measures and a judgment on whether they are reasonably practicable to implement.
TEEL	: Temporary Emergency Exposure Limits. TEEL-1: Maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing other than mild transient health effects or perceiving a clearly defined objectionable odor. TEEL-2: Maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action. TEEL-3: Maximum concentration in air below which it is believed nearly all individuals could be exposed without experiencing or developing life-threatening health effects.
UFL	: Upper Flammability Limit. Expressed as % by volume of flammable gas in air. This is the maximum concentration of gas in air mixture which can ignite. Gas air mixtures above this concentration do not ignite.
Vapor Cloud Explosion	: An accidental release of flammable liquid or gas, there is possibility that it may form a cloud which can spread along the wind direction. Delayed ignition of the cloud away from the source of release results in Vapor cloud explosion (flash back) and associated blast/ over pressure effects.

ANNEXURE 2: ABBREVIATIONS

AIChE.	American Institute Of Chemical Engineers.
ALARP.	As Low As Reasonably Practicable.
BTU.	British Thermal Unit.
CCPS.	Centre For Chemical Process Safety.
DMP.	Disaster Management Plan
ECC.	Emergency Control Centre.
EIA.	Environmental Impact Assessment.
EMP.	Environment Management Plan.
F & E I.	Fire And Explosion Index.
HAZOP.	Hazard Operability.
HSD.	High Speed Diesel.
IDLH.	Immediately Dangerous To Life And Health.
IPL.	Independent Protection Layer.
KCal.	Kilocalories.
lb.	Pound.
LOC.	Level Of Concentration.
LOPA.	Layers Of Protection Analysis.
MCA.	Maximum Credible Accident.
MF.	Material Factor.
MIDC.	Maharashtra Industrial Development Corporation.
MARPLOT.	Mapping Applications For Response, Planning And Local Operational Tasks.
MoEF.	Ministry Of Environment And Forests.
MSDS.	Material Safety Data Sheet.
MT.	Metric Ton.
NFPA.	National Fire Protection Association.
PFD.	Probability Of Failure On Demand.
PHA.	Preliminary Hazard Analysis.
QRA.	Quantitative Risk Assessment.
RH.	Risk Assessment And Hazard Management.
SIF.	Safety Integrated Function.
TEEL.	Temporary Emergency Exposure Limits.
UK.	United Kingdom.

ANNEXURE 3: REFERENCES

1. *Technical EIA Guidance Manual for Synthetic Organic Chemicals, prepared for the Ministry of Environment and Forests Government of India.*
2. *MOND INDEX Manual 1993.*
3. *“TNO Yellow Book”. Method for calculation of the Physical Effects of the escape of Dangerous Material (Liquid & Gases) Published by the Directorate General of Labour, Ministry of Social affair, Netherlands (1979).*
4. *Frank P. Lees – Loss Prevention in the Process Industries – Volume I.*
5. *Risk Assessment for Process Industries, Loss Prevention News April - June 2001.*
6. *Techniques for assessing Industrial Hazards (World Bank Technical Paper, ISSN 0253; No. 55).*
7. *Ref. Table 3.8 – Vapor Pressure of Organic Compounds, R. H. Perry, C.C., Chemical Engineers Handbook, 5th Edition (1969) McGraw – Hill Book co. (New York, London).*
8. *Guideline for Quantitative Risk Assessment “Purple Book”.*