CHAPTER- 7
RISK ASSESSMENT AND DISASTER MANAGEMENT

7.1 INTRODUCTION

M/S. Deccan Remedies Limited proposes to set up a Bulk Drugs & Drug Intermediates manufacturing facility at Survey No. 75 (A), Kothur (V), Bidar Road, Zaheerabad (M), Medak District, Telangana.

The project site co-ordinates are between

17° 43' 42.4" N and 77° 35' 16.5" E
17° 43' 32.7" N and 77° 35' 14.5" E
17° 43' 29.6" N and 77° 35' 09.1" E
17° 43' 30.0" N and 77° 35' 07.7" E
17° 43' 30.5" N and 77° 35' 07.2" E
17° 43' 43.3" N and 77° 35' 05.1" E.

7.2 SITE LOCATION AND FACILITIES

M/s. Deccan remedies Limited, is bounded by agricultural fields in all directions and Road followed by agricultural lands in North direction. Only civil structures are in existence, it is proposed to provide the following facilities.

- Production Area
- Admin Block
- Ware House
- QC/QA laboratory
- Utilities Block
- Services area
- Generator Room
- Effluent Treatment Plant
- Compressed air units
- Cooling towers
- Purified Water system
- Scrap yard

7.3 OBJECTIVES AND SCOPE

The production of Bulk Drugs, Drug Intermediates involves usage of many chemicals which are both hazardous and non-hazardous in nature. Risk analysis has been carried out to identify the hazardous materials and quantify the hazards to arrive at safe disaster management plan and emergency preparedness plan for storage and handling of the potentiality hazardous material also.The purpose of carrying out risk assessment

study for **M/S. Deccan remedies Limited** Industries is to obtain clearance from the Ministry of Environment and forests (MOEF) which calls for a study on nature of hazards due to proposed location of process and storage units and also to study whether any accident,ifoccurs,leads to any off-site disaster. In this endeavour, the study objectives are outlined here under.

1. **Hazard identification and Visualization of Maximum Credible Accident Scenarios.**
   To identify major hazards relating to fire, explosion and toxicity due to chemicals, processes and storages of the proposed units.

2. **Hazard Analysis and Risk Assessment**
   Hazard analysis is the process of determining the release probabilities and quantities, emission or release rates, the routes/pathways by which the released substances could reach the receptors, the fate of the substances in environmental media through which they are transported or moved and the characteristics of the receptors at risk.

3. **Disaster Management**
   To provide guidelines for Disaster Management Plan(DMP) for on-site emergencies and Emergency Preparedness Plan(EPP) for off-site emergency, based on above 1& 2 studies of proposed plant.

7.4 PRODUCTION DETAILS

The manufacturing capacities of are presented in **Table 7.1**

Table 7.1
Manufacturing Capacity of Proposed Products

S.No	Product	Quantity TPM	Quantity in TPA
	API's		
1	Guaifenesin	90.0	1080.0
2	Methocarbamol	55.0	660.0
3	Phenazopyridine HCl	5.0	60.0
4	Flucanazole	5.0	60.0
5	Mephenesine	2.0	24.0
6	Mefenamic Acid	5.0	60.0
7	Chlorophenesine	2.0	24.0

8	Domperidone	4.0	48.0
9	Nitazoxanide	1.0	12.0
10	MelitracinHCl	0.5	6.0
11	Flupenithol	0.05	0.6
12	Ambroxil	7.45	89.4
	Total API's	**177.0**	**2124.0**
	Intermediates		
13	1 - (3 - Chloropropyl)-2-Benzimidazolinone	5.0	60.0
14	1-Isopropyl-1,3-dihydro-2H-benzimidazol-2-one	2.0	24.0
15	2,4-Difluoro-alpha-(1H-1,2,4-triazolyl) acetophenone	8.0	96.0
16	2(2,4-Difluro)-4-Amino-1H-1,2,4Trizoleacetophenone.HCl	5.0	60.0
17	3,3-dimethyl-2-benzofuran-1(3H)-one.	1.0	12.0
18	1- Phathalanol -3,3-dimethyl-1-Phenyl-1.	1.0	12.0
19	10,10-dimethylanthracen-9(10H)-one	0.5	6.0
20	9-[3-(dimethylamino)propyl]-9,10-dihydro-10,10-dimethylanthracene-9-ol	0.5	6.0
21	2-(Trifluoromethyl)thioxanthen-9-one	0.001	0.0
	Total Intermediates	**23.0**	**276.0**
	Total (API's + Intermediates)	**200.0**	**2400.0**

7.4.1 PROCESS DESCRIPTION

The details of process are given in **Enclosure I of Chapter 2**

7.5 HAZARD ANALYSIS AND RISK ASSESSMENT

7.5.1 Introduction

Hazard analysis is the process of determining the release probabilities and quantities, emission or release rates, the routes/pathways by which the released substances could reach the receptors, the fate of the substances in environmental media through which they are transported or moved and characteristics of the receptors at risk. The basis of risk

estimation is to determine the dose-effect relationship between achemical and receptor.Estimation of risk follows only when the hazard analysis determines the frequency.

Risk evaluation is the process of identifying, whether the estimated level of risk is tolerable. Tolerable risk is not equated with acceptability; it refers to a willingness to live with a risk so as to secure certain risk benefits, and in the confidence that the risk is being properly controlled.

7.5.2 Common definitions:

The common terms used in risk Assessment and Disaster Management are elaborated below:

"Risk" is defined as a likelihood of an undesired event (accident, injury or death) occurring within a specified period or under specified circumstances.This may be either a probability depending on the circumstances.

"Hazard" is defined as a physical situation, which may cause human injury, damage to property or the environment or some combination of these criteria.

"Hazardous substance" means any substance or preparation, which by reason of its chemical or physic chemical properties or handling is liable to cause harm to human beings, other living creatures, plants, micro-organisms, property or the environment.

"Hazardous process" is defined as any process or activity in relation to an industry which may cause impairment to the health of the persons engaged or connected therewith or which may result in pollution of their general environment.

"Disaster" is defined as a catastrophic situation that causes damage, economic disruptions, loss of human life and deterioration of health and health services on a scale sufficient to warrant an extraordinary response from outside the affected area are community. Disasters occasioned by man are factory fire explosions and release of toxic gases or chemical substances etc.

"Accident" is an unplanned event, which has a probability of causing personal injury or property damage or both.

"**Emergency**" is defined as a situation where the resources out pass the demand. This highlights the typical nature of emergency; it will be after experiences that enough is not enough in emergency situations. Situations of these kinds are avoidable but it is not possible to avoid them always.

In the sections below, the identification of various hazards, probable risks in a process industry manufacturing optical brighteners, maximum credible accident analysis, consequence analysis are addressed which gives a broad identification of risks involved in the plant.

7.5.3 Hazard Identification

Identification of hazards in the synthetic chemicals organic plant is of primary significance in the analysis, quantification and cost effective control of accidents involving flammable compounds. A classical definition of hazard states that hazard is not in fact the characteristic of system/plant/storage that presents potential for an accident. Hence, all the components of a system/plant/process need to be thoroughly examined to assess their potential for initiating or propagating an unplanned event/sequence of events which can be termed as an accident. Typical schemes of predictive hazard evaluation and quantitative risk analysis suggest that hazard identification step plays a key role in estimation of probability of an unexpected event and its consequences from the basis of quantification of risk in terms of damage to property, environment or personal. Therefore the type, quantity location and conditions of release of a toxic or flammable substance have to be identified in order to estimate its damaging effects, the area involved, and the possible precautionary measures required to be taken.

Some of the hazard identification procedures followed are as follows:

1. Fire Explosion and Toxicity Index(FETI) Approach;
2. HAZOP studies
3. Maximum Credible Accident and Consequence Analysis(MCACA);

7.5.3.1 Identification of Major Hazards from the unit

The Hazard identification process adopted is to identify hazardous chemicals as per the statutory requirements of Manufacture storage and import of Hazardous Chemical Rules,1989. The identified chemicals for the risk assessment are presented in **Table 7.2**

Table 7.2
List of Raw materials and Inventory

Name of Raw Material	Inventory Tonns	Physical form	Nature of storage	CAS Number
(2-methoxy phenoxy)-propane-1,2-diol	25.1	Solid	Bags	93-14-1
1 H 1,2,4 Triazole	1.7	Solid	Bags	288-88-0
1,3 di fluoro benzene	2.3	Liquid	Drums	372-18-9
2 – Amino - 5 – Nitrothiazole.	0.2	solid	Bags	121-66-4
2,3-dimethylaniline	4.2	Liquid	Drums	87-62-7
2,6 Diamino pyridine	1.3	Solid	Drums	141-86-6
2-Amino-3,5-dibromobenzaldehyde	3.3	solid	Bags	50910-55-9
2-Hydroxyethyl Piperazine	0.1	Liquid	Drums	103-76-4
2-Trifluoromethylthioxanthen-9-one.	0.0	Solid	Bags	1693-28-3
4-amino 1,2,4-triazole	5.0	solid	Bags	584-13-4
4-Chlorobenzotrifluoride	0.0005	Liquid	Drums	98-56-6
5-Chloro-1-(Piperidin-4-yl)-2-Benzimidazolinone.	2.3	solid	Bags	53786-28-0
Acetic acid	8.0	Liquid	Drums	64-19-7
Acetone	2.7	Liquid	Tank form	67-64-1
Activated Carbon	0.7	Solid	Bags	7440-44-0
Aluminium Chloride	7.3	Solid	Bags	7446-70-0
Ammonia (Gas)	2.0	Gas	Cylinders	1336-21-6
Ammonia solution	38.7	Liquid	Drums	1336-21-6
Aniline	1.3	Liquid	Drums	62-53-3

Aspirin	0.4	Solid	bags	50-78-2
Bromochloropropane	4.5	Liquid	Drums	109-70-6
C.S. falkes	35.8	Solid	Bags	1310-73-2
Carbon	0.1	Solid	Bags	7440-44-0
Chloro acetyl chloride	6.2	Liquid	Drums	79-04-9
Chlorobenzoic acid	3.4	Solid	Bags	118-91-2
Cyclohexane	1.3	Liquid	Drums	110-82-7
DiMethyl Amino Propyl Chloride. HCl in water (50%)	1.2	Liquid	Drums	5407-04-5
Dimethylformamide	6.7	Liquid	Drums	68-12-2
Dimethyl carbonate	14.1	Liquid	Drums	616-38-6
Ethylene dichloride	38.8	Liquid	Drums	107-06-2
Epichlorohydrin	29.9	Liquid	Drums	106-89-8
Ethyl acetate	10.2	Liquid	Tank form	141-78-6
Guciaol	33.3	Liquid	Tank form	90-05-1
HCl	34.1	Liquid	Drums	7647-01-0
Iso propyl alcohol	12.1	Liquid	Tank form	67-63-0
Lithium hydroxide	0.0002	solid	Bags	1310-65-2
Magnesium metal	0.018	solid	Bags	7439-95-4
Magnesium Turnings	0.2	solid	Bags	7439-95-4
Methylene dichloride	63.3	Liquid	Tank form	75-09-2
Methanol	27.2	Liquid	Drums	67-56-1
Methyl Iodide	0.048	Liquid	Drums	74-88-4
Methyl Magnesium Chloride in 3.0M T.H.F	13.6	Liquid	Drums	676-58-4
Methylaceto acetate	4.5	Liquid	Drums	105-45-3
Methyl isobutyl ketone	4.5	Liquid	Drums	108-10-1
N-Methyl-2-pyrrolidine	0.001	Liquid	Drums	872-50-4
O-Cresol	0.8	solid	Bags	95-48-7
O-Phenyldiamine	4.0	solid	Bags	95-54-5

O-Xylene	2.9	Liquid	Drums	95-47-6
P - Chlorophenol	0.9	Liquid	Drums	106-48-9
Phenyl Magnesium Chloride	3.3	Liquid	Drums	100-59-4
Phosphoric acid	0.017	Liquid	Drums	7664-38-2
Phtalic Anhydride	2.1	Solid	Bags	85-44-9
Potassium Carbonate	0.7	Solid	Bags	584-08-7
Potassium hydroxide	7.2	Solid	Bags	1310-58-3
Sodium acetate	1.9	Solid	Bags	127-09-03
Sodium bi carbonate	2.6	Solid	Bags	144-55-8
Sodium Borohydride	0.5	Solid	Bags	16940-66-2
Sodium carbonate	0.1	Solid	Bags	497-19-8
Sodium chloride	2.2	Solid	Bags	7647-14-5
Sodium hydro sulphate	0.1	solid	solid	7681-38-1
Sodium hydroxide	8	Solid	Bags	1310-73-2
Sodium nitrite	4.0	Solid	Bags	7632-00-0
Sulphuric Acid	1.6	Liquid	Drums	7664-93-9
Tetra hydro furan	3.3	Liquid	Drums	109-99-9
Thionyl chloride	0.5	Liquid	Drums	7719-09-7
Thiosalcylic acid	0.0004	Solid	Bags	147-93-3
Trimethylsulphoxinym iodide	2.4	Solid	Bags	1774-47-6
Toluene	140.3	Liquid	Tank form	108-88-3
trans-4-Aminocyclohexanol	1.4	solid	Bags	27489-62-9
Triethylamine	0.2	Liquid	Drums	121-44-8

7.5.3.2 Hazardous Characteristics of Raw Materials

Out of the total 77 raw materials, 21 chemicals are listed in Part II of Schedule I of MSHIS Rules, 1989, None of the chemical inventories are exceeding threshold quantities listed in schedule III of MSIHS Rules. Out of the 21 Chemicals listed bulk storages are proposed for 5 chemicals only. List of Hazardous chemicals is given in **table no.7.3**. Physical properties & hazardous characteristics of key raw materials is given in **table 7.4**

Table 7.3
List of hazardous chemicals
(Listed in part II of schedule I of MSIHC Rules)

S.No	Raw material	Physical form	Type of hazard	Maximum Storage quantity (Tonns)	Threshold Quantity (Rule 5,7,9 and 13 &15	Threshold Quantity (Rule 10 to 12)	Level of Hazard
1	Acetic acid	Liquid	Flammable	8.0	Not specified	Not specified	Level 1 Hazard
2	Acetone	Liquid	Flammable	2.7	Not specified	Not specified	Level 1 Hazard
3	Ammonia	Liquid	Flammable	38.7	60 t	600 t	Level 1 Hazard
4	Ethylene di chloride	Liquid	Flammable	38.8	Not specified	Not specified	Level 1 Hazard
5	Epichlorohydrin	Liquid	Flammable	29.9	Not specified	Not specified	Level 1 Hazard
6	Ethyl acetate	Liquid	Flammable	10.2	Not specified	Not specified	Level 1 Hazard
7	Hydrochloric acid	Liquid	Corrosive	34.1	25 t	250 t	Level 1 Hazard
8	Isopropyl alcohol	Liquid	Flammable	12.1	Not specified	Not specified	Level 1 Hazard
9	Methanol	Liquid	Flammable	27.2	Not specified	Not specified	Level 1 Hazard
10	MIBK	Liquid	Flammable	4.5	Not specified	Not specified	Level 1

							Hazard
11	O-Cresol	Solid	Corrosive	0.8	Not specified	Not specified	Level 1 Hazard
12	O-Xylene	Liquid	Flammable	2.9	Not specified	Not specified	Level 1 Hazard
13	Phosphoric acid	Liquid	Corrosive	0.017	Not specified	Not specified	Level 1 Hazard
14	Phtalic Anhydride	Solid	Corrosive	2.1	Not specified	Not specified	Level 1 Hazard
15	Potassium hydroxide	Solid	Corrosive	7.2	Not specified	Not specified	Level 1 Hazard
16	Sodium hydroxide	Solid	Corrosive	43.8	Not specified	Not specified	Level 1 Hazard
17	Sulphuric Acid	Liquid	Reactive	1.6	Not specified	Not specified	Level 1 Hazard
18	Tetra hydro furan	Liquid	Flammable /toxic	3.3	Not specified	Not specified	Level 1 Hazard
19	Thionyl chloride	Liquid	Corrosive	0.5	Not specified	Not specified	Level 1 Hazard
20	Triethyl amine	Liquid	Flammable	0.2	Not specified	Not specified	Level 1 Hazard
21	Toluene	Liquid	Flammable	140.3	Not specified	Not specified	Level 1 Hazard

Note :

Level I Hazard: Chemical is listed in schedule of chemicals but threshold limit did not cross 1st threshold or 2nd threshold limit as per the schedule I of MSIHC Rules 2000.

Table 7.4

Physical properties & Hazard characteristics of Key Raw materials

S.No	Name of the Material	Molecular Weight	Boiling point °C	Specific gravity	Flash Point in °C	Lower Explosive Limits volume % in air	Upper Explosive Limits volume % in air	IDLH ppm	TWA / TLV ppm	Solubility in water % w/w	Vapour pressure @ 21 mm Hg	LC 50/ LD50 mg/kg	NFPA Rating		
													Health	Fire	Reactivity
1	Acetone	58	56	0.79	-18	2.6	12.8	20,000	750	Soluble	194	-	2	3	0
2	Cyclohexane	84	80.7	0.78	-17	1.3	8.4	10,000	300	0.0055	78.8	65	1	3	0
3	Dimethyl formamide	73	153	0.95	62	2.2	-	500	-	Soluble	2.8	-	-	-	-
4	Ethyl aceate	88	77	0.9	-4	2.2	11.5	10,000	400	7.7	86	11.3	1	3	0
5	Ethylene dichloride	99	83.5	1.253	13	6.2	16.9	1000	10	0.81	71	770	2	3	0
6	Isopropyl alcohol	60	82	0.79	12	2.0	12.0	20,000	400	Soluble	35	5.8	1	3	0
7	Methanol	32	64	0.8	15	6.0	36.5	25,000	400	Soluble	35	-	1	3	0
8	Methylene dichloride	85	40	1.33	-	13.0	22.0	-	100	1.9	382	2.0	2	1	0
9	Methyl isobutyl	100	116	0.8	13	1.4	7.5	-	100	1.7	16.5	-	2	3	0

10	N- methyl 2-pyrolidine	99	202	1.03	95	2.2	12.2	-	-	Soluble	0.35	3.5	-	-	-
11	Tetra hydrofuran	68	66	0.9	-15	2.3	11.8	-	200	-	133	-	2	3	1
12	Toluene	92	110.6	0.87	4	1.27	7.0	2000	100	0.05	23	-	2	3	0
13	O- Xylene	106	138	0.87	23	1.14	7.0	10,000	100	0.02	7	-	2	3	0

7.6 Fire & Explosion Index (F&EI):

7.6.1 Methodology

Dow Chemical Company issued a guideline for hazard determination and protection. By this method a chemical process unit is rated numerically for hazards. The numerical value of the Fire and Explosion Index (F&EI) which is most widely used for hazard evaluation in chemical process industries is a globally accepted norm.

The guide applies to process unit only and not to auxiliary units such as power generating stations, plant water systems, control rooms, fired heaters, structural requirements, corrosive nature of material handled and personal safety equipment. These are regarded as basic features that do not vary according to the magnitude of the fire and explosion hazard involved. The guide also does not cover the processing and handling of explosives such as dynamite, TNT etc.

7.6.2 Computation of F&EI

The computation of fire and explosion index of each unit is based on the material factor. This is a measure of the intrinsic rate of potential energy release from fire explosion of most hazardous material or mixture of materials present in significant quantity, whether it is raw material, intermediate, product, solvent etc., by combustion or chemical reaction. "In significant quantity" here means such quantity that the hazard represented by the material actually exists. The National Fire Protection Agency (NFPA) of USA have specified standard values for material factor which should be used for F&EI calculations and are available in DOW's hazard classification guide.in case it is not readily available, it can be calculated using the heat of combustion, flammability indices etc.

General process hazard are factors that play a primary role in determining the magnitude of loss of incident. It takes into account the nature of the reaction, ventilation, accessibility, drainage facilities etc., special process hazards are factors that contribute primarily to the probability of a loss incident. They consist of specific process conditions that have shown themselves to be major causes of fire and explosion incidents. It takes into account toxicity of the material, operatingpressure, operation near flammable range, quantity of material, packing, use of thermic fluid exchange system etc., The F&EI calculated as a product of material factor, general process hazard factor, and special process hazard factor.

7.6.3 Hazard Ranking

The hazard ranking based on F&EI value is as follows

Table 7.5 Degree of Hazard for F&EI

F&EI Index Range	Degrees of Hazard
1-60	Light
61-96	Moderate
97-127	Intermediate
128-158	Heavy
159 & above	Severe

Table 7.6 provides some of the preventive actions for fire hazards and fire suppression and **table 7.7**provide Electrical hazards and prevention of electric hazards

Table 7.6
Suggested preventive measures for fire hazards

Prevention of fire hazards	Fire suppression
Well planned design and layout Proper ventilated systems Chemical data sheets Proper training of personnel Proper maintenance of surroundings Use of fire extinguishers, alarms, sensors, detectors Fire fighting equipment Sprinkler systems Hazardous operations should be isolated Using fire resistant material in construction	Fire hydrant system Water sprinklers Fire extinguishers

Table 7.7
Suggested preventive measures for Electric hazards

Electrical hazards	Prevention of electric hazards
Short circuits Electrostatic hazards Acrs and spark hazard Combustible and explosive materials Improper wiring Insulation failure	Grounding of electrical equipment Prevention of static electricity Bending and grounding Humidification Antistatic materials Ionizers and electrostatic neutralizers Magnetic circuit breaker Proper maintenance of wiring and equipment Use of explosion proof devices and non sparking switches in flammable liquid storage areas

7.6.3.1 Maximum Credible Accident Analysis and Its Mitigation Measures

A Maximum Credible Accident (MCA) can be characterized as the worst credible accident. In other words: an accident in an activity, resulting in the maximum consequence distance that is still believed to be possible. A MCA-analysis does not include a quantification of the probability of occurrence of the accident. Another aspect, in which the pessimistic approach of MCA studies appears, is the atmospheric condition that is used for dispersion calculations.

The Consequence Analysis has been done for selected scenarios by ALOHA (version 5.4.4) of EPA. The details of software used for MCA analysis are described below.

- A computer based version ALOHA 5.4.4 is used to calculate toxic and explosive effect of the accidental release of liquid chemicals within the plant area.
- ALOHA (Areal Locations of Hazardous Atmosphere) is a computer program designed especially for use by people responding to chemical release as well as for emergency planning and training.

- ALOHA was jointly developed by the National Oceanic and Atmospheric Administration (NOAA) and the Environment Protection Agency (EPA).
- The mathematical model is based on the Emergency Response Planning Guidelines (ERPGs) which gives Toxic Levels of Concern (LOCs) to predict the area where a toxic liquid concentration might be high enough to harm people.
- ALOHA models key hazards-toxicity, flammability, thermal radiation (Heat), and over pressure (expansion blast force)-related to chemical releases that result in toxic gas dispersion, fire and/or explosion.

7.6.3.2 Heat Radiation & Vapour cloud Fire distances of Hazardous Storages

The 5 bulk storages proposed have Fire threat possibilities. Bulk storages proposed are given in **table 7.8** The heat radiation distances in case of pool fire for flammable above ground storage tanks are presented in the below **Table 7.9**

Table 7.8
Bulk storages Proposed

Sr No	Capacity (KL)	Name of the solvent	MOC	Dia in M	Height in M
1	20	Acetone	SS	2.7	3.6
2	20	IPA	SS	2.7	3.6
3	20	Toluene	SS	2.5	3.9
4	20	Ethylacetate	SS	2.6	3.79
5	20	Methylene Dichloride	SS	2.6	3.8

All the bulk storages proposed are above ground tanks.

Table 7.9
Heat Radiation Damage Distancesfor storage tanks – Tank Farm

S.No	Name of the solvent		Storage Tank Details				Scenario details (Pool Fire-Leaking tank)			
		FEI Index	Tank Capacity (KL)	No.s	Diameter (m)	Height (m)	Release Rate (Kg/sec)	Heat radiation damage distances in m for KW/m2		
								10	5	2.0
1	Acetone	95	20	1	2.7	3.6	23.3	10	10	13
2	Isopropyl alcohol	90	20	1	2.7	3.6	23.3	<10	<10	13
3	Toluene	100	20	1	2.5	3.9	24.5	<10	10	15
4	Ethyl acetate	94	20	1	2.6	3.79	25	<10	<10	12
5	Methylene dichloride	19	20	1	2.6	3.8	30.2	<10	<10	<10

Note:

- **2 kW/(sq m)** -- people will feel pain after 45 seconds and receive second degree burns after 3 minutes;
- **5 kW/(sq m)** -- people will feel pain after 13 seconds and receive second degree burns after 40 seconds; and
- **10 kW/ (sq m)** -- people will feel pain after 5 seconds and receive second degree burns after 14 seconds.

7.6.3.3 Toxic chemicals storage and toxic impact distances:

Following chemicals are classified as toxic chemicals used by the company. Toxic influence distances are estimated using ALOHA model in case of Drum/ tank Leakages and presented below

Table 7.10

Toxic threat zones on release of chemicals

S.No	Name of the solvent	Capacity of Drum	Scenario Details						
			Release rate (kg/sec)	AEGL-3 Distance Red (m)	AEGL-3 Red (ppm)	AEGL-2 Orange Distance (m)	AEGL-2 Orange (ppm)	AEGL-1 Yellow Distance (m)	AEGL-1 Yellow (ppm)
1	Ammonia	50 Kgs	0.83	93	1100	244	160	529	30
2	Acetone	100 kgs	1.67	63	5700	88	3200	399	200
3	Methylene di chloride	100 Kgs	1.67	47	6900	187	560	320	200
4	Methyl iodide	100 kgs	1.67	299	125	460	50	632	25
5	Toluene	100 Kgs	1.67	62	3700	178	560	516	67

Note:

AEGL-1 (Yellow zone): The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic non sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

AEGL-2 (Orange zone): The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

AEGL-3 (Red zone): The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life threatening health effects or death.

7.6.3.4 Analysis of quantitative risk assessment data:

Based on the above quantitative risk assessment, following conclusions can be made.

- Flammability threat zones and heat radiation zones for flammable chemicals are within the plant premises
- FEI index for flammable chemicals is moderate for 3 chemicals, intermediate for 1 and light for 1 chemicals
- Storage quantities of flammable chemicals are well below the threshold quantities
- Toxic threat zones (red category) is beyond factory premises for methyl iodide
- Toxic threat zone (Orange category) is within factory premises for all toxic chemicals except acetone
- Toxic threat zone (Yellow Category) is within factory premises for all toxic chemicals. However Yellow zone concentrations are well within TLV values of the chemicals

7.6.3.5 Health Hazards from exposure to hazardous substances and control measures.

Existing hazards considered from operational/equipment manuals. Detailed Hazard identification and health based risk assessment of various operations and processes are carried out.

Based on analysis 5 chemicals are identified as toxic chemicals in liquid form. Toxic concentrations distances are determined based on the modelling data and presented. Following table summarizes the health hazards, antidotes if any and PPEs recommended for people & other suggested measures to control the escape/leakage of chemicals

Table 7.11
Safety precautions for handling of toxic chemicals

S.No	Chemical	Health Hazards	PPE's proposed	Antidotes if any suggested	Storage and handling precautions suggested
1	Ammonia	Very hazardous in case of skin contact (corrosive, irritant, permeator), of eye contact (irritant), of ingestion. Non-corrosive to the eyes. Non-corrosive for lungs. Liquid or spray mist may produce tissue damage particularly on mucous membranes of eyes, mouth and respiratory tract.	Face shield, Full suit, certified or approved Vapor respirator. Gloves. Boots.	No specific antidote	Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 25°C (77°F). Do not breathe gas/fumes/ vapor/spray. Never add water to this product. In case of insufficient ventilation, wear suitable respiratory equipment. Avoid contact with skin and eyes. Keep away from incompatibles such as metals, acids. Keep drums in upright condition. Always keep drums in closed condition
2	Acetone	Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation. Slightly hazardous in	Splash goggles. Lab coat. Vapor respirator. Be sure to use an	No specific antidote	Storage: Store in a segregated and approved area (flammables area). Keep container in a cool, well-ventilated area. Keep container tightly

		case of skin contact (permeator). The substance is toxic to central nervous system (CNS). The substance may be toxic to kidneys, the reproductive system, liver, skin. Repeated or prolonged exposure to the substance can produce target organs damage	approved/certified respirator or equivalent. Gloves		closed and sealed until ready for use. Keep away from direct sunlight and heat and avoid all possible sources of ignition (spark or flame). Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, reducing agents, acids, alkalis.
3	Methylene dichloride	Very hazardous in case of eye contact (irritant), of ingestion, of inhalation. Hazardous in case of skin contact (irritant, permeator). Inflammation of the eye is characterized by redness, watering, and itching. The substance is toxic to lungs, the nervous system, liver, mucous membranes, central nervous system (CNS). Repeated or	Splash goggles. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.	No specific antidote	Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe gas/ fumes/ vapor/spray. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice

		prolonged exposure to the substance can produce target organs damage			immediately and show the container or the label. Avoid contact with skin and eyes.
4	Methyl iodide	Causes eye irritation, redness, pain, conjunctivitis skin causes skin irritation, pain, stinging, reddening of the skin. Inhalation causes respiratory tract irritation. May cause lung damage. May cause spleen & liver damage. Ingestion harmful if swallowed. Aspiration hazard. May cause irritation of digesitve tract. May cause CNS effect	Face shield, Full suit, certified or approved Vapor respirator. Gloves. Boots.	No specific antidote	Storage: store in a cool, dry, well – ventilated area away from heat, spark, open flame, sources of ignition, incompatible materials, corrosive area. Do not expose to air, light. Store under inert atmosphere. Minimize dust generation & accumulation. Use only in a well ventilated area. Use all protective safety equipments. Keep container tightly closed.
5	Toluene	Causes eye irritation, corneal injury, skin: irritation may cause cyanosis of the extremities, may cause irritation of digestive tract, Aspiration of material into the lungs may cause chemical pneumonitis	Face shield, Full suit, certified or approved Vapor respirator. Gloves. Boots.	No specific antidote	Storage: Store in tightly close container, cool, dry well ventilated area away from incompatible substances. Keep away from heat sparks and flame, keep away from sources of ignition Wash thoroughly after handling, ground and bond containers when transferring material. Avoid contact with skin and eyes and clothing.

7.7 Recommendations and suggested safety measures

7.7.1 Building Planning

- Floors must be of unskid /non- slippery type
- Enough space for employees to work
- Passages between working places
- Proper arrangements of temperature control; like fans, A.C, heaters

7.7.2 Material Handling

- Careless handling of heavy materials and components should be avoided
- Use of full mechanical material handling system
- All material handling equipment should be repaired and maintained properly
- Containers employed to transfer liquids should not be defective or leaking
- Proper labelling of solvents
- Substitution of more harmful material by one which is less danger to health
- Exhausts and ventilations should be provided

7.7.3 Safety aspects

- Occupational safety and health policy
- Safety organization
- Safety inspection manual
- Safety audits
- Work environment monitoring system
- Emergency preparedness plan for onsite and off-site
- Accident reporting, investigation and implementation of recommendations
- Training on safety, fire and first aid
- Specially trained personnel
- Standard operating procedures
- Calibration and testing records of various instruments, balances and lab equipment
- Emergency exits
- Adoption of green chemistry
- Identification and training of emergency squads and first aid members
- General safety sign boards
- Publishing of safety bulletins or News letters

7.7.4 Safety measures for Transportation, Storage & Handling of Chemicals

- Solvent is proposed to be received by road tankers and stored in barrels.
- Solvent unloading standard procedure will in place and will be implemented for safe unloading of road tanker.
- Static earthing provision will be made for tanker unloading.
- Drum handling trolleys will be used for transportation of drums up to plant.
- Muffler on the silencer of the tanker during entering in factory premises.
- Display Boards will be provided on all storage tanks which includes the name of the chemicals, stored Material of construction and date of painting.
- Hazardous display board and national fire prevention association code will be displayed on storage area.
- On-site detectors for fire based on heat &/or smoke detection with alarm system will be provided as required.
- Fire extinguishers will be provided as required.
- First aids boxes will also be provided at different places wherever required.
- Water showering system will be provided to the flammable chemicals storage area, wherever required to avoid the vaporization due to increase in atmosphere temperature.
- Area will be declared as "NO SMOKE ZONE".

7.7.5 Risk mitigation measures

- All process reactors, wherever solvents are used shall be provided with nitrogen blanketing system
- All storage tanks of solvents are provided with Condensers
- All reactors handling solvents are provided with vent condensers with chillers
- All centrifuges are connected to condensers to avoid fugitive solvent emissions
- Material data sheets shall be available at user places.
- Engineering controls for leak detection and control of storage tanks
- Availability of neutralization agents to control impact of any leakages of chemicals
- Closed material handling system through pipes
- Spill control kits and procedures are established.

- Provide personal protective equipment (PPE) such as gloves, goggles and respirators.
- Operators training on control measures by on job training/induction training.
- Carry out practice drills for cleaning up spills
- Annual health checks shall be carried out for all employees who are exposed to chemicals
- Information to District authorities to tackle off-site emergency situations
- Ensuring availability of antidotes in the plant and nearby hospital where tie up is there for the company to tackle any off-site emergency situation

7.8 Hazard and Operability Study (HAZOP)

Safety and reliability of modern processing plant can be improved by using procedures that recognize and eliminate potential problems in the design stage. This is especially important because of the increasing need to operate the different units, for economic reasons, more closely to known risk situations. Hence, it requires refined methods like HAZOP study technique for identifying hazardous situations and problems and eliminating them at the design stage.

Based on process reactions, a list of process reactions were identified for taking additional precautions and presented in **table 7.12**

Table 7.12
Hazardous processes and precautions suggested

Unit process	Chemicals involved	Equipment &utilities	Temp/ Pressure	Emissions	Safety measures
Product : Phenazopyridine hydrochloride					
Stage I Diazonium salt	Aniline, Sodium Nitrite, 2,6 - D.A.P, Hydrochloric acid	Scrubber, Chilled water, GLR, PPE, water, Centrifuge	35-40 deg	HCl	Neutralization to prepare sodium chloride vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product :Methocarbamol					
Stage 2	Guaifenesin,	Scrubber,	25-30	NH3	Recycle to prepare

Amidation	Dimethyl carbonate, Toluene, Aq. Ammonia	Chilled water, GLR, PPE, water, Centrifuge	deg		Aq. Ammonia Sol. vent is scrubbed with water PPE to be used by work force
Product : Fluconazole					
Stage I **Friedel Crafts**	ALCl3, Chloroacetyl chloride, Methylene dichloride, 1,3-diflurobenzene, HCl	Scrubber, GLR, PPE, Water	40-45 deg	HCl	Neutralization to prepare sodium chloride vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : MelitracenHCl					
Stage 3 Dehydration	H2SO4, Stage-2, Toluene	Scrubber, GLR, PPE, Water, Hot oil circulation	140 deg	SO2	Neutralization to prepares sodium sulphate vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : Nitrazoxanide					
Stage I Chlorination	Thionyl chloride, 2-Amino-5-Nitrothiazole, Cyclohexane	Scrubber, GLR, PPE, Water	40-45 deg	SO2	Neutralization to prepare sodium sulphate vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : 2,4-Difluoro-alpha-(1H-1,2,4-triazolyl) acetophenone					
Stage I Fridel Crafts	ALCl3, Chloro acetyl chloride, Methylene dichloride, 1,3-diflurobenzene, HCl	Scrubber, GLR, PPE, Water	40-45 deg	HCl	Neutralization to prepare sodium chloride vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : 2,(2,4-Difluoro)-4-amino-(1H-1,2,4-triazole acetophenoneHCl					

Stage I Fridel Crafts	ALCl3, Chloro acetyl chloride, Methylene dichloride, 1,3-diflurobenzene, HCl	Scrubber, GLR, PPE, Water	40-45 deg	HCl	Neutralization to prepare sodium chloride vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : 10,10-dimethylanthracen-9(10H)-one					
Stage III Dehydration	H2SO4, Stage 2, toluene	Scrubber, GLR, PPE, water, Hot oil circulation	140 deg	SO2	Neutralization to prepare sodium sulphate vent is scrubbed with sodium hydroxide solution. PPE to be used by work force
Product : 9-[3-(dimethylamino)propyl]-9,10-ihydro-10,10-dimethylanthracen-9-ol					
Stage III Dehydration	H2SO4, Stage-2, toluene	Scrubber, GLR,PPE, water Hot oilcirculation	140 deg	SO2	Neutralization to prepare sodium sulphate vent is scrubbed with sodium hydroxide solution. PPE to be used by work force

7.8.1HAZOP WORK SHEETS

Typical hazop study for the proposed products is presented in the table below.

Table 7.13
HAZOP Study for Nitrazoxamide

S.No	Deviation	Causes	Consequences	Actions to be taken
1	More Charging of $SOCl_2$	1) Valve seating corroded or struck up in 'open' position 2) Faster addition	1) More So2 and HCl are produced , load on scrubber is increased as SO2 and HCl are vented out into atmosphere causes pollution	1) Valve is to be serviced/ replaced 2) 5 % C.S. lye solution flow rate to be increased

			2) Temp High	
2	No Charging of $SOCl_2$	1) No SOCl2 in M.T 2) Wrong indication of level indicator 3) Bottom valve struck up in closed position	1) Without addition of RM running of agitator, waste of poer and time 2) If level shows less the yield will be less If level shows more, waste of Raw material and more by product formation 3) No material loss, but waste of time	1) Charging of SOCl2 from storage tank to day tank 2) Level indicator bottom & top valves rectification 3) Bottom valve servicing or replacement
3	Less Charging of $SOCl_2$	1) Pipe is partially closed 2) Valve is not properly opened 3) Damaged gasket coming in the way	1) Delay in the reaction 2) Waste of power	1) Choke to be removed 2) Valve to be serviced or replaced 3) Gasket replacement

7.9 Disaster Management Plan

7.9.1 Introduction

A disaster is a catastrophic situation in which suddenly, people are plunged into helplessness and suffering and, as a result, need protection, clothing, shelter, medical and social care and other necessities of life.

Disasters can be divided into two main groups In the first, are disasters resulting from natural phenomena like earthquakes, volcanic eruptions, storm surges cyclones, tropical storms. Floods, avalanches, landslides, and forest fires. The second group includes disastrous events occasioned by man, or by man's impact upon the environment. Examples are armed conflict.

Industrial accidents, radiation accidents, factory fires, explosions and escape of toxic gases or chemical substances, river pollution, mining or

other structural collapses, air, sea rail and road transport accidents and can reach catastrophic dimensions in terms of human loss.

7.9.2 Objectives of Emergency Management Plan (On-Site)

A quick and effective response during emergency can have tremendous significance on whether the situation is controlled with little loss or it turns into a major emergency therefore, the objectives of this onsite emergency plan (ONSEP)

During Emergency: is to provide basic guidance to the personnel for effectively combating such situations to minimize loss of life, damage to property and loss of property.

- To Locate emergency and if possible to eliminate
- To minimize loss to personnel and property, in quickest time possible
- Fire fighting equipments and safety Appliances should be made available, in readily usable condition, in the event of emergency
- To decide for shutdown of the plant in case of emergency
- To localize the hazard/ accident
- To fix responsibilities to the persons in the plant in case of emergencies
- To arrange rescue operations and treatment to the persons affected
- To provide safety to other persons present in the plant at the time of hazard
- To contain the hazard within the plant
- To get assistance from neighbouring industries under Mutual Aid, fire Station, Hospitals etc.
- To alert the statutory authorities concerned for further action in case the hazard is likely to extend to the outside area of the plant
-

During Normal Time:

- To keep the required emergency equipment in stock at right places and ensure their working condition;
- To provide proper guidelines to all personnel for emergency operations and escape
- Preserve relevant records and evidence for the emergency case and subsequent enquiry
- Investigation and remedial measures to avoid reoccurrence of the hazard

7.9.3 Elements of onsite Emergency Plan

- Important elements considered in this plan are:
- Identification of emergencies
- Emergency organization
- Emergency facilities
- Emergency procedure
- Communications during emergency
- Rescue, Transport and Rehabilitation
- Roles and responsibilities of key personnel and essential employees
- Mutual aid

7.9.4 Emergencies Identified

Following are the potential emergencies anticipated from Deccan remedies Limited

- Fire accidents at Bulk solvent storage & HSD areas
- Fire accidents at Boiler area, DG area
- Fire accidents in drier area
- Toxic gas release from storage of chemicals
- Major Spillage of solvents & other chemicals
- Fire/Explosion/Toxic gas release from cylinders

7.9.5 Emergency Organization

The responsibilities of key personnel for emergencies are clearly defined as follows

An emergency control room as the focal point has been earmarked. The control room flashes information to various agencies as shown in the chart. This is located in an area of minimum risk and close to road. Security and Time office room is the emergency control point.

7.9.6 Emergency Facilities

a) Emergency Control Centre (ECC)

It is a location where all key personnel like Site Controller, Emergency Coordinators can take stock of situation or can assemble and monitor aspects related to emergency and take decisions related to emergency.

The following information and facilities would be maintained at the ECC Plant control room: Latest copy of Onsite Emergency Plan and Off Site Emergency Plan (as provided by District Emergency Authority)

- Intercom Telephone
- P&T Telephone
- Telephone Directories (internal and P&T)

- Factory Layout, Site Plan
- Electrical cable rooting plan, locations of hazardous inventories, sources of safety equipment, hydrant layout, location of pump house, road plan, assembly by points, vulnerable zones, escape routes;
- Emergency shutdown procedures for generators and fuel supply system;
- Nominal roll of employees;
- List and addresses of key personnel;
- List and addresses of first aid providers;
- List and addresses of employees trained in fire fighting;
- List and addresses of qualified trained persons;
- Material safety data sheets of raw materials;
- Duties of key personnel;
- Important addresses and telephone numbers including those of fuel supplying company, government agencies, neighbouring industries and other sources of help, outside experts;

b) Assembly Points

Assembly points are those locations where the persons who are not connected with emergency operations can await either for further instructions or for rescue transport and rehabilitation. Assembly point will be located far away from production area.

a) **Emergency control systems**

The following emergency control systems are suggestedby M/s. Deccan remedies Limited

- Lightening protection for all buildings and high raised chimneys.
- Double Earthing & Bonding for electrostatic hazards for all reactors
- Mobile earthing for drums while charging material
- Closed arrangement for solvent transferring.
- Pressure Relief system & Rupture Discs
- Earth Rite system for road tanker loading and unloading.
- FLP fittings at Flammable materials handling areas.
- Product containment booth at raw material sifting.
- Addressable fire detection system.
- Fire protection systems :
- Portable Fire Extinguishers
- Fire Hydrant system covering all blocks
- Wind Sack

- Occupational Health Centre.
- Safe handling procedures.
- Spill Control kits.

d) Location of First Aid Boxes

The first aid boxes will be made available at the following places- production blocks, administrative office, time office, and will be under the charge of EHS in-charge.

e) Fire protection system

An elaborate fire protection system to cover the entire plant including manufacturing blocks, Bulk storage tanks and utility areas is proposed. Water storage of 100 KL is maintained in the fire sump to meet any emergency. Details of fire fighting equipments are given below

f) Fire Hydrant System

A self-operated fire hydrant network with a separate fire water pump house will be installed in the plant to take care of fire accidents independently in the incipient stage of fire to minimise the loss of property and life. The fire hydrant system contains the following main items:

- Fire Water Reservoir with 1 lakh liters capacity
- Fire water pump house.
- Diesel Engine coupled fire water Main Pump.
- Electrical Motor coupled Booster Pump.
- Fire hydrant mains
- Necessary fire hoses with reinforced plastic hose boxes.

g) Fire Fighting Equipment

Dry Powder extinguishers
Carbon dioxide extinguishers
Dry Chemical Powder extinguishers
Foam Type extinguishers

Proposed PERSONAL PROTECTIVE EQUIPMENT

Item	Quantity	Item	Quantity
Air Breathing Apparatus	2 10	Safety Belts Helmets	2 20
Gum boots	1	Asbestos Hand Gloves	5 4
PVC Suit with Hood	30		

Ordinary Air Masks	10	PVC Hand Gloves	2
Eye Goggles	10	Elec. Rubber Gloves	6
Aprons	1	Ear Muffs	
Fire Suit			

h) Emergency Escapes

Emergency escapes in the plant area and floor wise emergency will be conspicuously marked.

7.10 ORGANISATION

General Manager will be the over all in-charge of the plant operations and is assisted by all Plant Manager &department heads. Production activities are looked after by both the Production Head/Managers, EHS activities Safety I/C, Engineering aspects by head (Maintenance) Plant Electrical maintenance by Electrical Engineer, material inventory by stores head, Personnel & Administration wings, other department heads are directly reporting to General Manager.

7.11 MAN POWER

Well qualified and experienced Chemists/Executives/Assistants/Managers in finished dosage manufacturing Industry will be employed.

SHIFT TIMINGS

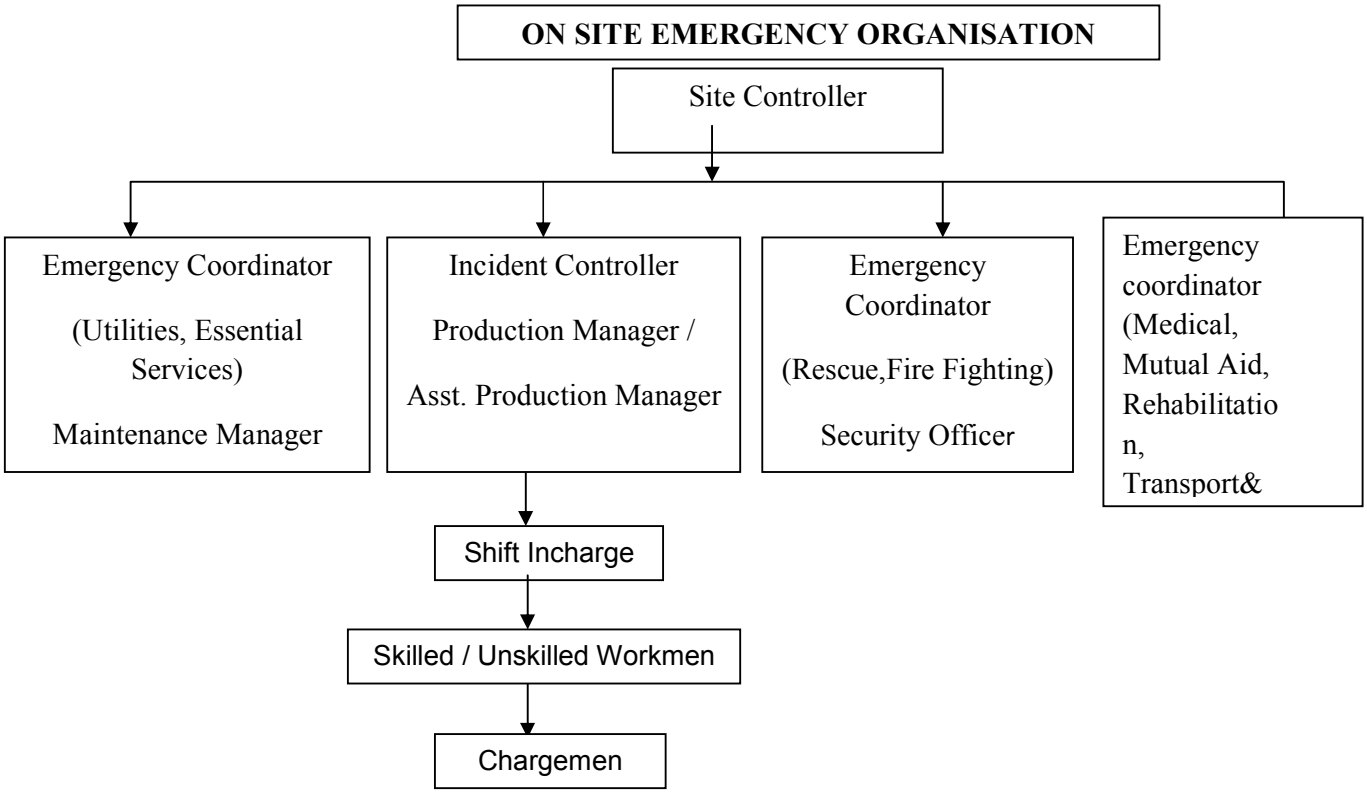
A Shift	06 Hrs - 14 Hrs
B Shift	14 Hrs – 22.00Hrs
C Shift	22.00Hrs– 06.00Hrs
General Shift	9.00 Hrs – 6.00Hrs

7.11.1 EMERGENCY ORGANISATION

An emergency organisation is drawn up to execute emergency operations. General Manager is designated as the Site Controller. He reports to Managing Director along with other functionaries like Q.C., Process Development. Production Manager is designated as the Incident Controller. In the absence of General Manager, Production Manager assumes role of Site Controller. Maintenance Manager is Emergency Coordinator (Utilities). Personnel Executive is Emergency Coordinator for Rescue, Rehabilitation. Shift Incharge, Chargemen, Boiler Operators, Chilling Plant Operator, Electrical Incharge, Chemists are designated as

Essential Employees and would assist Incident Controller, Emergency Co-ordinators in mitigating the effects of emergency and also in rescue, rehabilitation, first aid etc. Detailed duties are laid out along with General Organisation Chart and Emergency Chart.

All Managers are usually present during day shift are designated as Key Personnel and Coordinate different functions during non-emergency and emergency situation



7.12 MOCKDRILL

Mock Drills would be organized once in six months to evaluate the preparedness and functioning of OSEP. It is also planned to undertake few informed and non-informed mock drills (or rehearsals) for meeting emergencies. Such rehearsals would be carefully analyzed and shortcomings would be identified and necessary corrections would be taken up. Site controller is responsible for planning and execution and evaluation of mock drills. Also information would be given to statutory authorities. It is proposed to at-least conduct two mock drills in a year and over a period of time all the sections in all the shifts would be covered. When truck drivers carrying product are in the plant, they also would be trained regarding transportation emergencies and how to react to minimize the damage or effect on people.

7.12 REVIEW OF ONSITE EMERGENCY PLAN

- Onsite Emergency Plan would be reviewed whenever there is a change in product, or product route of manufacture, or addition of new equipment or change in Site Controller.
- Site Controller is responsible for such update and making available latest copy or Onsite Emergency Plan to all concerned in the organization as will as to the Statutory Authorities.

7.14 OCCUPATIONAL HEALTH SURVEILLANCE:

M/S Deccan remedies Limited proposed to establish occupational health center with the following emergency handling facilities

- Stretcher
- Bed
- Self breathing equipment
- First aid boxes
- Ambulance is on call
- One company vehicle will be made available in day and night shifts

The unit will tie up with Nearest Hospitals in Zaheerabad. Annual health check up for all employees who are working in production areas and stores areas, including casual workers, will be done through the hospital. It is suggested to including general health check up, lung function test, Liver function tests, urine and blood examinations. It is suggested to maintain Antidotes as suggested for toxic gas hazards in the referral hospital always to meet any emergencies