ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

7.0 ADDITIONAL STUDIES

7.2 RISK ASSESSMENT

7.2.1 Introduction

Hazard analysis involves the identification and quantification of the various hazards (unsafe conditions) that exist in the proposed plant. On the other hand, risk analysis deals with the recognition and computation of risks, the equipment in the plant and personnel are prone to, due to accidents resulting from the hazards present in the plant.

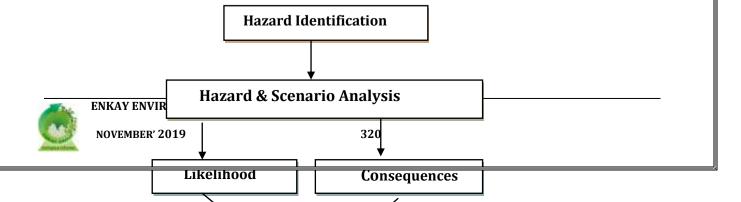
Risk analysis follows an extensive hazard analysis. It involves the identification and assessment of risks the neighboring populations are exposed to as a result of hazards present. This requires a thorough knowledge of failure probability, credible accident scenario, vulnerability of population etc. Much of this information is difficult to get or generate. Consequently, the risk analysis is often confined to maximum credible accident studies.

In the sections below, the identification of various hazards, probable risks in the proposed plant, maximum credible accident analysis, consequence analysis are addressed which gives a broad identification of risks involved in the plant. The Disaster Management Plan (DMP) has been presented based on the risk estimation for storage of Methanol, Ethanol, Methylene dichloride, Chloroform, Acetone, Toluene, Ethyl Acetate and Acetonitrile only which are installed.

7.2.2 Approach to the Study

Risk involves the occurrence or potential occurrence of some accidents consisting of an event or sequence of events. The risk assessment study covers the following:

- Identification of potential hazard areas;
- Identification of representative failure cases;
- Visualization of the resulting scenarios in terms of fire (thermal radiation) and explosion;
- Assess the overall damage potential of the identified hazardous events and the impact zones from the accidental scenarios;
- Assess the overall suitability of the site from hazard minimization and disaster mitigation point of view;
- Furnish specific recommendations on the minimization of the worst accident possibilities;
 and
- Preparation of broad Disaster Management Plan (DMP), On-site and Off-site Emergency Plan, which includes Occupational and Health Safety Plan.



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Figure 7.1: Process Of Risk Analysis

7.3 HAZARD IDENTIFICATION

Identification of hazards in the modification of the existing plant is of primary significance in the analysis, quantification and cost effective control of accidents involving chemicals and process. A classical definition of hazard states that hazard is in fact the characteristic of system/plant/process 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.

7.3.1 Classification of Major Hazardous Units

Hazardous substances may be classified into three main classes namely flammable substances, unstable substances and toxic substances. The major hazardous materials to be stored, transported, handled and utilized within the facility have been summarized in the **Table No. 7.1**. The storage details and properties are given in **Table No. 7.2** and **Table No. 7.3** respectively.

Table No. 7.1: Hazardous Materials Stored, Transported and Handled

S. No	Materials	Hazardous Properties			
1.	Methanol	UN 1230	Dangerous Goods class 3	Flammable Liquid	
2.	Ethanol	UN 1170	Dangerous Goods class 3	Flammable Liquid	
3.	Methylene Dichloride	UN 1593	Dangerous Goods class 3	Flammable Liquid	
4.	Acetone	UN 1090	Dangerous Goods class 3	Flammable Liquid	
5.	Toluene	UN 1294	Dangerous Goods class 3	Flammable Liquid	
6.	Ethyl Acetate	UN 1173	Dangerous Goods class 3	Flammable Liquid	
7.	HSD	UN 1202	Dangerous Goods class 3	Flammable Liquid	
8.	Hexane	UN 1208	Dangerous Goods class 3	Flammable Liquid	

Table No. 7.2: Category Wise Schedule of Storage Tanks

Material	Capacity (KL)	Classification
Methanol	30	Flammable Liquid
Ethanol	15	Flammable Liquid
Methylene Dichloride	30	Flammable Liquid
Acetone	15	Flammable Liquid
Toluene	15	Flammable Liquid



ACTIVE PHARMACEUTICALS INGREDIENTS

APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Ethyl Acetate	10	Flammable Liquid
HSD	15	Flammable Liquid
Hexane	15	Flammable Liquid

Table No. 7.3: Properties of Materials Used in the Plant

Chemical	Codes/Label	TLV	BP	MP	FP	UEL	LEL
				°c		%)
Methanol	Flammable	200 ppm	64.6		11	36	6
Ethanol	Flammable	1000 ppm	79	- 117	13	19	3.3
Methylene	Flammable	25 ppm	40	- 97		23	13
Dichloride							
Acetone	Flammable	500 ppm	56	- 95	-18	13	2.2
Toluene	Flammable	50 ppm	111	- 95	4	7.1	1.1
Ethyl Acetate	Flammable	400 ppm	77	- 84	-4.4	11.5	2
HSD	Flammable	100 ppm	282 - 338	- 30 to -18	52	6.5	0.6
Hexane	Flammable	50 ppm	69	- 95	- 22	7.5	1.1

TLV : Threshold Limit Value BP : Final Boiling Point

MP : Melting Point FP : Flash Point

UEL : Upper Explosive Limit LEL : Lower Explosive Limit

7.4 HAZARD ASSESSMENT AND EVALUATION

7.4.1 Methodology

An assessment of the conceptual design is conducted for the purpose of identifying and examining hazards related to feed stock materials, major process components, utility and support systems, environmental factors, proposed operations, facilities, and safeguards.

To minimize the risk of hazards, industry should maintain a management plan and the process of Hazard management must involve the following four phases:

- Mitigation,
- Preparedness,
- Response
- Recovery

7.4.2 Preliminary Hazard Analysis (PHA)

A preliminary hazard analysis is carried out initially to identify the major hazards associated with storages and the processes of the plant. This is followed by consequence analysis to quantify these hazards. Finally, the vulnerable zones are plotted for which risk reducing measures are deduced and implemented. Preliminary hazard analysis for storage area and whole plant is given in **Table No. 7.4** and **Table No. 7.5**.

Table No. 7.4: Preliminary Hazard Analysis for Storage Areas

Unit	Capacity (KL)	Hazard Identified
Methanol	30	Fire/Explosion

ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Ethanol	15	Fire/Explosion
Methylene Dichloride	30	Fire/Explosion
Acetone	15	Fire/Explosion
Toluene	15	Fire/Explosion
Ethyl Acetate	10	Fire/Explosion
HSD	15	Fire
Hexane	15	Fire/Explosion

Table No. 7.5: Preliminary Hazard Analysis for the Whole Plant in General

PHA Category	Description of Plausible Hazard	Recommendation	Provision
Environ-mental factors	If there is any leakage and eventuality of source of ignition.		All electrical fittings and cables are provided as per the specified standards. All motor starters are flame proof.
Environ-mental factors	Highly inflammable nature of the liquid Chemical may cause fire hazard in the storage facility.	A well designed fire protection including foam, dry powder, and CO2 extinguisher should be provided.	Fire extinguisher of small size and big size are provided at all potential fire hazard places. In addition to the above, fire hydrant network is also provided.

7.4.3 Maximum Credible Accident Analysis (MCAA)

Hazardous substances may be released as a result of failures or catastrophes, causing possible damage to the surrounding area. This section deals with the question of how the consequences of the release of such substances and the damage to the surrounding area can be determined by means of models. Major hazards posed by flammable storage can be identified taking recourse to MCA analysis. MCA analysis encompasses certain techniques to identify the hazards and calculate the consequent effects in terms of damage distances of heat radiation, toxic releases, vapour cloud explosion, etc. A host of probable or potential accidents of the major units in the complex arising due to use, storage and handling of the hazardous materials are examined to establish their credibility. Depending upon the effective hazardous attributes and their impact on the event, the maximum effect on the surrounding environment and the respective damage caused can be assessed. The reason and purpose of consequence analysis are many folds like:

- Part of Risk Assessment;
- Plant Layout/Code Requirements;
- Protection of other plants;
- Protection of the public;
- · Emergency Planning; and
- Design Criteria.



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

The results of consequence analysis are useful for getting information about all known and unknown effects that are of importance when some failure scenario occurs in the plant and also to get information as how to deal with the possible catastrophic events. It also gives the workers in the plant and people living in the vicinity of the area, an understanding of their personal situation.

Selected Failure Cases

The purpose of this listing (refer Table 7.9) is to examine consequences of such failure individually or in combination. It will be seen from the list that a vast range of failure cases have been identified. The frequency of occurrence of failure also varies widely.

• Damage Criteria

The chemical storage and unloading at the storage facility may lead to fire and explosion hazards. The damage criteria due to an accidental release of any hydrocarbon arise from fire and explosion. The vapors of these Chemical are not toxic and hence no effects of toxicity are expected.

Tank fire would occur if the radiation intensity is high on the peripheral surface of the tank leading to increase in internal tank pressure. Pool fire would occur when chemicals are collected in the dyke due to leakage gets ignited.

Fire Damage

A flammable liquid in a pool will burn with a large turbulent diffusion flame. This releases heat based on the heat of combustion and the burning rate of the liquid. A part of the heat is radiated while the rest is convicted away by rising hot air and combustion products. The radiations can heat the contents of a nearby storage or process unit to above its ignition temperature and thus result in a spread of fire.

The radiations can also cause severe burns or fatalities of workers or fire fighters located within a certain distance. Hence, it will be important to know beforehand the damage potential of a flammable liquid pool likely to be created due to leakage or catastrophic failure of a storage or process vessel. This will help to decide the location of other storage/process vessels, decide the type of protective clothing the workers/fire fighters' need, the duration of time for which they can be in the zone, the fire extinguishing measures needed and the protection methods needed for the nearby storage/process vessels. **Table No. 7.7** tabulates the damage effect on equipment and people due to thermal radiation intensity.

Table No. 7.7: Damage Due to Incident Radiation Intensities

Sr.	Incident	Type of Damage Intensity		
No.	Radiation (kW/m²)	Damage to Equipment	Damage to People	
1	37.5	Damage to process equipment	100% lethality in 1 min. 1% lethality in 10 sec.	
2	25.0	Minimum energy required to ignite wood	50% Lethality in 1 min. Significant injury	



ENKAY ENVIRO SERVICES PVT. LTD., JAIPUR

ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Sr.	Incident	Type of Damage Intensity			
No.	Radiation (kW/m²)	Damage to Equipment	Damage to People		
		at indefinitely long exposure without a flame	in 10 sec.		
3	19.0	Maximum thermal radiation intensity allowed on thermally unprotected adjoining equipment			
4	12.5	Minimum energy to ignite with a flame; melts plastic tubing	1% lethality in 1 min.		
5	4.5		Causes pain if duration is longer than 20 sec, however blistering is un-likely (First degree burns)		
6	1.6		Causes no discomfort on long exposures		

Source: Techniques for Assessing Industrial Hazards by World Bank.

The effect of incident radiation intensity and exposure time on lethality is given in **Table-7.8**.

Table no. 7.8 Radiation Exposure and Lethality

Radiation Intensity (kW/m²)	Exposure Time (seconds)	Lethality (%)	Degree of Burns
1.6		0	No Discomfort even after long exposure
4.5	20	0	1 st
4.5	50	0	1 st
8.0	20	0	1 st
8.0	50	<1	3 rd
8.0	60	<1	3 rd
12.0	20	<1	2 nd
12.0	50	8	3 rd
12.5	Inst	10	
25.0	inst	50	1
37.5	inst	100	

7.4.5 Scenarios Considered for MCA Analysis

• Chemical Storage

The details of storages in the proposed plant are given Table-7.2 above. In case of chemical released in the area catching fire, a steady state fire will occur. Failures in pipeline may occur due to corrosion and mechanical defect. Failure of pipeline due to external interference is not considered as this area is licensed area and all the work within this area is closely supervised with trained personnel.

• Modeling Scenarios

Based on the storage and consumption of various chemicals the following failure scenarios for the proposed plant have been identified for MCA analysis and the scenarios are discussed in **Table No.**

7.9. The chemical properties considered in modeling are given in **Table No. 7.10**.

Table No. 7.9: Scenarios Considered For MCA Analysis



ACTIVE PHARMACEUTICALS INGREDIENTS

APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

S. No.	Fuel/Chemical	Total Quantity (KL)	Scenarios considered
1.	Failure of Methanol Tank	30	Pool fire
2.	Failure of Ethanol Tank	15	Pool fire
3.	Failure of Methylene Dichloride Tank	30	Pool fire
4.	Failure of Acetone Tank	15	Pool fire
5.	Failure of Toluene Tank	15	Pool fire
6.	Failure of Ethyl Acetate Tank	10	Pool fire
7.	Failure of HSD Tank	15	Pool fire
8.	Failure of Hexane Tank	15	Pool fire

Table-7.10: Properties of Chemicals Considered For Modeling

S. No.	Fuel/substance	Molecular weight	Boiling Point (°C)
1	Methanol	34.04	64.6
2	Ethanol	46.1	79
3	Methylene Dichloride	84.93	40
4	Acetone	58.08	56
5	Toluene	92.1	111
6	Ethyl Acetate	88.1	77
7	HSD	114.2	282 - 338
8	Hexane	86.2	69

7.4.6 Pool Fire Models used for MCA Analysis

Heat Radiation program '**RADN**' has been used to estimate the steady state radiation effect from storage of fuel at different distances. The model is based on the equations compiled from various literatures by Prof. J. P. Gupta, Department of Chemical Engineering, IIT Kanpur.

7.4.7 Results and Discussion

The results of MCA analysis are tabulated indicating the distances for various damages identified by the damage criteria, as explained earlier. Calculations are done for radiation intensities levels of 37.5, 25, 12.5, 4.5 and 1.6-kW/m², which are presented in **Table-7.11** for different scenarios. The distances computed for various scenarios are from the center of the pool fire.

Table-7.11: Occurrence of Various Radiation Intensities- Pool Fire

Thermal Radiation Level	Damage Distance from the Centre of the pool (M)			
	Methanol	Ethanol	Methylene Dichloride	Acetone
37.5 kW/m ² (100% lethality in 1	14	8	17	11
min)				
25 kW/m ² (50% lethality in 1 min)	25	16	27	18
12.5 kW/m ² (1% lethality in 1 min)	49.8	33	52	36
4.5 kW/m ² (Causes 1st degree burns	109	69	111	79
on exposure more than 50 sec)				
1.6 kW/m ² (Causes no discomfort	218	151	219	158
even after long exposure)				
Thermal Radiation Level	Damage Distance from the Centre of the pool (M)			
	Toluene	Ethyl Acetate	HSD	Hexane
37.5 kW/m ² (100% lethality in 1	Within pool	Within pool	Not attained	Within

ACTIVE PHARMACEUTICALS INGREDIENTS

APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

min)				pool
25 kW/m ² (50% lethality in 1 min)	9	12	Not attained	15
12.5 kW/m ² (1% lethality in 1 min)	22	26	7	31
4.5 kW/m ² (Causes 1st degree burns	54	59	28	68
on exposure more than 50 sec)				
1.6 kW/m ² (Causes no discomfort	113	119	66	137
even after long exposure)				

7.4.8 Hazardous Events with Greatest Contribution to Fatality Risk

The hazardous event scenarios likely to make the greatest contribution to the risk of potential fatalities are summarized in **Table No. 7.12**. 'Onsite facility' refers to the operating site at Udaipur, whereas 'offsite facility' refers to transport and handling systems, which are away from the operating site.

Table-7.12: Hazardous events contributing to on-site facility risk

Hazardous Event	Risk Rank	Consequences of Interest
Onsite vehicle impact on personnel	3	Potential for single fatalities, onsite impact only
Entrapment/struck by machinery	3	Potential for single fatalities, onsite impact only
Fall from heights	3	Potential for single fatalities, onsite impact only
Electrocution	3	Potential for single fatalities, onsite impact only
Storage tank rupture	3	Potential for single fatalities, onsite impact only

7.4.9 Risk Assessment Summary

The preliminary risk assessment has been completed for the proposed plant and associated facilities and the broad conclusions are as follows:

- There will be no significant community impacts or environmental damage consequences;
 and
- The hazardous event scenarios and risks in general at this facility can be adequately
 managed to acceptable levels by performing the recommended safety studies as part of
 detailed design, applying recommended control strategies and implementing a Safety
 Management System.

7.4.10 Risk Reduction Opportunities

The process of bulk drug manufacturing activities is quite complex and has inherent risks of on-site and off-site environmental overheads.

The following opportunities will be considered as a potential means of reducing identified risks during the detailed design phase:

 Buildings and plant structures designed for cyclone and seismic events (where appropriate), to prevent structural collapse and integrity of weather (water) proofing for storage of dangerous goods.

ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

- Provision for adequate water capacity to supply fire protection systems and critical process water
- Isolate people from load carrying/mechanical handling systems, vehicle traffic and storage and stacking locations.
- Installation of fit-for-purpose access ways and fall protection systems to facilitate safe access to fixed and mobile plant.
- Provision and integrity of process tanks, waste holding tanks and bounded areas as per relevant standards
- Containment of hazardous materials.
- Security of facility to prevent unauthorized access to plant, introduction of prohibited items, and control of onsite traffic; and
- Development of emergency response management systems commensurate with site specific hazards and risks (fire, explosion, rescue and first aid).
- The industrial units using hazardous chemicals as raw materials in processes, products
 and wastes with inflammable, explosive, corrosive, toxic and noxious properties will be
 required to have onsite and offsite emergency plans in place and put them to test by
 organizing regular mock drills.
- Industry should create a portfolio of disaster reduction actions, compiling best practice and
 lessons learned from previous disasters, and a catalogue of technologies for disaster
 reduction. The chemical industry should share well-developed codes, translated into
 several languages and adapted to the different environments in which we operate.

7.5 STORAGE AND HANDLING OF HAZARDOUS CHEMICALS

A storage and handling of hazardous chemical in a chemical industry is inevitable, land they carry inherent characteristic risk to the employees due to the properties of chemicals such as toxicity & flammability. Accident due to fire and explosion by flammable substances are possible in process industry. The disastrous effect of fire, explosion and release of toxic fumes in storage and production area, is due to inappropriate design, improper storage, improper handling, poor maintenance or deficiencies in the operation of the plant. Chemical in any form can be stored, handled and used if their physical, chemical and hazardous properties are thoroughly understood and necessary precautions are taken.

Each chemical has its specific character. Hence, chemicals do not co-exist. They need their independent space, while storing. When two chemicals come in contact, they react generating heat and by product gases. Ambient temperature and moisture can trigger the reaction. Halogenated compounds acquire aggravated properties. It is only wise to treat every chemical as Toxic.

ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Chemicals are potential enough to destroy the flesh and the skin is ultra sensitive to chemicals. Chemicals on contact, the affected parts of the body should be washed thoroughly with plenty of water for at least 15 minutes, to dilute the aggressive nature of the chemical, as water is the only universal solvent and the best diluents. Then only further treatment is to be followed.

Chemicals are handled in standard containers like MS, HDPE, GI Drums, PVC Carboys, etc. All the chemicals are to be arranged and stored in accordance with their compatibility, dry, well ventilated, with flameproof electrical equipments and lighting. All the chemicals are to be provided with identification labels.

Eye wash/Drench shower is to be provided at a strategic location for emergency purpose.

Chemical Safety Data Sheets and handling procedure, First Aid measures are to be prepared and displayed for information and safety of the working personnel.

7.5.1 Hazards/Exposure Control of Chemicals

The hazards involved and its control measures for the following chemicals which are being handled / stored in the premises are given below:

I. METHANOL

Engineering controls:

Methanol is routinely stored in tank farms consisting of above-ground, floating roof tanks and smaller, internally baffled floating baffle tanks. Tanks must be grounded to avoid hazards associated with static discharge. Ignition control may be by nitrogen padding, natural gas padding, or by designation of a hazard zone with ignition control. Because methanol is commonly stored with other solvents and feed stocks, all piping and valves subject to carrying methanol should be consistently labeled, and direction of flow should be indicated. All storage materials, including totes and drums, require berming and adequate ventilation. Examples of engineering controls that can be used to prevent exposure to methanol include:

- Installation of local ventilation hoods
- Ventilated enclosures around work processes (fume hoods, glove,boxes)
- Use of closed piping and storage systems
- Use of automatic systems to pump methanol from storage containers to process systems or containers

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Respiratory protection:



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

- **Emergency Use:** Self-contained breathing apparatus (SCBA) or positive pressure airline with full face mask with escape pack should be worn in areas of a large release or unknown concentration.
- **Eye Protection:** Safety glasses for handling cylinders, Chemical goggles with full face shield for connecting, disconnecting or opening cylinders.
- **Skin Protection:** Chemical-resistant gloves for handling cylinders. Chemical resistant outer garment should be worn when connecting or disconnecting cylinders. Total encapsulating chemical suit may be necessary in large release area.
- Other Protective Equipment: Safety shoes are recommended when handling cylinders. Safety shower and eyewash fountain should be readily available.
- **Caution:** Contact with eyes causes irritation, redness, pain and ingestion cause Neurological, Gastro intestinal disorders.

Fire Fighting Measures:

EXTINGUISHING MEDIA
 Use alcohol-resistant foam, carbon dioxide (CO2) or dry chemical.

UNUSUAL FIRE AND EXPLOSION HAZARDS

- Highly flammable. Vapours may form explosive mixtures with air. Vapours are
 heavier than air and may travel along the ground to some distant source of
 ignition and flash back. Suppress (knock down) gases/vapours/mists with a
 water spray jet.
- Hazardous combustion products may include carbon monoxide, formaldehyde, and carbon dioxide (CO2).

• SPECIAL FIRE FIGHTING PRECAUTIONS/INSTRUCTIONS

 Water may be ineffective. Do not use a solid water stream as it may scatter and spread fire. Fire or intense heat may cause violent rupture of packages. Fire-fighters should wear self-contained, NIOSH-approved breathing apparatus and full protective clothing. In the event of fire, cool tanks with water spray. After fire, flush area with water to prevent re-ignition. Do not allow run-off from fire fighting to enter drains or water courses

II. Methylene Dichloride

Engineering controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits.

• Eye/face protection:



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Splash goggles. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

• Skin protection:

In case of contact, Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

• Protective Equipment

Gloves, Lab coat & Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

Fire Fighting Measures:

As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Use water spray to keep fire-exposed containers cool. No flash point in conventional closed tester, but forms flammable vapor-air mixtures in larger volumes and may be an explosion hazard in a confined space.

Extinguishing Media:

Use water spray, dry chemical, carbon dioxide, or appropriate foam.

III. ACETONE

• Engineering controls

• Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

• Eye/face protection:

• Splash goggles. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

• Skin protection:

• In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

• Protective Equipment

• Gloves, Lab coat & Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

Fire Fighting Media and Instructions:



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

• Flammable liquid, soluble or dispersed in water. SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use alcohol foam, water spray or fog.

IV. ETHYL ACETATE

Engineering Controls:

- 1 A ventilation system that does not create sparks and is grounded should be used separately.
- 2 The ventilation exits should be directly connected to the outside area.
- 3 The local ventilation equipment should be used. The airtight procedure should be used if necessary in order to control mists.
- 4 Provide sufficient fresh air to replenish the air exhausted by the exhaust system.

• Personal Protection:

- 1 Below 2000ppm: full respiratory protectors equipped with chemical filter cartridge for organic vapors, respiratory protectors with organic vapor filters powered for air purification, gas masks with organic vapor filters, respiratory protectors with full self-contained, full air supply or continuous air supply.
- 2 Unknown Concentration: positive-pressure self-contained respiratory apparatus, positive-pressure full air-supply respiratory apparatus with positive-pressure self-contained respiratory apparatus.
- 3 Escape: Gas mask with organic vapor filter cartridge, life escape self-contained breathing apparatus.
- 4 Hand Protection:
- 5 Impermeable gloves made from 4H, Barricade, Responder, CPF3, Trellchem HPS, Tychem 10000 preferred.
- 6 Eye Protection:
- 7 Chemical goggles, facial shields.
- 8 Skin & Body Protection: The above-mentioned one-piece protective rubber clothing, work boots and safety showers.

V. ETHANOL

Engineering Control:

For flammable liquids and flammable gases, local exhaust ventilation or a process enclosure ventilation system may be required. Ventilation equipment should be explosion-resistant.

RESPIRATOR

Type A Filter of sufficient capacity

EYE

• Safety glasses with side shields.



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

· Chemical goggles.

HANDS/FEET

• Wear chemical protective gloves, eg. PVC.

Fire Fighting Measures

- Extinguishing Media
- Water spray or fog.
- Foam.

Fire Fighting

- Alert Fire Brigade and tell them location and nature of hazard.
- May be violently or explosively reactive.
 When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 500 metres in all directions

7.6 DISASTER MANAGEMENT PLAN

7.6.1 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, 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 which can reach catastrophic dimensions in terms of human loss.

There can be no set criteria for assessing the gravity of a disaster in the abstract since this depends to a large extent on the physical, economic and social environment in which it occurs. What would be consider a major disaster in a developing country, ill equipped to cope with the problems involved, and may not mean more than a temporary emergency elsewhere. However, all disasters bring in their wake similar consequences that call for immediate action, whether at the local, national or international level, for the rescue and relief of the victims. This includes the search for the dead and injured, medical and social care, removal of the debris, the provision of temporary shelter for the homeless, food, clothing and medical supplies, and the rapid reestablishment of essential services.

7.6.2 Objectives of Disaster Management Plan [DMP]

The Disaster Management Plan is aimed to ensure safety of life, protection of environment, protection of installation, restoration of production and salvage operations in this same order of priorities. For effective implementation of the Disaster Management Plan, it should be widely circulated and personnel trained through rehearsals/drills.

The Disaster Management Plan should reflect the probable consequential severalties of the undesired event due to deteriorating conditions or through 'Knock on' effects. Further the management should be able to demonstrate that their assessment of the consequences uses good supporting evidence and is based on currently available and reliable information, incident data from internal and external sources and if necessary the reports of outside agencies.

To tackle the consequences of a major emergency inside the plant or in the immediate vicinity of the plant, a Disaster Management Plan has to be formulated and this planned emergency document is called "Disaster Management Plan".

The objective of the Industrial Disaster Management Plan is to make use of the combined resources of the plant and the outside services to achieve the following:

- Effect the rescue and medical treatment of casualties:
- Safeguard other people;
- Minimize damage to property and the environment;
- Initially contain and ultimately bring the incident under control;
- Identify any dead;
- Provide for the needs of relatives;
- Provide authoritative information to the news media:
- Secure the safe rehabilitation of affected area; and
- Preserve relevant records and equipment for the subsequent inquiry into the cause and circumstances of the Emergency.

In effect, it is to optimize operational efficiency to rescue, rehabilitate and render medical help and to restore normalcy.

7.6.3 Emergencies

I. General, Industrial, Emergencies

The emergencies that could be envisaged in the plant and fuel storage are as follows:

- A situation of fire at the tank farm of all storages;
- Slow isolated fires;
- Fast spreading fires;
- Structural failures;
- Contamination of food/water; and
- Sabotage/Social disorder.



ACTIVE PHARMACEUTICALS INGREDIENTS APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

II. Specific Emergencies Anticipated

Fire and Explosion

Fire consequences can be disastrous, since they involve huge quantities of fuel either stored or in dynamic inventory in pipe lines or in nearby areas. Preliminary hazard analysis has provided a basis for consequence estimation. Estimation can be made by using various pool fire, tank fire consequence calculations. During the study of Risk Assessment, the nature of damages is worked out and probability of occurrence of such hazards is also drawn up.

7.6.4 Emergency Organization

It is recommended to setup an Emergency Organization. A senior executive who has control over the affairs of the plant should lead the Emergency Organization. He shall be designated as Site Controller. General Manager [O & M] shall be designated as the Incident Controller. In the case of stores, utilities, open areas, which are not under the control of the Production Heads, Senior Executive responsible for maintenance of utilities would be designated as Incident Controller. All the Incident Controllers would be reporting to the Site Controller.

Each Incident Controller, for himself, organizes a team responsible for controlling the incidence with the personnel under his control. Shift In-charge would be the reporting officer, who would bring the incidence to the notice of the Incidence Controller and Site Controller. Emergency Coordinators would be appointed who would undertake the responsibilities like fire fighting, rescue, rehabilitation, transport and provide essential and support services. For this purposes, Security In-charge, Personnel Department, Essential services personnel would be engaged. All these personnel would be designated as Key personnel.

In each shift, electrical supervisor, electrical fitters, pump house in-charge, and other maintenance staff would be drafted for emergency operations. In the event of power or communication system failure, some of staff members in the office/plant offices would be drafted and their services would be utilized as messengers for quick passing of communications. All these personnel would be declared as essential personnel.

I. Emergency Communication

Whoever notices an emergency situation such as fire, growth of fire, leakage etc would inform his immediate superior and Emergency Control Center. A place nearer to the Gate House Complex shall be identified as Emergency Control Center. The person on duty in the Emergency Control Center would appraise the Site Controller. Site Controller verifies the situation from the Incident Controller of that area or the Shift In-charge and takes a decision about an impending On Site Emergency. This would be communicated to all the Incident Controllers, Emergency coordinators. Simultaneously, the emergency warning system would be activated on the instructions of the Site Controller.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

II. Emergency Responsibilities

The responsibilities of the key personnel are appended below:

Site Controller

On receiving information about emergency he would rush to Emergency Control Center (ECC) and take charge of ECC and the situation. His responsibilities would be as indicated below:

- Assesses the magnitude of the situation on the advice of Incident Controller and decides;
 - ➤ Whether the effected area needs to be evacuated:
 - ➤ Whether personnel who are at assembly points need to be evacuated;
- Declares Emergency and orders for operation of emergency siren;
- Organizes announcement by public address system about location of emergency;
- Assesses which areas are likely to be affected, or need to be evacuated or are to be alerted;
- Maintains a continuous review of possible development and assesses the situation in consultation with Incident Controller and other Key Personnel as to whether shutting down the plant or any section of the plant is required and if evacuation of persons is required;
- Directs personnel for rescue, rehabilitation, transport, fire, brigade, medical and other designated mutual support systems locally available, for meeting emergencies;
- Controls evacuation of affected areas, if the situation is likely to go out of control or effects are likely to go beyond the premises of the factory, informs the District Emergency Authority, Police, Hospital and seeks their intervention and help;
- Informs Inspector of Factories, Deputy Chief Inspector of Factories, RPCB and other statutory authorities;
- Gives a public statement if necessary;
- Keeps record of chronological events and prepares an investigation report and preserves evidence; and
- On completion of On Site Emergency and restoration of normalcy, declares all clear and orders for all clear warning.

III. Incident Controller

- Assembles the incident control team;
- Directs operations within the affected areas with the priorities for safety to personnel minimize damage to the plant, property and environment and minimize the loss of materials;
- Directs the shutting down and evacuation of plant and areas likely to be adversely affected by the emergency;
- Ensures that key personnel help is sought;



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

- Provides advice and information to the Fire and Security Officer and the Local Fire Services as and when they arrive;
- Ensures that all non-essential workers/staff of the affected areas are evacuated to the appropriate assembly points, and the areas are searched for casualties;
- Has regard to the need for preservation of evidence so as to facilitate any inquiry into the causes and circumstances, which caused or escalated the emergency;
- Co-ordinates with emergency services at the site;
- Provides tools and safety equipment to the team members;
- Keeps in touch with the team and advices them regarding the method of control to be used;
 and
- Keeps the Site Controller of Emergency informed of the progress being made.

IV. Emergency Coordinator - Rescue, Fire Fighting

- On knowing about emergency, rushes to ECC;
- Helps the Incident Controller in containment of the emergency;
- Ensure fire pumps are in operating condition and instructs pump house operator to ready for any emergency with standby arrangement;
- Guides the fire fighting crew i.e. firemen, trained plant personnel and security staff;
- Organizes shifting the fire fighting facilities to the emergency site, if required;
- Takes guidance of the Incident Controller for firefighting as well as assesses the requirements of outside help;
- Arranges to control the traffic at the gate and the incident area;
- Directs the security staff to the incident site to take part in the emergency operations under his guidance and supervision;
- Evacuates the people in the plant or in the nearby areas as advised by Site Controller;
- Searches for casualties and arranges proper aid for them;
- Assembles search and evacuation team;
- Arranges for safety equipment for the members of this team;
- Decides which paths the evacuated workers should follow; and
- Maintains law and order in the area, and if necessary seeks the help of police.

V. Emergency Coordinator-Medical, Mutual Aid, Rehabilitation, Transport and Communication

- In the event of failure of electric supply and thereby internal telephone, sets up communication point and establishes contact with the ECC;
- Organizes medical treatment to the injured and if necessary will shift the injured to nearby hospitals;
- Mobilizes extra medical help from outside, if necessary;



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

- Keeps a list of qualified first aid providers for the plant and seeks their assistance;
- Maintains first aid and medical emergency requirements;
- Makes sure that all safety equipment is made available to the emergency team;
- Assists Site Controller with necessary data to coordinate the emergency activities;
- Assists Site Controller in updating emergency plan, organizing mock drills, verification of inventory of emergency facilities and furnishing report to Site Controller;
- Maintains liaison with Civil Administration;
- Ensures availability of canteen facilities and maintenance of rehabilitation center.
- Liaises with Site Controller/Incident Controller;
- Ensures transportation facility;
- Ensures availability of necessary cash for rescue/rehabilitation and emergency expenditure;
- Controls rehabilitation of affected areas on discontinuation of emergency; and
- Makes available diesel/petrol for transport vehicles engaged in emergency operation.

VI. Emergency Coordinator - Essential Services

- Assists Site Controller and Incident Controller;
- Maintains essential services like Diesel Generator, Water, Fire Water, Compressed Air/Instrument Air, power supply for lighting;
- Plans alternate facilities in the event of power failure, to maintain essential services such as lighting, etc;
- Organizes separate electrical connections for all utilities and emergency services so that in the event of emergency or fires, essential services and utilities are not affected;
- Gives necessary instructions regarding emergency electrical supply, isolation of certain sections etc. to shift in-charge and electricians; and
- Ensures availability of adequate quantities of protective equipment and other emergency materials, spares etc.

VII. General Responsibilities of Employees during an Emergency

During an emergency, which becomes more enhanced and pronounced when an emergency warning is raised, the workers who are in-charge of process equipment should adopt safe and emergency shut down and attend to any prescribed duty as essential employee. Assessing the situation to determine whether an emergency exists requiring activation of your emergency procedures. If no such responsibility is assigned, he should adopt a safe course to assembly point and await instructions. He should not resort to spreading panic. On the other hand, he must assist emergency personnel towards meeting the objectives of DMP.

ACTIVE PHARMACEUTICALS INGREDIENTS
APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

7.6.6 Emergency Facilities

I. Emergency Control Center (ECC)

The following information and equipment are to be provided at the Emergency Control Center (ECC).

- Intercom, telephone;
- P and T telephone;
- Self contained breathing apparatus;
- Fire suit/gas tight goggles/gloves/helmets;
- Hand tools, wind direction/velocities indications;
- Public address megaphone, hand bell, telephone directories; (internal, P and T) Plant layout, site plan;
- Emergency lamp/torch light/batteries;
- Plan indicating locations of hazard inventories, plant control room, sources of safety equipment, work road plan, assembly points, rescue location vulnerable zones, escape routes:
- Hazard chart;
- Emergency shut-down procedures;
- Nominal roll of employees;
- List of key personnel, list of essential employees, list of Emergency Co-ordinators;
- Duties of key personnel;
- Address with telephone numbers and key personnel, emergency coordinator, essential employees; and
- Important address and telephone numbers including Government agencies, neighboring
 industries and sources of help, outside experts, fuel fact sheets and population details
 around the factory.

II. Assembly Point

Number of assembly points, depending upon the plant location, would be identified wherein employees who are not directly connected with the disaster management would be assembled for safety and rescue. Emergency breathing apparatus, minimum facilities like water etc. would be organized.

In view of the size of plant, different locations would be ear marked as assembly points. Depending upon the location of hazard, the assembly points are to be used.

III. Fire Fighting Facilities

First Aid and Firefighting equipment suitable for emergency should be maintained in each section in the plant. This would be as per statutory requirements. However, fire hydrant line covering major areas would be laid. It would be maintained as 6 kg/cm² pressure. Fire alarms would be located in the bulk storage areas. Do not block fire escape route .Keep all fire doors closed. Know the escape routes in your environment. Know the locations of break glass fire



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

alarm buttons and firefighting equipment, and make sure they are easily accessible. Fire officer will be the commanding officer of fire fighting services.

IV. Location of Wind Sock

Wind socks shall be installed at appropriate places in the plant to indicate direction of wind for emergency escape.

V. Emergency Medical Facilities

Stretchers, gas masks and general first aid materials for dealing with chemical burns, fire burns etc would be maintained in the medical center as well as in the emergency control room. Medical superintendent of the medical center will be the head of the casualty services ward. Private medical practitioners help would be also be sought. Government hospital would be approached for emergency help.

Apart from plant first aid facilities, external facilities would be augmented. Names of Medical Personnel, Medical facilities in the area would be prepared and updated. Necessary specific medicines for emergency treatment of Patient's Burns would be maintained.

Breathing apparatus and other emergency medical equipment would be provided and maintained. Also, the help of nearby industries would be taken on mutual support basis.

VI. Ambulance

Availability of an ambulance with driver in all the shifts would be ensured to transport injured or affected persons. Number of persons would be trained in first aid so that, in every shift first aid personnel would be available.

7.6.7 Emergency Actions

I. Emergency Warning

The emergency would be communicated both to the personnel inside the plant and the people outside. An emergency warning system shall be established for this purpose.

II. Emergency Shutdown

There are number of facilities, which can be provided to help deal with hazardous conditions, when a tank is on fire. The suggested arrangements are:

- 1. Stop feed;
- 2. Dilute contents;
- 3. Remove heat;
- 4. Deluge with water; and
- 5. Transfer contents.

Whether a given method is appropriate depends on the particular case.

III. Evacuation of Personnel

There could be a number of persons in the storage area and other areas in the vicinity. The area would have adequate number of exits, staircases. In the event of an emergency, unconnected personnel have to escape to assembly point. Operators have to take emergency



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

ACTIVE PHARMACEUTICALS INGREDIENTS

shutdown procedure and escape. Time Office shall maintain a copy of deployment of employees in each shift, at ECC. If necessary, persons can be evacuated by rescue teams.

IV. All Clear Signal

Also, at the end of an emergency, after discussing with Incident Controllers and Emergency Cocoordinators, the Site Controller orders an all clear signal. When it becomes essential, the Site Controller communicates to the District Emergency Authority, Police, and Fire Service personnel regarding help required or development of the situation into an Off-Site Emergency.

V. Employee Information

During an emergency, employees would be warned by raising siren in specific pattern. Employees would be given training of escape routes and taking shelter. Employees would be provided with information related to fire hazards, antidotes and first aid measures. Those who would be designated as key personnel and essential employees should be given training for emergency response.

VI. Public Information and Warning

The industrial disaster effects related to this plant may mostly be confined to the plant area. The detailed risk analysis has indicated that the pool fire effects would not be felt outside. However, as an abundant precaution, the information related to Chemical in use would be furnished to District Emergency Authority for necessary dissemination to general public and for any use during an offsite emergency. Plants of this size and nature have been in existence in our country for a long time.

VII. Co-ordination with Local Authorities

Keeping in view of the nature of emergency, two levels of coordination are proposed. In the case of an On Site Emergency, resources within the organization would be mobilized and in the event extreme emergency local authorities help would be sought.

In the event of an emergency developing into an offsite emergency, local authority and District Emergency Authority (normally the Collector) would be appraised and under his supervision, the Off Site Disaster Management Plan would be exercised. For this purpose, the facilities that are available locally, i.e. medical, transport, personnel, rescue accommodation, voluntary organizations etc. would be mustered. Necessary rehearsals and training in the form of mock drills would be organized.

VIII. Mutual Aid

Mutual aid in the form of technical personnel, runners, helpers, special protective equipment, transport vehicles, communication facility etc would be sought from the neighboring industries.

IX. Mock Drills

Emergency preparedness is an important part of planning in Industrial Disaster Management. Personnel would be trained suitably and prepared mentally and physically in emergency

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

response through carefully planned, simulated procedures. Similarly, the key personnel and essential personnel would be trained in the operations.

X. Important Information

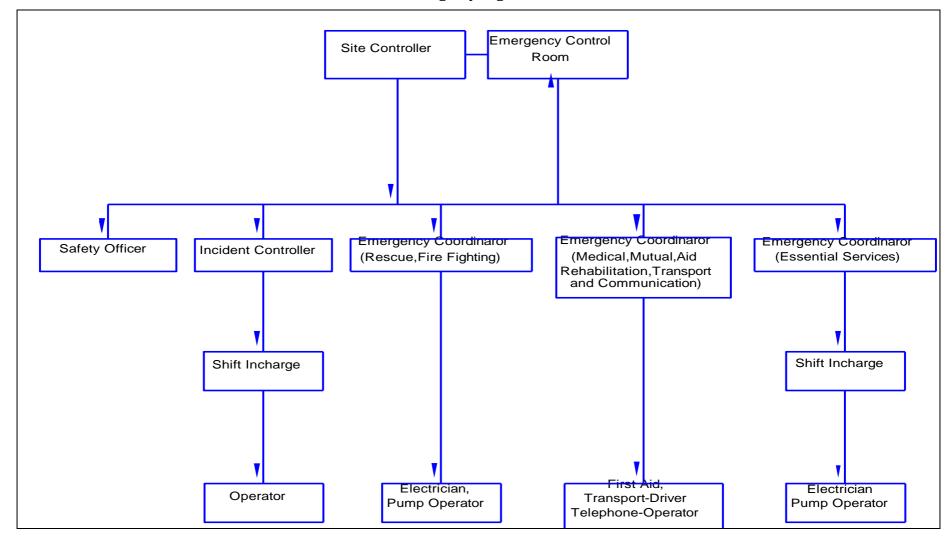
Once the Plant goes on stream, important information such names and addresses of key personnel, essential employees, medical personnel outside the plant, transporters address, address of those connected with Off Site Emergency such as Police, Local Authorities, Fire Services, District Emergency Authority would be prepared and maintained. The on-site emergency organization chart for various emergencies is shown in **Fig**:-

THEIR PURIFIED DERIVATIVES FOR MANUFACTURING OF HERBAL EXTRACTS AND ACTIVE PHARMACEUTICALS INGREDIENTS

APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Figure No. 7.1.
On-Site Emergency Organization Chart





DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

7.7 OFF-SITE EMERGENCY PREPAREDNESS PLAN

If an accident takes place in chemical industry /unit and its effects are felt outside its premises, the situation thus created is called an offsite emergency.

The task of preparing the Off-Site Emergency Plan lies with the District Collector; however the off-site plan will be prepared with the help of the local district authorities. The proposed plan will be based on the following guidelines.

7.7.1Introduction

Off-site emergency plan would follow the on-site emergency plan. When the consequences of an emergency situation go beyond the plant boundaries, it becomes an off-site emergency. Off-site emergency is essentially the responsibility of the public administration. However, the plant management will provide the public administration with the technical information relating to the nature, quantum and probable consequences on the neighboring population.

The off-site plan in detail will be based on those events, which are most likely to occur, but other less likely events, which have severe consequence, will also be considered. Incidents which have very severe consequences yet have a small probability of occurrence would also be considered during the preparation of the plan. However, the key feature of a good off-site emergency plan is flexibility in its application to emergencies other than those specifically included in the formation of the plan.

The roles of the various parties who will be involved in the implementation of an off-site plan are described below. Depending on local arrangements, the responsibility for the off-site plan would either rest with the plant management or with the local authority. Either way, the plan would identify an emergency co-ordinating officer, who would take the overall command of the off-site activities. As with the on-site plan, an emergency control center would be setup within which the emergency co-ordinating officer can operate.

An early decision will be required in many cases on the advice to be given to people living "within range" of the accident - in particular whether they should be evacuated or told to go indoors. In the latter case, the decision can regularly be reviewed in the event of an escalation of the incident. Consideration of evacuation may include the following factors:

- In the case of a major fire but without explosion risk (e.g. an oil storage tank), only houses close to the fire are likely to need evacuation, although a severe smoke hazard may require this to be reviewed periodically; and
- If a fire is escalating and in turn threatening a store of hazardous material, it might be necessary to evacuate people nearby, but only if there is time; if insufficient time exists, people should be advised to stay indoors and shield themselves from the fire. This latter case particularly applies if the installation at risk could produce a fireball with very severe thermal radiation effects.



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Although the plan will have sufficient flexibility built in to cover the consequences of the range of accidents identified for the on-site plan, it will cover in some detail the handling of the emergency to a particular distance from each major hazard works.

7.7.2 Aspects Proposed to be considered in the Off-Site Emergency Plan

The main aspects, which should be included in the emergency plan, are:

Organization

Detail of command structure, warning systems, implementation procedures, emergency control centers.

Names and appointments of incident controller, site main controller, their deputies and other key personnel.

Communications

Identification of personnel involved, communication center, call signs, network, list of telephone numbers.

• Specialized Knowledge

Details of specialist bodies, firms and people upon whom it may be necessary to call e.g. those with specialized fuel knowledge, laboratories.

• Voluntary Organizations

Details of organizers, telephone numbers, resources etc.

• Fuel Information

Details of the hazardous substances stored and a summary of the risk associated with them.

• Meteorological Information

Arrangements for obtaining details of weather forecasts and weather conditions prevailing at that time.

• Humanitarian Arrangements

Transport, evacuation centers, emergency feeding, treatment of injured, first aid, ambulances and temporary mortuaries.

• Public Information

Arrangements for

- (a) dealing with the media press office;
- (b) informing relatives, etc.

• Assessment of Emergency Plan

Arrangements for:

- (a) Collecting information on the causes of the emergency;
- (b) Reviewing the efficiency and effectiveness of all aspects of the emergency plan.

345



ACTIVE PHARMACEUTICALS INGREDIENTS
APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

7.7.3 Role of the Emergency coordinating Officer

The various emergency services would be co-ordinated by an emergency co-ordinating officer ${\bf r}$

(ECO), who will be designated by the district collector. The ECO would liaison closely with the

site main controller. Again depending on local arrangements, for very severe incidents with

major or prolonged off-site consequences, the external control would be passed to a senior local

authority administrator or even an administrator appointed by the central or state government.

The ECO will be equipped with address and phone numbers of important agencies.

7.7.4 Role of the Local Authority

The duty to prepare the off-site plan lies with the local authorities. The emergency planning

officer (EPO) appointed should carry out his duty in preparing for a whole range of different

emergencies within the local authority area. The EPO should liaison with the plant, to obtain the

information to provide the basis for the plan. This liaison should ensure that the plan is

continually kept upto date.

It will be the responsibility of the EPO to ensure that all those organizations which will be

involved off site in handling the emergency, know of their role and are able to accept it by having

for example, sufficient staff and appropriate equipment to cover their particular responsibilities.

Rehearsals for off-site plans should be organized by the EPO.

7.7.5 Role of Police

Formal duties of the police during an emergency include protecting life and property and

controlling traffic movements.

Their functions should include controlling bystanders, evacuating the public, identifying the dead

and dealing with casualties, and informing relatives of death or injury.

7.7.6 Role of Fire Authorities

The control of a fire should be normally the responsibility of the senior fire brigade officer who

would take over the handling of the fire from the site incident controller on arrival at the site. The

senior fire brigade officer should also have a similar responsibility for other events, such as

explosions. Fire authorities in the region should be apprised about the location of all stores of

flammable materials, water and foam supply points, and fire-fighting equipment. They should be

involved in on-site emergency rehearsals both as participants and, on occasion, as observers of

exercises involving only site personnel.

ENKAY ENVIRO SERVICES PVT. LTD., JAIPUR

NOVEMBER' 2019

346

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

7.7.7 Role of Health Authorities

Health authorities, including doctors, surgeons, hospitals, ambulances, and so on, should have a vital part to play following a major accident, and they should form an integral part of the emergency plan.

For major fires, injuries should be the result of the effects of thermal radiation to a varying degree, and the knowledge and experience to handle this in all but extreme cases may be generally available in most hospitals.

Major off-site incidents are likely to require medical equipment and facilities additional to those available locally, and a medical "mutual aid" scheme should exist to enable the assistance of neighboring authorities to be obtained in the event of an emergency.

7.7.8 Role of Government Safety Authority

This will be the factory inspectorate available in the region. Inspectors are likely to satisfy themselves that the organization responsible for producing the off-site plan has made adequate arrangements for handling emergencies of all types including major emergencies. They may wish to see well-documented procedures and evidence of exercise undertaken to test the plan.

In the event of an accident, local arrangements regarding the role of the factory inspector will apply. These may vary from keeping a watching brief to a close involvement in advising on operations.

The action plan suggested for control of the off-site emergencies is given in **Table No. 7.13**.

Table No. 7.13: Off-Site Action Plan

S. No.	Action required to be taken to mitigate disaster by aid giving agency	Responsible agencies for taking action	Equipments/material facilities required at site to mitigate emergency
A1	Arrangements for evacuation/rescue of persons from zone of influence to predetermined camps	Police Department	Self Breathing apparatus with spare cylinder Chemical gas mask with spare canister Vehicle with PA system Transportation for evacuation of people
2	Caution to public by announcement		
3	Traffic and Mob control by cordoning of the area		
4	Law & order		
5	Request to railway authority for keeping the nearest by railway gate open & to stop the up & down trains at the nearest railway station		-
B1	Control of fire	District Fire Brigade	Self breathing apparatus with spare cylinders
	Scrubbing of the flashed off gas cloud with water curtain		Foam/water fire tenders Gas mask with spare canisters Lime water
	To rescue trapped persons		Lille water

APPLICANT: LEPRO HERBALS PVT. LTD.

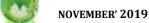
DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

S. No.	Action required to be taken to mitigate disaster by aid giving agency	Responsible agencies for taking action	Equipments/material facilities required at site to mitigate emergency
	If fire is big, keep surrounding area cool by spraying water		Neck to toe complete asbestos suit, PVC hand gloves, gumboots, safety
	Communication to TNEB to continue or cut off electric supply Communication to water supply department		goggles Mobile scrubbing system along with suction arrangement.
	for supplying water	**	
C1	Medical facilities for affected persons (first aid and treatment)	Hospital and public health	Ambulance with onboard resuscitation unit, first aid, stretchers
D1	Identification of concentration of gas in zone of influence	Pollution control board	Gas detector
E1	Removal of debris and damaged structures	Municipal corporation	Provide bulldozers Provide cranes
F1	Monitor the incoming and outgoing transports	Transport department	Provide traffic police at site Provide emergency shifting vehicles at site Provide stock of fuel for vehicles
2	Arrange emergency shifting of affected persons and non affected person to specified area		
3	Arrange diesel/petrol for needed vehicles		
G1	Give all information related to meteorological aspects for safe handling of affected area for living beings	Meteorological Department	Provide wind direction and velocity instruments with temperature measure Mobile van for meteorological
2	Forecast if any important weather change		parameter measurements
Н1	Representatives of all departments are in the local crisis group; therefore they are expected to render services available with them. Since it is a group of experts with authority, the mitigating measures can be implemented speedily. The representatives from locals are also there so that communication with local people is easy and quick.	Local Crises Group	Must have all resources at hand, specially disaster management plan and its implementation method. All relevant information related to hazardous industry are generally available with crisis group News paper editor is a part of the group so that right and timely media release can be done
2	The district emergency or disaster control officer is the president and he is used to mock drill etc. so action can be taken in right direction in time		
I1	Collector is the President of District Crisis Group therefore all district infrastructure facilities are diverted to affected zone	District Crisis group	All necessary facilities available at district can be made available at affected zone Control of law and order situation
2	All other functions as mentioned for local crisis group		

7.8 OCCUPATIONAL HEALTH AND SAFETY

For large industries, where multifarious activities are involved during construction, erection, testing, commissioning, operation and maintenance, the men, materials and machines are the basic

ENKAY ENVIRO SERVICES PVT. LTD., JAIPUR



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

inputs. Along with the boons, industrialization generally brings several problems like occupational health and safety.

The industrial planner, therefore, has to properly plan and take steps to minimize the impacts of industrialization and to ensure appropriate occupational health and safety including fire plans. All these activities again may be classified under construction and erection, and operation and maintenance.

7.8.1 Occupational Health

Occupational health needs attention both during construction and erection and operation and maintenance phases. However, the problem varies both in magnitude and variety in the above phases.

• Construction and Erection

The occupational health problems envisaged at this stage can mainly be due to constructional accident and noise. To overcome these hazards, in addition to arrangements to reduce it within TLV's, necessary protective equipments shall also be supplied to workers.

• Operation and Maintenance

The problem of occupational health, in the operation and maintenance phase is primarily due to noise which could affect hearing. The necessary personal protective equipments will be given to all the workers. The working personnel shall be given the following appropriate personnel protective equipments.

- Industrial Safety Helmet;
- Crash Helmets;
- Face shield with replacement acrylic vision;
- Zero power plain goggles with cut type filters on both ends;
- Zero power goggles with cut type filters on both sides and blue color glasses;
- Welders equipment for eye and face protection;
- Cylindrical type earplug;
- Ear muffs;
- Canister Gas mask;
- Self contained breathing apparatus;
- Leather apron;
- Aluminized fiber glass fix proximity suit with hood and gloves;
- Boiler suit;
- Safety belt/line man's safety belt;
- Leather hand gloves;
- Asbestos hand gloves;
- Acid/Alkali proof rubberized hand gloves;
- Canvas cum leather hand gloves with leather palm;
- Lead hand glove;
- Electrically tested electrical resistance hand gloves; and



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Industrial safety shoes with steel toe.

Full-fledged hospital facilities will be available round the clock for attending emergency arising out of accidents, if any. All working personnel will be medically examined at least once in every year and at the end of his term of employment. This is in addition to the pre-employment medical examination.

7.8.2 Safety Plan

Safety of both men and materials during construction and operation phases is of concern. Safety plan shall be prepared and implemented in the proposed plant. The preparedness of an industry for the occurrence of possible disasters is known as emergency plan. The disaster in the plant is possible due to collapse of structures and fire/explosion etc.

Keeping in view the safety requirement during construction, operation and maintenance phases, the plant would formulate safety policy with the following regulations:

- To allocate sufficient resources to maintain safe and healthy conditions of work;
- To take steps to ensure that all known safety factors are taken into account in the design, construction, operation and maintenance of plants, machinery and equipment;
- To ensure that adequate safety instructions are given to all employees;
- To provide wherever necessary protective equipment, safety appliances and clothing and to ensure their proper use;
- To inform employees about materials, equipment or processes used in their work which are known to be potentially hazardous to health or safety;
- To keep all operations and methods of work under regular review for making necessary changes from the point of view of safety in the light of experience and upto date knowledge;
- To provide appropriate facilities for first aid and prompt treatment of injuries and illness at work;
- To provide appropriate instruction, training, retraining and supervision to employees in health and safety, first aid and to ensure that adequate publicity is given to these matters;
- To ensure proper implementation of fire prevention methods and an appropriate fire fighting service together with training facilities for personnel involved in this service;
- To organize collection, analysis and presentation of data on accident, sickness and incident involving people injury or injury to health with a view to taking corrective, remedial and preventive action;
- To promote through the established machinery, joint consultation in health and safety matters to ensure effective participation by all employees;
- To publish/notify regulations, instructions and notices in the common language of employees;
- To prepare separate safety rules for each type of occupation/processes involved in a plant;
 and

350



APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

• To ensure regular safety inspection by a competent person at suitable intervals of all buildings, equipments, work places and operations.

7.8.3 General Safety Measures

- Proper ventilation system will be provided at storage and processing areas of chemicals so that to maintain PEL valves of chemicals and solvents.
- Good housekeeping, disposal methods will be followed to control the fugitive emissions of chemicals.
- In order to prevent the work men from facing the musculo -skeletal disorders, backache, pain in minor and major joints etc, manual carrying of weights to the shop floor from the ground floor will be avoided totally. All liquid raw materials/solvents will be transferred through closed piping system either by pumping or by gravity, to reduce the carrying load on work men against gravity. Safe carrying weights (up to 15 kgs) only allowed to carry by work men. Stair cases with suitable gradient will be constructed in the work sheds. Material handling trolleys will be provided to carry/handle the solid materials from one place to other.
- Employees will be educated, trained and, informed about the chemicals and their properties by displaying the material safety data sheets (MSDS) in the processing areas.
- Awareness about potential hazards, work hazards, fire hazards, and health hazards associated with the chemicals which are being used by the industry will be developed among the employees.
 - Apart from the above, the following **general safety precautions** will be implemented in the plant.
 - Shielding guards will be provided to all belt pulleys, couplings and all moving parts of the machinery.
- All electrical cables and electrical equipment will be properly grounded and earthed.
- Poster display regarding safety, health and environmental protection will be arranged in the plant to make awareness of safety and health.
- All responsible employees will be educated and trained to handle the firefighting equipment.
- NO SMOKING policy will be strictly implemented in the entire plant area.
- Emergency exits will be provided at the selected places.
- No employee will be allowed to expose to a noise level greater than 85dB(A) for a period of more than 8 hours per day without hearing protection.
- Periodical health check up of employees will be held as a part of occupational health surveillance.
- One shower type eye wash will be provided in the plant area.
- Fire extinguisher will be provided where ever is needed.
- All flammable chemicals and solvents will be kept away from ignition sources and heat.
- Storage of chemicals will be as per their compatibility.



DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

• Proper exhaust ventilation will be provided to the process area to maintain the airborne concentrations and solvents below their TLV values.

7.8.3 Safety Organization

• Construction and Erection Phase

A qualified and experienced safety officer shall be appointed. The responsibilities of the safety officer include identification of the hazardous conditions and unsafe acts of workers and advice on corrective actions, conduct safety audit, organize training programs and provide professional expert advice on various issues related to occupational safety and health. He is also responsible to ensure compliance of Safety Rules/ Statutory Provisions. In addition to employment of safety officer by CPC, every contractor, who employs more than 250 workers, shall also employ one safety officer to ensure safety of the worker, in accordance with the conditions of contract.

• Operation and Maintenance Phase

When the construction is completed the posting of safety officers shall be in accordance with the requirement of Factories Act and their duties and responsibilities shall be as defined thereof.

7.8.4 Safety Circle

In order to fully develop the capabilities of the employees in identification of hazardous processes and improving safety and health, safety circles would be constituted in each area of work. The circle would consist of 5-6 employees from that area. The circle normally shall meet for about an hour every week.

7.8.5 Safety Training

A full-fledged training center shall be set up at the plant. Safety training shall be provided by the Safety Officers with the assistance of faculty members called from Professional Safety Institutions and Universities. In addition to regular employees, limited contractor labors shall also be provided safety training. To create safety awareness safety films shall be shown to workers and leaflets shall be distributed. Some precautions and remedial measures proposed to be adopted to prevent fires are:

- Compartmentation of cable galleries, use of proper sealing techniques of cable passages and crevices in all directions would help in localizing and identifying the area of occurrence of fire as well as ensure effective automatic and manual fire fighting operations;
- Spread of fire in horizontal direction would be checked by providing fire stops for cable shafts;
- Reliable and dependable type of fire detection system with proper zoning and interlocks for alarms are effective protection methods for conveyor galleries;
- Housekeeping of high standard helps in eliminating the causes of fire and regular fire watching system strengthens fire prevention and fire fighting; and
- Proper fire watching by all concerned would be ensured.

7.8.6 Health and Safety Monitoring Plan

The health of all employees shall be monitored once in a year for early detection of any ailment due to exposure to heat, fumes and noise.



THEIR PURIFIED DERIVATIVES FOR MANUFACTURING OF HERBAL EXTRACTS AND ACTIVE PHARMACEUTICALS INGREDIENTS

APPLICANT: LEPRO HERBALS PVT. LTD.

DOCUMENT NO.: EESPL/LHPL/008/EC/Ind./2018-19/431

Plan and fund allocation to ensure the occupational health and safety of all contract and casual workers have been given below:-

S. No.	Parameters	Frequency
a.	Blood Pressure	Every Year
b.	Blood Group and RH	Every Year
C.	Blood Sugar (RBS)	Every Year
d.	Spirometry	Every Year
e.	Audiometry	Every Year
f.	Vision	Every Year
g.	Drug Allergy	Every Year

The fund allocation for Occupational Health and Safety of all contract and casual workers are as given below:-

Particulars	:	Fund Allocation (In Rs.)
Workers	:	20.0Lacs
