Additional Studies

1.1 Introduction

This chapter on Additional Studies includes Public Consultation involving two components, public hearing (PH) and other one being inviting responses or objections through internet / by post by placing the summary of EIA report on the web site, Risk Assessment (RA) studies, Social Impact Assessment (SIA) studies and Rehabilitation & Resettlement (R&R) Action Plans, as applicable. In case of the proposed project, it is situated in the notified industrial area (Paithan MIDC) and hence, as per provisions of the EIA Notification-2006 and as amended till date, it shall not require public hearing. Similarly, as the proposed project is in notified industrial area, there is no R&R Action Plans involved. However, being chemical manufacturing industry, Risk and Hazard Management occupies prime importance and is discussed in detailed as follows:

1.2 Risk and Hazard Management { Approved TOR 6 } { Specific TOR 13 }

Increasing use of hazardous chemicals as raw materials, intermediates and finished products in chemical manufacturing industry has attracted attention of the Government and the public at large in view of the chemical disasters that have occurred in the past. The serious nature of the accidents, which cause damage to the plant, personnel and public, has compelled industries to pay maximum attention to the safety issues and also to effectively manage the hazardous material and operations. It is mandatory for the industries handling hazardous chemical to maintain specified safety standards and generate an on-site emergency plan and keep it linked with off-site emergency plan. The safety management includes the implementation of preventive methods or accident prevention methods to avoid incident or accident and handling of emergency in case of accident.

The company is setting up a plant for manufacturing of pharmaceutical products and its intermediates at MIDC Paithan. Company has plans to manufacture 8 products as per the production capacities. The details are as given in the earlier part of the report. Special studies were carried out on risk and hazard management for the AD Pharmachem Pvt. Ltd.at Paithan MIDC.

1.2.1 Objectives of Risk and Hazard Management

- 1) Identify hazards and nature of hazard in the process, storage and handling of hazardous chemicals.
- Carry out Qualitative risk Assessment (QRA) for the process and suggest mitigation measures.
- Carry out QRA of the storage of hazardous chemicals and estimate the threat zones for Most Credible and Worst case scenarios.
- 4) Suggest mitigation measures to reduce the risk/probability of the accident to the minimum.
- 5) Incorporate these measures for ensuring safe operations and safe layout and for effective preparation of On-site and Off-site emergency plans.
- 6) Suggest Guidelines for on-site and off site emergency plan.

1.2.2 Methodology:

A] Identify hazards based on

- Processes description received.
- Identify Hazardous Chemicals handled and stored.
- Inventory of Hazardous chemicals
- Proposed storage facilities for hazardous chemicals
- Plant layout
- Safety measures to be adopted by the company

B] Hazard Assessment:

- By Qualitative Risk Assessment
- By Quantitative Risk Assessment by Hazard index calculations and estimate threat zones by using ALOHA.

C] Recommendations:

- Recommend mitigation measures based upon the above
- Recommending guidelines for the preparation of On-site Emergency plan.

1.3 Hazard Identification

Following are the major areas of hazard identified:

- 1) Reaction and separation sections of production unit.
- 2) The storage and handling of hazardous raw materials.

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1.3.1 Reaction and Separation Sections of Production Unit

Qualitative Risk Assessment

The manufacturing processes are described earlier in the **Chapter 2**. Basically these involve reactions carried out in batch reactor, separation and recovery of solvents (Used as reaction media), un-reacted components, neutralization, followed by separation and purification of the product. In such pharmaceutical API production plants, in the reaction section, separation sections are the major hazards. The hazards identified are.

- 1. Fire and explosion
- 2. Toxic release
- 3. Exposure to hazardous chemicals.

All the above hazards are also associated with storage of hazardous chemicals.

1.3.1.1 Identification of Hazards in the Reaction Section:

Manufacturing processes of the following products involve hazardous reaction of Brominationin presence of H_2O_2 (30-50%).

4-Bromo Anisole and 4-Bromo Phenetole [4-Bromo Ethoxy Benzene], only the change in raw material is Anisol and Ethoxybenzene in case of 4-Bromo Ethoxy Benzene.

Major Hazards:

Major Hazard in this case is handling of Liquid Bromine and Bromination reaction which is slightly exothermic, which in case of accumulation of reactants can lead to potentially dangerous situation of temperature and pressure rise leading to run away conditions which may lead to explosion, fire and toxic release of chemicals.

Mitigation measures:

It is strongly recommended to take all the preventive measures to minimize the probability of the accident to the minimum and make the process and reactor operation as intrinsically safe as possible. Because prediction of realistic estimation of the extent of damage and damage control after the accident is extremely difficult in case of reactor accident.

HAZOP study is the most effective and recommended method for identification of hazards in reaction and separation sections and for incorporating necessary changes in (Standard Operating Procedure) SOP's and to provide effective instrumentation alarms and interlocks as mitigation measures to make the process/plant operation inherently safe.

Hence for these and all other processes, HAZOP study has been carried out. All the

recommendations of HAZOP study should be incorporated in the SOP and safety systems should be installed in the plant.

Major recommendation of the report, given below will be implemented.

For Exothermic Reactions:

The major reason for occurrence of uncontrollable rise in temperature is accumulation of unreacted reactants. This accumulation of un-reacted reactant has to be avoided at any cost.

For this basic and the most important mitigation measures suggested are:

- 1. Setting up a SOP for all critical operations, reactions and separations.
- 2. Once the SOP and operating parameters have been finalized, strictly following it, 24x7, particularly for batch operations without any change of procedure.
- 3. Must have in built system to check that the procedures (SOP)are not violated at any time, and no short cuts are taken in batch processes. Manufacturing and production of API's are in majority batch processes.
- 4. Have following alarm and interlock system (essential for highly exothermic reactions and alarms recommended for all exothermic reactions)
 - Utility failure alarm
 - Agitator failure alarm
 - High temperature alarm
 - Alarm for High rate of addition of limiting reactant, which is added at controlled rate.
 - Raw material (limiting reactant) addition rate should be controlled by flow control loop. (FT, FIC, FCV). Controlling parameter being reactor temperature.
 - FCV and/or On-Off valve should be interlocked with the reaction mass temperature and agitator tripping.

Similarly, all the instrumentation, alarms and interlock systems recommended for recovery of solvents/reaction media by distillation, as well as precautions suggested for handling of Bromine, solvents and toxic chemicals will be implemented. More details on storage and handling of hazardous chemicals are given in the later part of the report.

1.3.3.2 Storage and handling of raw materials: List of Solvents required and to be stored with their Properties are given in **Table 1.1.** List of Raw materials required with details on their quantity, size and number of Carboys / drums required for storage in Ware House is made available in **Table 1.2**, while properties of the same Raw materials is presented in **Table**

1.3.Solid raw materials (chemicals) required and to be stored in warehouse are listed in **Table 1.4**.

		Liters	M	Tanks	Dia. X height						ppm
1	Acetonitrile	10000	12	01	2.00 * 4.0	2	3	0	81	2	60
2	IsoPropanol	20000	25	01	2.00 * 8.0	2	3	0	84	12	200
3	Ethyl Acetate	20000	25	01	2.00 * 8.0	2	3	0	77	- 4	400
4	Methanol	20000	25	01	2.00 * 8.0	1	3	0	66	11	200
5	n- Butyl amine	30000	30	01	2.20*8.0	3	3	0	77	-14	5
6	Dimethyl Formamide	20000	20	01	2.00 * 8.0	2	2	0	153	57	10
2 3 4 5 6	IsoPropanol Ethyl Acetate Methanol n- Butyl amine Dimethyl Formamide	20000 20000 20000 30000 20000	25 25 25 30 20	01 01 01 01 01	2.00 * 8.0 2.00 * 8.0 2.00 * 8.0 2.20*8.0 2.00 * 8.0	2 2 1 3 2	3 3 3 2	0 0 0 0	84 77 66 77 153		12 - 4 11 -14 57

 Table No. 1.1: List of Solvents to be Stored with their Properties

All these are Class A chemicals defined in 10.1 PETROLEUM ACTS AND THE RULES framed there under. This is an Act to consolidate and amend the law relating to the import, transport, storage, production, refining and blending of petroleum. The salient features of the Act are as under:

Section 2:It deals with the definition of petroleum with its classification on the basis of flash point.

(a) "Petroleum" means any liquid hydrocarbon or mixture of hydrocarbons and any inflammable mixture (liquid, viscous or solid)containing any liquid hydrocarbons.

(b) "Classification": There are 3 classes of petroleum as under:

i) Petroleum Class 'A': Means petroleum having a flash point below 23°C (e.g. Petrol, Hexane, Toluene, Naphtha).

Sr. No.	Raw Materials	State	Maximum Qty. stored kg/liters	Size of Carboy/drums	No of Carboys /drums Stored
1	Methylene di Chloride	Liquid	3000	50	60
2	n- Butyl Bromide	Liquid	20000	250	80
3	Anisole	Liquid	5000	250	20
4	Liquid Bromine	Liquid	5004	18	278
5	Formamine	Liquid	2000	200	10
6	EthoxyAnisole	Liquid	2000	200	10
7	Hydrogen Peroxide	Liquid	3000	50	60
	{30 %}				
8	Sodium Bromide {35%}	Liquid	5000	250	20
9	Dimethyl Sulphate	Liquid	1000	200	10
10	37 % HCL1	Liquid	5000	50	100

Table No. 1.2: List of Raw Materials to be Stored (Quantity and Storage Facility)

11	70 % Sulphuric Acid	Liquid	5000	50	100
12	Tetra Butyl Ammonium	Powd	25000	50	500
	Bromide	er			
13	Potassium Thiocyanate	Powd	5000	50	100
		er			

For Over ground and underground storage, hazard identification and mitigation measures are given in Annexure 1{I}.

Sr. No.	Raw Materials	State	Nh	Nf	Nr	B P ^o C	TLV/ TWA	IDLH
1	Methylene dichloride	Liquid	2	1	0	39.5	50	2300
							ppm	
2	n- Butyl Bromide	Liquid	NA	NA	NA	101	NA	NA
3	Anisole	Liquid	2	2	0	153	NA	NA
4	Liquid Bromine	Liquid	3	0	0	58	0.5	NA
							ppm	
5	Formamine	Liquid	2	1	0	210	10 ppm	NA
6	EthoxyAnisole	Liquid	NA	NA	NA	NA	NA	NA
7	Hydrogen Peroxide	Liquid	3	0	1	108	1 ppm	NA
	{30 %}							
8	Sodium Bromide {35 %	Liquid	NA	NA	NA	NA	NA	NA
	solution}							
9	Dimethyl Sulphate	Liquid	4	2	0	188	0.1	NA
		-					ppm	
10	37 % HCl	Acid	NA	NA	NA	NA	NA	NA
11	70 % Sulphuric Acid	Acid	NA	NA	NA	NA	NA	NA

Table No. 1.3: List of Raw Materials to be Stored (Properties)

Based on the above data, with reference to low TLV values and Boiling points, following chemicals are identified as toxic chemicals, which need special precautions to minimize the hazards due to exposure to workers for health and environment protection.

Chemicals with low TLVs and Low boiling points

- 1. Liquid Bromine
- 2. Methylene Dichloride

Chemicals with low TLVs and High boiling points:

- 1. Formamine
- 2. Dimethyl Sulphate

Mitigation Measures: Following Mitigation Measures are suggested

Liquid Bromine in particular and low boiling toxic chemicals in general:

Bromine storage and Handling:

- 1. Bromine will be stored in 3 liter size glass bottles at 15°C. A free space of 8-10% by volume should be left in the container.
- 2. Bromine glass bottles will be stored in a separate enclosed place, in the warehouse and it will be provided with exhaust and scrubber.
- 3. Bromine will be handled by workers with proper PPE's suitable and breathing masks.
- 4. Bromine will be charged to the overhead tank at less than 20[°] C. It will be provided with exhaust connected to a packed bed scrubber with provision for dilute Caustic solution circulation to ensure complete absorption of Bromine. Sodium Bromide Solution will be sent to Bromine recovery companies.
- 5. Detailed standard P&I diagram to be finalized will include the scrubber system details.
- 6. Where ever feasible, leak detectors and concentration of VOCs will be monitored.
- 7. Other raw materials stored in closed and sealed drums, well below their boiling points, well segregated in ware house.
- 8. The chemicals will be transferred directly from the drums/carboys by air operated/hand operated pumps, directly to the overhead tanks and then to the reactor.
- 9. Workers will be handling these chemicals with proper training, awareness and using proper PPE's.
- 10. All overhead charging tanks will be provided with vent condensers with chilled water (with normal Flame arrestors) to minimize the loss and pollution.
- 11. These chemicals will be transferred from drums kept on the weigh scale to ensure that only the required quantity is charged in to the reactor.

Special Precautions in Handling of Bromine:

Danger from Bromine: Highly Toxic Liquid

It produces vapors which is very toxic if breathed in. The liquid causes severe burn to the eyes and skin. The concentration of vapors in the atmosphere should not exceed 1.3 mg/m^3 for 15 minutes exposure.

Routes of Entry: Absorbed through skin, Dermal contact, Inhalation and Ingestion.

Description: Brownish liquid cause severe burn.

Handling Instruction: Wear goggles, face shield, chemical resistant gloves and online breathing apparatus, Air pressure suit and Gum Boot etc., whenever handling. Before handling Bromine

bottle, cool it properly in ice water tub. Keep 20% Sodium Thiosulphate solution ready in 200 liter drum for spillage control (Neutralization).

First Aid:

Eyes: Flush immediately with water for 15 minutes lifting eyelids occasionally.

Split Skin or clothing: Remove contaminated clothing and shoes immediately. Wash affected area with sodium Thiosulphate solution (20% or 0.1 M). If irritation is present, get medical attention from Health Services immediately.

Inhalation: Remove from exposure area to fresh air immediately. If breathing has stopped administer artificial respiration. If breathing is difficult, administer oxygen. Keep the affected person warm and at rest.

Ingestion: Do not more than wash out the mouth with water do not induce vomiting. Sips of water may help cool the throat and help keep the airways open. See a doctor.

Spills/Leaks: Report all spills/leaks. Extinguish any possible ignition sources. Stop leak if you can do so without risk. Evacuate the area.

Emergency Response:

Wear S.C.B.A., and full turnout gear. Do not touch spilled material. Use Sodium Thiosulphate solution (20% or 0.1 M) to reduce vapors. Keep upwind of spill. For small spills, take up with sand or other absorbent material and place into sealed containers for later disposal. For large spills, dike far ahead of spill. Keep unnecessary people away. Isolate area and deny entry.

Disposal:

Bromine will be used during manufacturing of Finofibrate. All the byproduct- Potassium Bromide will be recovered through safe handling procedure and send back to the supplier/ original manufacturer.

Special Measures to Handle Methylene Dichloride:

Potential Hazards:

Classified as a neurotoxin, dichloromethane has been proven to cause damage to the brain and central nervous system (CNS). The Environmental Protection Agency (EPA) has classified it as a probable human carcinogen, since high levels of exposure to the chemical has been proven to cause liver and lung cancer in animals.

The following health risks are associated with exposure to Methylene Dichloride:

Inhalation: It can cause coughing, wheezing and/or shortness of breath. Higher levels of dichloromethane inhalation can lead to headache, mental confusion, nausea, vomiting, dizziness and fatigue.

Skin Exposure: Redness and irritation may occur, if skin comes in contact with liquid dichloromethane and if it remains on the skin for an extended period of time, it may lead to skin burns.

Eye Exposure: Contact with eyes can cause severe irritation and possibly chemical burns to the eyes.

Safety Precautions When Handling Methylene Dichloride:

When handling dichloromethane in the workplace, use the following safety precautions:

- Wear protective clothing. Footwear should cover the entire foot.
- Always wear PPE such as chemical splash goggles and safety gloves.
- Work in a well-ventilated area (preferably in an environment with a fume extraction system).

Storage:

Dichloromethane is highly volatile and should be stored in a cool, dry area in tightly closed, labeled containers. This chemical needs to be kept away from metals, light and any source of heat or ignition.

What to Do When Exposed to Methylene Dichloride:

Here are the safety steps that need to be taken, if someone else gets exposed to dichloromethane:

- Employ effective engineering controls, good work practices and proper maintenance procedures.
- Ideally, all work with methylene dichloride should be conducted in a chemical fume hood or in another type of appropriate exhaust ventilation. Using enclosed processes may also control exposure.
- Provide appropriate personal protective equipment (PPE) such as safety glasses with side shields, splash-proof goggles, and/or chemical-resistant aprons, coveralls, lab coats and gloves.
- Require that workers change any clothing that becomes contaminated with methylene dichloride.
- Eating, drinking, smoking and the storage of food should be prohibited in areas, where methylene dichloride is stored or used.

- Exposures that cannot be controlled with ventilation or other work practices may require the use of a respirator.
- When possible, replace methylene dichloride with a chemical that has been shown not to cause cancer or other adverse health effects in animals or humans.
- It is recommended that workers who are or who may be exposed to methylene dichloride be given a copy of this fact sheet.
- Immediately and thoroughly wash with soap and water all areas of the body that come into contact with methylene dichloride. Know the location and proper operation of safety showers in your immediate work area.

Disposal / Recovery:

- Methylene chloride/ dichloride should be collected with other halogenated solvents.
- It will recover all the through safe handling procedure and send back to the supplier/ original manufacturer.

Handling:

- Breathing vapours and any other bodily contact will be avoided by using recommended PPE's.
- All personnel handling bromine will be fully trained and provided with suitable protective clothing. Enclosed systems should be used for processes involving bromine.
- Pipe work and tanks will be checked regularly for leaks.
- Before transferring bromine between containers, a check should be made that the receiving container has room for it.
- Suitable leak detectors will be installed with Alarms.
- Health Management Plan has been prepared for toxic chemicals and is given separately. Attached as **Annexure 1 {II**}.

Sr.	Chemical	Maximum	Size of	No. of
No.		Qty. stored(kg)	Container	Container
1	Dimethyl Amine Hydrochloride	25000	50	500
2	Dycano di Amide	25000	50	500
3	4-Methoxy Acetophenone	4000	50	80
4	Tetra Butyl Ammonium Bromide	25000	50	500
5	Pioglitazone Base	1000	25	40
6	Potassium Thiocyanate	5000	50	100

Warehouse Design:

Warehouse for the storage of chemicals in drums of the area will be constructed. This will be constructed as per the IS code 3594 and other relevant standards. The details of raw materials to be stored in warehouse are given in following **Table 1.2**.

Additional measures suggested for improving Warehouse Safety:

Measures suggested for improvement in the design of warehouse:

- Dividing warehouse into fire compartments, by suitably designed firewalls, to limit the spread of fire.
- Limiting the quantity of hazardous chemicals stored.
- It is safe practice to store explosive, self-igniting, oxidizing and organic peroxides separately, preferably in different compartments.
- Storage of chemicals should be planned by categorizing these, based on their hazardous properties, like toxicity, flammability, explosivity for which MSDS needs to be critically studied.
- Based on the above, proper segregation of materials should be achieved.
- Installation of smoke, fire and toxic gas leak detectors.
- It should be easily possible to reach and attend toxic chemical leakage.
- There should be enough space, and pathways for easy approach and escape.
- Having all flameproof fittings inside the warehouse.

Storage of Briquette

For the boiler, Briquette will be used as fuels. This will be stored in the areas earmarked for these fuels.

Mitigation Measures for Briquette Storage:

- Fire hydrant lines (self-auto-mode firefighting) will be laid around these areas.
- No work involving elevated temperatures will be permitted in this area without safety permit.
- There will be no high voltage (H.T.) transmission lines over & near Briquette storage.
- All useful materials will be stored far away from storage of Briquette area.
- Proper supervision staff with necessary communication facility will be deployed.
- Training will be arranged for all the staff in normal & emergency operating system.
- Proper training will be imparted for creating awareness among workers about sudden Briquette fire and emergency action plan. This will be part of On-site-emergency plan.

1.4 QRA for Chemicals Stored in Tanks:

Threat zones have been predicted for the following chemicals stored in overhead tanks, using

ALOHA 5.4.4 software:

- 1. Acetonitrile
- 2. Methanol
- 3. N- Butyl Amine
- 4. Ethylacetate

QRA results for N butyl amine:

QRA has been done based upon the atmospheric conditions given below based upon Wind rose

of the site for all the chemicals, except wherever mentioned.

Atmospheric Data: (Manual Input of Data)					
Wind: 5 m/s from NW at 3 m	Air Temperature: 35° C				
Ground Roughness: open country	Stability Class: D				
Cloud Cover: 0 tenths	No Inversion Height				
Relative Humidity: 5%					
Chemical is stored in 30 m ³ tank of 2.2 m diameter and 8 m length.					
Tank is 80% full, Circular Opening Diameter: Opening is 0.11 m from tank bottom					

The outcome of QRA computed for N-butyl Amine, Acetonitrile and Methanol with different leak sizes are presented in **Table 1.5**, **Table 1.6** and **Table 1.7** respectively.

Leakage no	fire		Threat Zone	2		
Leakage	Temp	Amount	Pool dia.	IDLH=300	PAC-2= 5	PAC-1=2
size		released		ppm	ppm	ppm
5 mm	35 °C	39 kg	2.1 m	13 m	116 m	188 m
5 mm	40 °C	40 kg	2.0 m	13 m	117 m	190 m
15 mm	40 °C	341 kg	6.7 m	38 m	370 m	621 m
				potentially	2nd degree	pain within
				lethal	burns	60 sec=
				within 60	within 60	2kW/m ²
				sec=10	sec=5.0	
				kW/m ²	kW/m ²	
Leakage pool	l fire					
15 mm	40 °C	464 kg	1.5 m	< 10 m	< 10 m	< 10 m

Table 1.5: QRA for N-butyl Amine

QRA results for Acetonitrile:

Table No. 7.6: QRA for Acetonitrile

	Leakage	e no fire	Threat Zone			
Leakge	Temp	Amount	Pool dia	IDLH=500	AEGL-2	AEGL-2
size		released		ppm	(60 min)	(60 min)
					=320 ppm	=60 ppm
5 mm	35 °C	39 kg	2.1 m	13 m	116 m	188 m
15 mm	15 °C	189 kg	9.9 m	21 m	33 m	102 m

QRA for Methanol:

Methanol is stored in Tank Diameter: 2 meters, Tank Length: 8 meters, Volume: 25.1 cubic meters.

Table No. 1.7: QRA for Methanol

Leak	Temp	Amount	Flame	Puddle	potentially	2 nd degree	Pain
Size		Released	Length	dia.	lethal	burns	within 60
					within 60	within 60	sec=2.0
					sec=10.0	sec=5.0	$kW/(m^2)$
					$kW/(m^2)$	$kW/(m^2)$	
15 mm*	35°C	458 kg	2 m	3.2 m	<10 m	<10 m	<10 m
25 mm	35°C	1212 kg	3 m	5.3 m	<10 m	<10 m	<10 m

*At 15 mm leak and 35°C results are:

Threat Modeled: Overpressure (blast force) from vapor cloud explosion

Type of Ignition: Ignited by spark or flame

Level of Congestion: congested

Model Run: Gaussian

No explosion: no part of the cloud is above the LEL at any time

1.5 QRA for Hazardous chemicals stored in warehouse:

- 1. Liquid Bromine
- 2. n- Butyl amine
- 3. Formamide
- 4. Dimethyl Sulphate

QRA for Bromine:

The estimation of threat zones was carried out by using ALOHA software under the following conditions.

Atmospheric Data: (Manual Input of Data)

Based on wind rose diagram of factory location at Paithan, the same data has been used for all

QRA calculations.

Atmospheric Data: (Manual Input of Data)	
Wind: 5 m/s from NW at 3 m	Air Temperature: 30° C
Ground Roughness: open country	Stability Class: D
Cloud Cover: 0 tenths	No Inversion Height
Relative Humidity: 5%	

Bromine is stored in containers specifically designed for Bromine with capacity of 7.3 liters, holding 5.78 liters Bromine at 80 % of volume (5.78*3.11) = 18 kg of Bromine. The results of QRA exercise for Bromine are tabulated in **Table 1.8**as follows:

Spillage Qty.	Temp	IDLH 3 ppm	AEGL 2	AEGL 1
Assumed	°C		60 Min =0.24 ppm	60 Min = 0.003 Ppm
5 kg	30	401 m	1.4 km	3.0 km
5 kg	15	391 m	1.4 km	3.0 km
500 g	30	122 m	458 m	1.2 km
500 g	15	118 m	444 m	1.2 km

Table No.	1.8:	ORA	for	Bromine
	1.0.	VIII	101	Diomine

Conclusion:

Even small spillage of Bromine from the container at normal atmospheric temp during summer and even winter can create potentially dangerous situations all over the plant and in the surrounding areas.

QRA for Dimethyl Sulphate:

Dimethyl Sulphate is stored in standard 200 lit drums, with ID of 0.574 m and height of 0.878 m. Other common conditions are drum 80 % full; the leakage is 10 % from the drum bottom. Following are the results of QRA for Dimethyl Sulphate documented in **Table 1.9**

	Table 1.9. give Result for Dimetinyi Sulphate													
Opening Size	Amount Released	Puddle dia.	IDLH 7 ppm	AEGL2 (60 min)0.12ppm	AEGL-1 (60 min) (0.024 ppm)									
5 mm	1.64 kg	3.6 m	<10 m	139 m	330 m									
20 mm	8.64 kg	6.5 m	23 m	258 m	636 m									

 Table 1.9: QRA Result for Dimethyl Sulphate

Worst Case:

20 mm opening size is assumed under the condition, the drum topples, when open and 20 mm opening is on the floor.

Conclusion:

Under the worst case scenario there will be potential serious situations. Since IDLH is distance is

around 5 m, all leakage control of sealing operation has to be done by trained operators working

SCABA. Rest of the personal must be evacuated and On Site Emergency Plan has to be put in operation.

QRA for n- Butyl Amine:

N –Butyle Amine is stored in 300 lit drum to contain 190 kg; Drum is 80% full.

Circular Opening Diameter: 0.5 cm; Opening is 0.11 mm from tank bottom. Outcome of QRA exercise for n-Butyl Amine is provided in **Table 1.10**as given below:

 Table 1.10: QRA Result for n-Butyl Amine

Opening Size	Temperature	Amount Released	Puddle dia	IDLH=300 ppm	PAC-2 = 5 ppm	PAC-1= 2 ppm
5 mm	30°C	39 kg	2.1 m	13 m	116	187
20 mm	15 °C	713 gm	2.8 m	10 m	105	169

QRA for Formamide:

Formamide is stored in standard 200 lit drums, with ID of 0.574 m and height of 0.878 m. Other common conditions are drum 80 % full the leakage is 10 % from the drum bottom Following are the results of QRA for Formamide compiled in **Table 1.11**.

 Table No. 1.11: QRA Result for Formide

Opening Size	Temp	Amount Released	Puddle dia	PAC- 3 =600 ppm	PAC-2 = 13 ppm	PAC-1= 10 ppm
5 mm	30 °C	79 Kg	3.8 m	< 10 m	< 10 m	< 10 m
20 mm	30 °C	379 gm	6.6 m	< 10 m	< 10 m	< 10 m

1.6 Fire Fighting System:

Firefighting system should be designed as per the IS or NFPA or other acceptable standards and hydrant piping should be laid across the factory. For Solvent storage tanks, cooling system, preferably automatic, should be designed and installed; OISD 117 Standards can be used as guidelines. Before commissioning of the proposed plant, Fire NOC needs to be obtained as per the requirement.

1.7 On-site Emergency plan

Draft On-site Emergency plan, including plan for taking help of industries in the MIDC area has already been prepared.

1.8 Occupational Health Center (OHC):

The company will have OHC and other medical facilities at the site as per the factories act and number of employees. Some guide lines are given below:

Under rule 73 W All factories carrying out hazardous processes must have OHC with services and facilities

A) For factories employing up to 50 workers:

- Medical officer on retainership basis,
- Minimum 5 workers trained in first aid, at least one shall be available during all working hours.
- Fully equipped first aid box.
- B) For factories employing 51 to 200 workers
- OHC with min. floor space of 15 sq. meters ii) part time medical officer iii) one qualified and trained dresser-cum- compounder throughout all working hours. iv) equipped first aid box.
- C) For factories employing more than 200 workers,
- Full time medical officer up to 500 workers and one more full time medical officer for every additional 1000 workers or part thereof.
- OHC with 2 rooms.
- One compounder and one ward boy 24 by 7
- OHC to be equipped with all emergency equipment.

OHC should be equipped with following as given in details in schedule:

- Requirement of Ambulance van for factory carrying on hazardous process shall be provided and maintained is defined under 73-X.
- For factories with less than 200 workers, management must have an arrangement for getting ambulance van at short notice.
- Company must have, MSDS for all hazardous chemicals at site.(Annexure 1 {III})
- Pre-employment medical checkup and six monthly medical check-up for all employees shall be done including contract workers and record must be available.
- Since the operation involve storage and handling of toxic chemicals, affecting liver, kidneys, lounges, medical test must include the specific teats to check functioning of these vital organs.

• The tests to be carried out for in consultation with the qualified OHC doctor, with reference to the health management plan submitted separately.

1.9 EHS policy:

Company shall prepare well defined EHS policy and it will be known to all employees and it will be displayed properly in the plant premises.

1.10 Safety Guidelines for transportation of Solvent & Hazardous Chemicals

Following recommendations will be followed while fixing the transport agency for transporting Class A solvents and other hazardous chemicals:

Class A Solvents transport: Rules to be followed and precautions to be taken are as per The Petroleum Act and the Petroleum rules 2002, clearly specified in PART IV "TRANSPORT ON LAND BY VEHILES" UNDER RULES 62 TO 86 mandatory for the transportation of Class A chemicals.

- A. Rule No 63: CCE Approval required for tank and vehicle used for transportation.
- B. Rule No 64: This deals with tank capacity limits and solvent filling limits in the tank.
- C. Rule No 65:That clearly specifies that the vehicle approved for Class A solvent will not be used for transportation of any other purpose.
- D. Rule No 69: No other article can be transported in the vehicle transporting Class A chemical.
- E. Rule No 70:This makes it mandatory to have spark arrestor fitted to the exhaust pipe of the vehicle and engine air intake fitted with effective flame-arrestor.
- F. Rule No 71: This specifies Electrical installation requirement for the tanker.
- G. Rule No 72: This specifies that it is mandatory to carry Fire Extinguisher of minimum 10 kg capacity.
- H. Rule No 73: This specifies that it is mandatory to have at least one person with knowledge attending the vehicle 24x7 during parking.
- I. Rule No 74: This specifies regarding parking of vehicle in the public place.
- J. Rule No 76: This specifies for loading and unloading of the tanker.
- K. Rule No 78: This specifies precautions against static charge, the most important being (7) of the same.
- L. Rule No 79: This specifies precautions against electrical hazard: No loading or unloading unless the engine is switched off.

- M. Rule No 83:This specifies tanker loading and unloading to be restricted between sunrise and sunset.
- N. Rule No 84: This prohibits smoking/open flame etc.

Common Guidelines for transport and handling hazardous chemicals and Class A solvents: It will be ensured that during the transportation, contents are not spilled. Personnel, including the driver and cleaner are properly trained about the hazardous properties of the material being carried and for transport of hazardous material, in general.

- Tanker must be RTO approved and tested and approved by CCE for Class A solvents. Frequently tested for integrity. Certificate must be available.
- Vehicle must have safety equipment/PPEs and antidote, if necessary.
- It is mandatory that driver possess a valid driver's license.
- The maximum speed limit is prescribed.
- Driver will be instructed to park the tanker at safe place and they should be available in the near vicinity.
- TREM (Transport Emergency) cards are to be provided to the drivers.

Annexure 1{I}: Hazard identification and Mitigation measures For Storage of Class A solvents in Over ground tanks.

Hazards:

Main hazards

The main hazards from the storage of flammable liquids are fire and explosion, involving either the liquid or the vapour given off from it. Fires or explosions are likely to occur when liquid or vapour is released and comes into contact with a suitable ignition source, or alternatively, when a heat or fire source comes into contact with the container.

Common causes or contributory factors of such incidents include:

- 1. Lack of awareness of the properties of flammable liquids.
- 2. Operator error, due to lack of training.
- 3. Inadequate or poor storage facilities.
- 4. Hot work on or close to flammable liquid containers.
- 5. Inadequate design, installation or maintenance of equipment.
- 6. Decanting flammable liquids in unsuitable storage areas.
- 7. Exposure to heat from a nearby fire.
- 8. Dismantling or disposing of containers containing flammable liquids.

Combustion of liquids: Combustion of liquids occurs when flammable vapours released from the surface of the liquid ignite.

The extent of a fire or explosion hazard depends on the amount of flammable vapour given off from a liquid which is determined by: A) temperature of the liquid. B) The volatility of the liquid. C) How long the liquid is exposed for; and the air movement over the surface.

Other physical properties of the liquid give additional information on how vapour/air mixtures may develop and also on the potential hazards. These physical properties include: flashpoint; auto-ignition temperature; viscosity; lower explosion limit; and upper explosion limit.

Effect of Flash Point:

Generally, a liquid with a flashpoint below the ambient temperature of the surroundings will give off sufficient vapour to mix with the air and be ignited. Lower the flashpoint of a liquid higher the risk.

Mitigation Measures:

- 1. Based on standard recommendations for moderate hazard is it is recommended to have Alcohol storage tanks should be in open in dyke walls and must have spill collection and control (recycle) arrangement to pump into another tank.
- 2. The storage tank will be in open with dyke walls.
- 3. Dyke wall dimensions should be such that clear volume is at least 1.2 times the tank capacity.
- 4. Clear distance between tanks will be provided as per the requirement of Petroleum Rules.
- 5. Location of pumps, location of tank farm in the factory should be as per the requirements of Petroleum rules.
- 6. Necessary approval from Chief Controller of Explosives will be obtained for the alcohol storage and factory lay out.

Maintenance and modifications:

Many incidents involving flammable liquids occur during maintenance and repairs. The likelihood is increased if the work is done by staff or outside contractors who have little knowledge of the hazards associated with flammable liquids. You should only employ experienced contractors. A guide which gives sound practical advice for selecting and managing contractors should be used while employing a contractor.

Hot work Permit:

It is absolutely essential to establish Hot work permit system for any hot work to be carried out in the factory, especially in the areas which store flammable solvents of Class A. And this should be strictly followed for any hot work carried out.

It is essential that no maintenance work is done until: the potential hazards of the work have been clearly identified and assessed; the precautions needed have been specified in detail; the necessary safety equipment has been provided; and adequate and clear instruction has been given to all those concerned.

In most cases, a permit-to-work (PTW) system should be used to control maintenance operations20 in areas where flammable liquids are stored or used. PTWs are formal management documents (see Figure 3). They should only be issued by those with clearly assigned authority to do so, and the requirements stated in them must be complied with before the permit is issued and the work covered by it is undertaken. Individual PTWs need to relate to clearly defined

individual pieces of work. PTWs should normally include: the location and nature of the work intended; identification of the hazards, including the residual hazards and those introduced by the work itself; the precautions necessary, for example, isolations; the personal protective equipment required; the proposed time and duration of the work; the limits of time for which the permit is valid; and the person in direct control of the work.

Information and training:

Adequate training and knowledge of the properties of flammable liquids are essential for their safe storage.

You need to inform all staff on the site about the hazards of storing flammable liquids, and about the need to exclude sources of ignition and heat from the designated storage areas. Those responsible for the operation of the store also need to receive specific training in how to deal with spillages and leaks, and emergency procedures.

Periodic retraining will normally be required. The training should include the following aspects:

- 1. The types of flammable liquid stored, their properties and hazards.
- 2. Use of protective clothing.
- 3. Housekeeping.
- 4. Reporting of faults and incidents, including minor leaks and spills.
- 5. Emergency procedures, including raising the alarm, calling the fire brigade and the use of appropriate fire-fighting equipment.

You will need written procedures for controlling the risks from the storage of flammable liquids, and these should be used as the basis for training.

Following are the major mitigation measures:

- 1. Good Ventilation in the storage area.
- 2. No ignition source. To be stored in good containers. No spillage. Control of spillage.
- 3. Adequate separation from each other and other storage areas and process areas.

Rules and regulations given Chapter III of Petroleum Rules 2002 will be followed. Important are illustrated below:

- 1. Part I GENERAL 28 to 32
- 2. Part IV 62 for bulk transportation by tankers.

Annexure 1{II}: Health Management Plan

There are number of hazardous chemicals will be stored and handled during the manufacture of the products. These chemicals will have adverse effect on the health of workers if they are exposed to higher concentrations more than PEL (Permitted Exposure Limits as per the national/ international standards) concentrations.

Health management plan is basically in three steps:

- Identify the risk
 - 1. Identify the hazardous chemicals based on NH, NF and NR ratings, TLV values.
 - 2. Identify the hazardous chemicals associated with exposure to chemicals.
 - 3. Identify the potential routes of exposure to the particular hazardous chemical substance.
- Based on the risks identified and exposure routs, mainly inhalation (Airborn)
 - 1. Implement the engineering measurement and concentration controls to keep the concentration below PEL.
- Medical plan
 - 1. Then develop Biological Monitoring plan, sampling and medical test plan in consultation with the qualified medical practitioner.
 - 2. Define abnormal result criterion in consultation with the qualified medical practitioner.
 - Initiating action to control air-born concentrations and medical treatment plan for the workers and consider supplementary diet plan or transferring the worker to the area of working

Details of this are given in are as follows.

ASSESSMENT AND MONITORING OF EXPOSURE TO CHEMICAL HAZARDS

Assessment and monitoring of exposure to hazardous chemical substances is an important aspect of initial and ongoing risk assessment and control. The primary prevention strategy should always be to prevent exposure to agents associated with toxic effects. When it is not possible to prevent such exposures, then the appropriate strategy is to limit exposure and minimise the possibility of adverse health effects. Exposure monitoring encompasses two basic techniques viz. **environmental air monitoring** (occupational hygiene) and **biological monitoring**. Environmental and biological monitoring are ways of investigating different problems and should be seen as complementary procedures. A practical approach in setting up an exposure monitoring programme for hazardous chemical substances is outlined in Table 3.

Table 3. A stepwise approach to developing an exposure monitoring programme for hazardous chemical substances

Step 1	What is the nature of the job? - outline the various activities.
Step 2	Identify the hazardous chemicals associated with exposure to chemicals in the various activities.
a. a	

Step 3 Identify the potential routes of exposure to the particular hazardous chemical substance.

Steps 1-3 are part of the risk assessment process. If a potential health risk is identified, proceed to Step 4.

Step 4	If the exposure route is mainly airborne, proceed to environmental monitoring (EM).
Step 5	If the exposure route is mainly through non-inhalation routes (skin, ingestion) or if major reliance on personal protective equipment, proceed to biological monitoring (BM).
Step 6	Develop a sampling strategy for EM and/or BM based on exposure zone characterization (groups of workers performing similar activities). For EM, it is preferable to do personal sampling. The timing of the sampling strategy for BM is based on the biological half-life of the substance in the sample medium (blood, urine) concerned. Conduct sampling in a standardized manner. Ensure that samples are appropriately stored after collection.
Step 7	Identify the appropriate analytical test that has a high degree of validity, and a quality- certified laboratory that will conduct the analysis of samples.
Step 8	Decide beforehand the criteria to be used to define an abnormal test result using the DOL/ ACGIH/NIOSH OELs for airborne substances or Department ofLabour (DOL)/ACGIH BEIs for BM samples.
Step 9	Outline the process of referral to confirm abnormal result in the case of BM, removal of the person from exposure; determining the presence of adverse health effects through medical surveillance and/or diagnostic medical assessment; initiating treatment in instances of acute toxicity; and where appropriate submitting a workers' compensation claim (COIDA) should there be abnormal results.
Step 10	Outline the procedure for notification of employer, worker (ongoing worker notification procedures) and enforcement agency (notify incident to DOL) as to the outcome of the exposure assessment.
Step 11	Ensure input of the information obtained in this process into systems and procedures in assessing the efficacy and improvement of existing control measures such as engineering controls, work procedures, education and training.
Step 12	Ensure evaluation and audit of the programme on a regular basis.

Following hazardous chemicals will be stored and handled:

Sr. No.	Raw Materials	State	Nh	Nf	Nr	BP °C	TLV/ TWA
1	n- Butyl amine FP= -14 °C	Liquid	3	3	0	77	5ppm
2	Dimethyl Formamide	Liquid	1	2	0	153	10 ppm
3	Liquid Bromine	Liquid	3	0	0	58	0.5 ppm
4	Formamide	Liquid	2	1	0	210	10 ppm
5	Dimethyl Sulphate	Liquid	4	2	0	188	0.1 ppm

Table

Based on the above data, with reference to low TLV values and Boiling points, following chemicals are identified as toxic chemicals, which need special precautions to minimize the hazards due to exposure to workers for health and environment protection.

Chemicals with low TLVs and Low boiling points:

- Liquid Bromine
- Methylene Dichloride

Chemicals with low TLVs and High boiling points:

- Formamine
- Dimethyl Sulphate

Liquid Bromine in particular and low boiling toxic chemicals in general:

Engineering and other measures for Bromine storage and Handling and for keeping it below PEL, in detail has been given in RH report:

Few are illustrated here:

Bromine will be stored in 3 liter size glass bottles at 15 °C. A free space of 8-10% by volume should be left in the container.

- 1. Bromine glass bottles will be stored in a separate enclosed place, in the warehouse and it will be provided with exhaust with scrubber.
- 2. Bromine will be handled by workers with proper PPEs suitable and breathing masks.
- Bromine will be charged to the overhead tank at less than 20 °C. It will be provided with exhaust connected to a packed bed scrubber with provision for dilute Caustic solution circulation to ensure complete absorption of Bromine. Sodium Bromide Solution will be sent to Bromine recovery companies.
- 4. Where ever feasible, leak detectors, and VOC concentration will be monitored.

- 5. The chemicals will be transferred directly from the drums/carboys by air operated /hand operated pumps, directly to the overhead tanks and then to the reactor.
- 6. Workers will be handling these chemicals with proper training, awareness and using proper PPE's.
- 7. All overhead charging tanks will be provided with vent condensers with chilled water (with normal Flame arrestors) to minimize the loss and pollution.
- 8. These chemicals will be transferred from drums kept on the weigh scale to ensure that only the required quantity is charged in to the reactor.

Other measures to handle Bromine and other toxic chemicals, Methylene Dichloride (Dichloromethane) are given details like: Routes of Entry, Handling Instruction, First Aid, Emergency Response are given in details in RH report.

Solvents Stored in Tank:

Details of storage are given in the RH report with necessary information on properties and precautions to be taken are given in **Annexure 7**{**I**}.

Engineering measures to have concentration of solvents within PEL values, for solvents stored in tanks for Acetonitrile, Methanol etc. will be:

- 1. Storage tanks will be fitted with overhead condensers with chilled water.
- 2. All transfers will be by pumps with mechanical seals to have zero leakage.
- 3. All receiving tanks for reactor charging, distillation collection will be fitted with overhead condensers with chilled water.
- 4. Class A storage and transport will be as per PESO rules and necessary statutory approvals will be obtained.

Biological monitoring:

Three types of effects on the human body given below:

- 1. Acute
- 2. Chronic
- 3. Allergic

Acute:

The effect is exerted immediately or within a few hours of exposure (implies rapid accumulation at the target organ site; the severity of the reaction is directly proportional to the exposure dose

rate) e.g. chemical asphyxiants (cyanide, carbon monoxide, hydrogen sulphide, nitrogen dioxide), irritants (chlorine, sulphur dioxide, ammonia) and corrosives (acids).

Chronic:

The effect is exerted after months or years of exposure (implies gradual accumulation at the target organ site; severity is directly proportional to the exposure dose rate) e.g. heavy metallic toxins such as lead. Certain substances demonstrate a delayed effect following a prolonged latency period (can occur with prolonged exposure or transient exposure) e.g. carcinogens such as asbestos.

Allergenic:

The effect is exerted through the immune system (multiple initial doses result in sensitization with the accumulation of antibodies; subsequent low-level exposure triggers a response; pronounced individual susceptibility) e.g. respiratory and skin sensitizers (chrome, nickel, platinum salts).

Based on the information given in **Appendix 1** the information and other information that may be available with qualified medical (OH) doctor, the medical tests, to be carried out in periodic medical check-up, will have to be finalized along with medical treatment or special diet plan, corrective action required.

Appendix 1

Following medical information is given below based on the literature available for toxic chemicals:

Chemical	Cronic	Acute	Short Term High Conc.
N,N-Dimethyl Formamide	May affect genetic material.	Skin Causes skin irritation with itching, burning, redness, swelling, or rash. It may be absorbed through the skin in toxic amounts and cause systemic effects similar to that of ingestion	
Dimethyl Sulphate	Chronic Effects on Humans: Classified A2 (Suspected for human.) by ACGIH, 2A (Probable for human.) The substance is toxic to blood, kidneys, lungs, the nervous system, liver, mucous	Extremely hazardous in case of skin contact (corrosive, irritant), of inhalation. Very hazardous in case of skin contact (permeator), of ingestion.	

Table

	membranes.		
n- Butyl amine	Very hazardous in case of skin contact (irritant, permeator), of ingestion.	Toxic Effects on Humans: Exposure can cause nausea, headache and vomiting. Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract.	
Liquid Bromine	Prolonged or repeated exposure may affect respiration and endocrine system (thyroid), metabolism, behavior/central nervous system, and cardiovascular system, and cause kidney and liver damage. Effects may be delayed.	Skin: Contact with liquid is corrosive and causes ulceration and skin burns. In milder cases, it might cause skin rash, pustles, measle-like erruptions, furuncles, and cold and clammy skin with cyanosis or pale color. Eyes: It is a lacrymator and causes eye irritation, eyelid inflammation at low concentration. At higher concentrations it may cause blepharospasm, photophobia, conjunctivitis, and burns.	Inhalation: Inhalation of smaller amounts may cause severe irritation of the respiratory tract with coughing, chest tightness, shortness of breath, and nosebleed. Inhalation of larger amounts may cause pulmonary edema
Hydrogen Peroxide {30 %}	Prolonged or repeated skin contact may cause dermatitis. Repeated contact may also cause corneal damage		

Annexure 1 {III}: Material Safety Data Sheet for Products & Raw Material

{Products}

Sr. No.	Raw materials/ products	Formula	State	Odor	Mol. Wt	Flash Point	Meltin g	Boilin g	LD ₅₀ (mg/k	Stability	Hazard	Color	Sp. Gr.	UEL %	LEL %	Odor threshold
					(g/mole)	(°C)	Point (⁰ C)	Point (⁰ C)	g)				(g/cc)			(ppm)
1.	Tetra Butyl Ammonium Bromide	C ₁₆ H ₃₆ N Br	Solid	NA	322.38	NA	103.5	NA	NA	Stable	Irritant to skin, eye Inhalation &. Ingestion	NA	NA	NA	NA	NA
2.	Tetra Butyl Ammonium Hydrogen Sulphate	C ₁₆ H ₃₇ N O ₄ S	Solid	NA	339.54	NA	169- 171	NA	NA	Stable	Irritant to skin, eye Inhalation &. Ingestion	White	NA	NA	NA	NA
3.	4- Bromo Anisole	C ₇ H ₇ BrO	Liqui d	NA	187.04	98	910	223	2200	Stable	Irritant to skin, eye Inhalation &. Ingestion	light yellow	NA	NA	NA	NA
4.	4-Bromo Phenetole	BrC ₆ H ₄ O C ₂ H ₅	NA	NA	201.6	103	4	233	NA	Stable	Irritant to skin, eye Inhalation &. Ingestion	NA	NA	NA	NA	NA
5.	4-Methyl Phenacyl Bromide	C ₉ H ₉ BrO	Cryst al	NA	213.07	44	48-50	238- 239		Stable	Irritant to skin, eye Inhalation &. Ingestion	White to Light Yellow	NA	NA	NA	NA
6.	Metformin Hydrochloride	C ₄ H ₁₁ N ₅ . HCl	Solid	NA	165.6	NA	223- 226	NA	1000	Stable	Irritation to eye, skin, inhalation, ingestion	NA	NA	NA	NA	NA
7.	Cetrimide	C ₁₇ H ₃₈ Br N	Crystl line	Odorle ss	336.39	NA	245- 250	150	3900	Stable	Irritation to eye, skin, inhalation, ingestion	Colorles s	NA	NA	NA	NA
8.	Pioglitazone	$C_{19}H_{20}N_2 \\ O_3S$	Solid	NA	356.4	NA	NA	NA	NA	Stable	Irritation to eye, skin, on inhalation, on ingestion	NA	NA	NA	NA	NA

Chapter 1: Additional Studies

{Raw Materials}

Sr. No.	Raw materials	Formula	State	Odor	Mol. Wt (g/mole	Flash Point (⁰ C)	Meltin g Point	Boilin g Point	LD ₅₀ (mg/k g)	Stability	Hazard	Color	Sp. Gr. (g/cc)	UEL %	LE L %	Odor threshold (ppm)
)		(⁰ C)	(⁰ C)	Ċ,							
1.	Tetra Butyl	Ammonii	um Bro	omide		1			<u> </u>							
1	n- Butyl amine	C ₄ H ₁₁ N	Liqui d	NA	73.14	-6.99	-49	78	366	Stable	Irritant to skin, eye Inhalation & ingestion	Colorless	NA	9.8	1.7	NA
2	n- Butyl Bromide	C ₄ H ₉ Br	Liqui d	NA	137.02	10	-112	100- 104	2761	Stable	Irritant to skin, eye Inhalation & ingestion	Light yellow	1.270	7	2.6	NA
3	AcetoNitrile	CH ₃ CN	Liqui d	Aroma tic	41.05	2	-46	81.6	2460	Stable	Irritant to skin, eye Inhalation & ingestion	Colorless	0.783	4.4	16	NA
4	Ethyl Acetate	$C_4H_8O_2$	Liqui d	Fruity	88.11	-4	83.5	75-78	620	Stable	Flammable	Colorless	0.902	11.5	2.0	50
2.	Tetra Butyl A	Ammoniun	n Hydro	ogen Sulp	ohate						-					
1	Tetra Butyl Ammonium Bromide	C ₁₆ H ₃₆ N Br	Solid	NA	322.38	NA	103.5	NA	NA	Stable	Irritant to skin, eye Inhalation & ingestion	NA	NA	NA	NA	NA
2	Methylene di Chloride	CH ₂ Cl ₂	Liqui d	NA	84.93	NA	-96.7	39.75	1600	Stable	Skin, eye irritation	NA	1.32	19	12	214
3	Potassium Thiocyanate	KSCN	Solid	NA	97.18	NA	170- 179	NA	NA	Stable	Skin, eye irritation	White	NA	NA	NA	NA
4	Sulphuric Acid {70%}	H_2SO_4	Liqui d	Odorle ss	98.08	NA	-35 to 10.36	270- 340	2140	Stable	Corrosive	Colorless	1.84	NA	NA	NA
3.	4-Bromo Ani	sole														
1	Anisole	C ₇ H ₈ O	Liqui d	NA	108.14	43	-37	154	3700	Stable	Flammable, Skin, eye irritation	Colorless	NA	NA	NA	NA
2	Liquid Bromine	Br ₂	Liqui d	Punge nt	159	NA	-7.25	58.78	3100	Stable	Irritant to skin, eye	Red- Brown	3.11	NA	NA	0.05

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Sr. No.	Raw materials	Formula	State	Odor	Mol. Wt (g/mole)	Flash Point (⁰ C)	Meltin g Point (⁰ C)	Boilin g Point (⁰ C)	LD ₅₀ (mg/k g)	Stability	Hazard	Color	Sp. Gr. (g/cc)	UEL %	LE L %	Odor threshold (ppm)
											Inhalation & ingestion					
3	Hydrogen Peroxide {30 %}	H_2O_2	Liqui d	NA	34.01	NA	NA	100	NA	Stable	Irritant to skin, eye Inhalation & ingestion	Colorless	1	NA	NA	NA
4	Sodium Carbonate	Na ₂ CO ₃	Solid	Odorle ss	105.99	NA	851	NA	NA	Stable	NA	White	NA	NA	NA	NA
4.	4-Bromo Phe	enetole														
1	Anisole	C ₇ H ₈ O	Liqui d	NA	108.14	43	-37	154	3700	Stable	Flammable, Skin, eye irritation	Colorless	NA	NA	NA	NA
2	Liquid Bromine	Br ₂	Liqui d	Punge nt	159	NA	-7.25	58.78	3100	Stable	Irritant to skin, eye Inhalation & ingestion	Red- Brown	3.11	NA	NA	0.05
3	Hydrogen Peroxide {30 %}	H ₂ O ₂	Liqui d	NA	34.01	NA	NA	100	NA	Stable	Irritant to skin, eye Inhalation & ingestion	Colorless	1	NA	NA	NA
4	Sodium Carbonate	Na ₂ CO ₃	Solid	Odorle ss	105.99	NA	851	NA	NA	Stable	NA	White	NA	NA	NA	NA
5.	4-Methoxy P	henacyl Br	omide													
1	4-Methoxy Acetophenon e	C ₉ H ₁₀ O ₂	Solid	Aroma tic	150.18	138	36-39	260- 154	1720	Stable	Irritant to skin, eye Inhalation & ingestion	White	NA	NA	NA	NA
2	Liquid Bromine	Br ₂	Liqui d	Punge nt	159	NA	-7.25	58.78	3100	Stable	Irritant to skin, eye Inhalation & ingestion	Red- Brown	3.11	NA	NA	0.05
3	Methanol	CH ₃ OH	Liqui d	Alcoho l	32.04	NA	-97.6	64.5	NA	Stable	Flammable	colorless	0.791 5	36.5 0	6.7 2	NA
6.	Metformin H	vdrochlori	ide													

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Sr. No.	Raw materials	Formula	State	Odor	Mol. Wt (g/mole)	Flash Point (⁰ C)	Meltin g Point (°C)	Boilin g Point (⁰ C)	LD ₅₀ (mg/k g)	Stability	Hazard	Color	Sp. Gr. (g/cc)	UEL %	LE L %	Odor threshold (ppm)
1	Di cyano di Amide	$C_2H_4N_4$	Solid	NA	84.08	NA	208- 211	NA	NA	Stable	NA	White	NA	NA	NA	NA
2	Dimethyl Amine Hydrochlorid e	C ₂ H ₇ N.C lH	Solid	NA	81.54	NA	171	NA	1070	Stable	Irritation to eye, skin, inhalation, ingestion	White	NA	NA	NA	NA
3	Dimethyl Formamide	C ₃ H ₇ NO	Liqui d	Punge nt	73.09	58	-61	153	2800	Stable	Flammable, Irritation to eye, skin, inhalation, ingestion	Colorless		15.2	2.2	
4	Carbon	С	Solid	NA	12.1	NA	3651.6	4826.6	NA	Stable	Irritant to skin, eye	Black	2-2.5	NA	NA	NA
5	Isopropanol	C ₃ H ₈ O	Liqui d	Rubbin g alcohol	60.1	12	-88.5	82	5,045	Stable	Irritating	Colorless	NA	NA	NA	NA
6	Hyflow or celite	SiO ₂	Solid	odorles s	NA	NA	NA	NA	NA	Stable	NA	Slight grey	2.3	NA	NA	NA
7.	Cetrimide															
1	Formamine	C6H12N 4	Liqui d	NA	140.188	103.9	280	252.60	NA	Stable	Irritation to eye, skin, inhalation, ingestion	Colorless	NA	NA	NA	NA
2	Sodium Bromide {35 %}	NaBr	Solid	NA	102.91	NA	755	1390	3500	Stable	Irritant to skin, eye	Colorless	NA	NA	NA	NA
3	Dimethyl Sulphate	$\overline{C_2H_6O_4S}$		NA	126.13	83	-32	188	NA	Stable	Irritation to eye, skin, inhalation, ingestion	White	NA	NA	NA	NA
4	Ethyl Acetate	$C_4H_8O_2$	Liqui d	Fruity	88.11	-4	83.5	75-78	620	Stable	Flammable	Colorless	0.902	11.5	2.0	50
5	Isopropanol	C ₃ H ₈ O	Liqui d	Rubbin g alcohol	60.1	12	-88.5	82	5,045	Stable	Irritating	Colorless	NA	NA	NA	NA

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Chapter 1: Additional Studies

Sr. No.	Raw materials	Formula	State	Odor	Mol. Wt (g/mole)	Flash Point (°C)	Meltin g Point (°C)	Boilin g Point (°C)	LD ₅₀ (mg/k g)	Stability	Hazard	Color	Sp. Gr. (g/cc)	UEL %	LE L %	Odor threshold (ppm)
8.	8. Pioglitazone															
1	Pioglitazone	$C_{19}H_{20}N_2$	NA	NA	356.4	NA	NA	NA	NA	Stable	Irritant to	NA	NA	NA	NA	NA
	Base	O ₃ S									skin, eye					
2	Methanol	CH ₃ OH	Liqui	Alcoho	32.04	NA	-97.6	64.5	NA	Stable	Flammable	colorless	0.791	36.5	6.7	NA
			d	1									5	0	2	
3	Hydrochloric	HCl	Liqui	Acidic	6.46	NA	-46	51	700	Stable	Corrosive	Colorless	1.18	NA	NA	0.25 to 10
	Acid {30 % }		d													
4	Carbon	C	Solid	NA	12.1	NA	3651.6	4826.6	NA	Stable	Irritant to	Black	2-2.5	NA	NA	NA
											skin, eye					