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"Human Lose and Cost Assesment Due to Leak of Glyceryl Trinitrate in A Pharmasuitical Industry"

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ABSTRACT
As we all know chemicals are highly hazardous and toxic in nature. They are hazardous till the stage of manufacturing to the stage of storage. this is a study which has been carried out in a pharma industry where the workers are exposed to Explosive and hazardous chemicals such as Glyceryl Trinitrate, Chlorine dioxide, Hydrogen peroxide, Methanol and other like these. In this research physical and chemical properties of chosen chemicals are studied. In the second step we have done checklist analysis where the needed data is collected which is going to be used for further steps.in the next step we have to select a highly hazardous or toxic chemical, Toxicity Calculation and hazardous risk is used to rank the chemicals based on the data gathered from checklist. After these selections are made for highly hazardous or toxic chemical, the next step is to find out what are the consequences and risk we are going to face if there is an accident or release of these toxic chemicals in environment. For this, Event Tree Analysis (ETA) is used in next step. In the next step we have to calculate the risk from ETA and find that how it is dispersed into atmosphere and till how much distance it's going to affect. In the next step we are to calculate human health and safety loss, using the distance found out by software and compensation amount collected from laws. In the final step we will make the precautionary & preventive measures to avoid the toxicity dispersion of chemicals in atmosphere with emergency preparedness in case of chemical release by any means.

Key words:
Event Tree Analysis,
Emergency Response Planning etc.

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I. METHODOLOGY:

The methdology shown below helps in finishing this project successfully and quickly. In which, the first step is to know about the chemicals used in pharma industry. The second step is Checklist analysis where the needed data are gathered which are going to be used for further steps. At next step, to select a highly hazardous chemical, Toxicity Index Calculation is used to rank the chemicals based on the data collected from checklist. After the selection of the hazardous chemical, the next step is to find out what is the next event going to happen if there is a release. For which, Event Tree Analysis (ETA) is used in this step. The next step after finding the final event from ETA is to find the how it is dispersed into atmosphere and how much distance it covered. It can be easily found out using the ALOHA Dispersion Software. The next step is human health and safety loss calculation using the distance found out by software and compensation amount gathered from law. The final step is to make the Precaution and preventive measure.

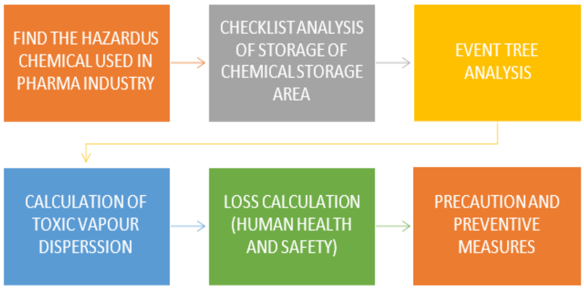


Figure 1: Methodology for Risk assessment

1.1 Theoretical Framework:

In this chapter I will present my empirical findings. The findings have been schematized and divided according to the research questions. First, I will present how the facility has implemented its SIS. Thereafter, organizational measures that contribute to the development of safety culture are presented. Here I only provide an overview of measures directed at safety. Similarly, within the last presented subsection, I present safety culture's effect on the SIS' performance, but only providing the cultural findings.

1.2 OVERALL REPORTING FRAMEWORK:

The facility needs incoming reports for numerous of reasons. Some of these are established in the organization's internal documents. Reporting is explained as a mean to follow the multiple requirements given by laws, regulations, customers and global headquarters. Reports contribute to compliance of the requirements given by the overall SMS named an HSE management system in the management system documents. The facility's SMS is in next instance used as mean to adhere to relevant national regulations and laws, and part of the HSE policy.

The current facility must comply with the Norwegian Internal Control regulations (1996) and the Working Environment Act (2005) that sets demands for systematic health, safety and environmental (HSE) – work.

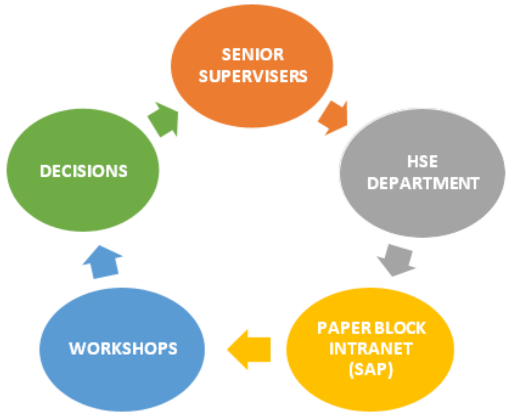


Figure 2: The facility's Implemented safety information system

Figure above illustrates how the current facility has implemented its SIS, seen through the three phases of data collection, processing and distribution of information to relevant decision-makers. The workshops represent the production system. It is in the workshops where the operative personnel conducts maintenance and operates heavy equipment on a regular basis.

II. HAZARD & RISK ASSESSMENT:

2.1.1 CHECKLIST ANALYSIS:

The next step of this project is Checklist analysis from which the data needed for this project can be gathered. Checklist is a type of informational job aid used to reduce failure by compensating for potential limits of human memory and attention. The checklist is one of the main tools available to assist in hazard identification. Its is should be used for just one purpose. It is more effective if the questions can be answered by a simple 'yes' or 'no' but require some thought in formulating an answer.

It is one of the most simplistic tools of hazard identification is the checklist. Like a standard or a code of practice, a checklist is a means of passing on lessons learned from experience. It is impossible to envisage high standards in hazard control unless this experience is effectively utilized. The checklist is one of the main tools available to assist in this. Checklists are applicable to management systems in general and to a project throughout all its stages. Obviously, the checklist must be appropriate to the stage of the project, starting with checklists of basic materials properties and process features, continuing on to checklists for detailed design and terminating with operations audit checklists. A checklist should be used for just one purpose only - as a final check that nothing has been neglected. Also, it is more effective if the questions cannot be answered by a simple 'yes' or 'no' but require some thought in formulating an answer.

Table 1: Checklist for Glyceryl trinitrate storage

S. no.	Contents	Yes	No
1	Whether the storage vessels are outdoor?	✓	
2	Whether the Glyceryl trinitrate is stored underground?	✓	
3	Any access points available?	✓	
4	Whether the access attach with roads?	✓	
	Corrosion		
5	Whether the corrosion rate is less than 0.5 mm/yr.?		✓
6	Are the vessels properly bonded and earthed as a protection of corrosion	✓	
7	Whether lining is provided for corrosion prevention?	✓	
	Accessories		
8	Whether the pump & gland seals have any minor leakages or any history?		✓
9	Whether it has bellows, assemblies or expansion joints?	✓	
10	Any pumps used for transporting chemicals?	✓	
11	Is the vessel provided with alarm for high level and low?	✓	
12	Any sensors available for detecting leakages?	✓	
	Maintenance, Cleaning & Inspection		
13	What periodical testings carried out on the vessels to find out integrity of vessels?	✓	
14	Is it tested frequently?	✓	
15 16	Whether the permit to work system is available? Are the maintenance team trained for the above purpose?	✓ ✓	
17	Are the maintenance crew supervised by senior and experienced person?	✓	
18	Pipelines or inlet to tank are cut off or shut off during maintenance work?	✓	
19	Before entering into the tank, it should be checked for any harmful gas or vapor?	✓	
20	Whether it is authorized by competent person?	✓	
21	Whether the maintenance crew knew of the all hazards present in storage tank?	✓	
22	Whether the Maintenance crew available with required PPE for the purpose?	✓	
23	Whether the tools used are non-sparking type?	✓	
24	Whether the safety harness with lifeline for the person entering the storage tank?	✓	
25	Whether extra two person available outside the tank to assist?		✓
26	Whether the rescue persons are available with SCBA during the emergency?		✓
27	During maintenance, whether any faults or anything which can lead to failure identified?		✓
28	Whether any special considerations available for the storage maintenance work?		✓
	Emergency Response and preparedness		
29	Is it a fire hazard?	✓	
30	Is it a toxic hazard?	✓	
31	How are the vessels isolated in the event of mishap?	✓	
32	Are the vessels provided with emergency vent, relief valve, burstingdisc, level indicator, pressure gauge and overflow line?	✓	
33	Are the vessels fitted with remote controlled isolation valves?	✓	
34	Are stand by tanks available for emptying in case of Emergencies?	✓	
35	Has any consequences analysis been carried out for these vessels?		✓
36	Any precaution or prevention measures available for dispersion intoatmosphere?	✓	
37	If fire or explosion risk means, whether the first aid firefightingequipment's available at site?	✓	
38	Emergency alarm system(s) is/are available?	✓	
39	Whether the emergency escape route is clearly displayed and known toworkers	✓	

	nearby?		
40	If toxic risk means, whether the PPE available at site for safe evacuationof worker?	✓	
41	Whether the first aid box available near storage area with requiredequipment's?	✓	
42	Whether the first aid trained personnel available nearby along withrequired training for both fire and toxic scenario?	✓	
43	Whether the on-site emergency plan available for fire & explosionscenario.	✓	
44	Whether the on-site emergency plans available for toxic scenario?	✓	
45	How often on-site emergency mock drill conducted?	✓	
46	Any different emergency sirens for toxic and fire scenario?		✓
47	Whether any precaution existing in the storage area?		✓
48	What are the numbers of emergency control center and assembly points available?	✓	
49	Whether trained operators in emergency procedures available in storage area?	✓	
50	Whether the ERT personnel are adequate in number?		✓
51	Whether the offsite emergency plans available?		✓

2.2 TOXICITY CALCULATION

The third step is Toxicity Calculation which is done to prioritize and select the chemical which is highly hazardous (toxic) for further analysis, So MOND Toxicity Calculation was chosen, due to availability of more hazardous chemicals.

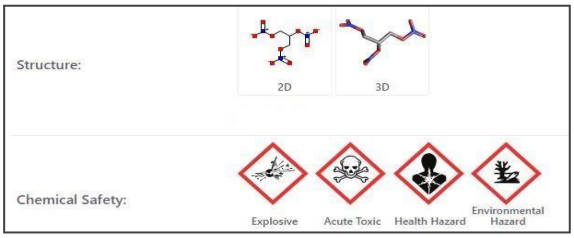
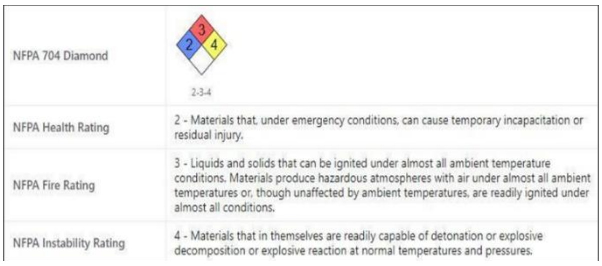


Figure 3 : Structure and hazard safety for Glyceryl trinitrate.

2.2.1 TOXICOLOGICAL INFORMATION

According to The National Institute for Occupational Safety and Health (NIOSH) taxological information of Glyceryl trinitrate. We have conducted some experiments to observe and calculate toxic level for Glyceryl trinitrate.



NFPA 704 Diamond	2-3-4
NFPA Health Rating	2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.
NFPA Fire Rating	3 - Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions.
NFPA Instability Rating	4 - Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures.

Figure 4: NFPA Diamond and rating: Glyceryl trinitrate.

2.3 TOXICITY SUMMARY

The oral LD50 of Glyceryl trinitrate in rats is 105 mg/kg and the of the intravenous form in rats is 23.2 mg/kg. An overdose of Glyceryl trinitrate can lead to a variety of hemodynamic effects. General effects may include vertigo, fever, flushed skin, and diaphoresis. Cardiorespiratory symptoms may include syncope, dyspnea, decreased heart rate, or palpitations. Neurologic manifestations can include paralysis, seizures, coma, and death. There are no known antidotes to an overdose of Glyceryl trinitrate, and it is not known whether its metabolites can be removed from the circulation. If hypotension occurs due to an overdose with Glyceryl trinitrate, elevate the lower limbs and administer an intravenous infusion of normal saline or other fluids if necessary to maintain central fluid volume.

III. HUMAN EXPOSURE

Main risks and target organs: Toxic effects of glyceryl trinitrate are caused by vasodilatation and methemoglobinemia. Venous and arterial vasodilatation causes lowering of blood pressure leading to shock. Heart, blood vessels and red blood cells are the target organs in glyceryl trinitrate poisoning. Summary of clinical effects: Features of poisoning may appear within a few minutes to one hour or more after exposure. There is tachycardia and hypotension followed by bradycardia and collapse. Flushing of the face, headache, dizziness, restlessness, syncope, convulsions and coma may be present. Some of the other features are vomiting, diarrhea, cyanosis and methemoglobinemia and respiratory failure. Effects of glyceryl trinitrate are enhanced by alcohol. Contraindications to the use of glyceryl trinitrate is in patients with hypo, head injury, severe anemia, cerebral hemorrhage and in patients predisposed to closed- angle glaucoma. Intravenous administration contraindicated in constrictive pericarditis and uncorrected hypovolemia.

FIRE HAZARDS

Will be easily ignited by heat, sparks or flames (HIGHLY FLAMABLE). Vapors may form explosive mixtures with air. Vapors may travel to source of ignition and flash back. Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks). Vapor explosion hazard indoors, outdoors or in sewers. Those substances designated with a (P) may polymerize explosively when heated or involved in a fire. Runoff to sewer may create fire or explosion hazard. Containers may explode when heated. Many liquids are lighter than water. Many reactions may cause fire or explosion. Gives off irritating or toxic fumes (or gases) in a fire. Risk of fire and explosion.

PERSONAL PROTECTION AND SANITATION:

There are various codes that are to be followed within such industries for better protection of workers in particular industry.

Table 2 Personal Protection and Sanitation for Industry:

Code	Description	Definition
Skin:	Prevent skin contact	Wear appropriate personal protective clothing to prevent skin contact.
	Frostbite	Compressed gases may create low temperatures when they expand rapidly. Leaks and uses that allow rapid expansion may cause a frostbite hazard. Wear appropriate personal protective clothing to prevent the skin from becoming frozen.
	N.R	No recommendation is made specifying the need for personal protective equipment for the body.
Eyes:	Prevent eye contact	Wear appropriate eye protection to prevent eye contact.
	Frostbite	Wear appropriate eye protection to prevent eye contact with the liquid that could result in burns or tissue damage from frostbite.
	N.R.	No recommendation is made specifying the need for eye protection.
Wash skin:	When contaminated	The worker should immediately wash the skin when it becomes contaminated.
	Daily	The worker should wash daily at the end of each work shift, and prior to eating, drinking, smoking, etc.
	N.R.	No recommendation is made specifying the need for washing the substance from the skin (either immediately or at the end of the work shift).
Remove:	When wet or contaminated	Work clothing that becomes wet or significantly contaminated should be removed and replaced.
	When wet (flammable)	Work clothing that becomes wet should be immediately removed due to its flammability hazard (i.e., for liquids with a flash point <1000 F.)
	N.R.	No recommendation is made specifying the need for removing clothing that becomes wet or contaminated
Change:	Daily	Workers whose clothing may have become contaminated should change into uncontaminated clothing before leaving the work premises.
	N.R	No recommendation is made specifying the need for the worker to change clothing after the workshift.
Provide:	Eyewash	Eyewash fountains should be provided in areas where there is any possibility that workers could be exposed to the substances; this is irrespective of the recommendation involving the wearing of eye protection
	Quick drench	Facilities for quickly drenching the body should be provided within the immediate work area for emergency use where there is a possibility of exposure. [Note: It is intended that these facilities provide a sufficient quantity or flow of water to quickly remove the substance from any body areas likely to be exposed. The actual determination of what constitutes an adequate quick drench facility depends on the specific circumstances. In certain instances, a deluge shower

		should be readily available, whereas in others, the availability of water from a sink or hose could be considered adequate.]
	Frostbite wash	Quick drench facilities and/or eyewash fountains should be provided within the immediate work area for emergency use where there is any possibility of exposure to liquids that are extremely cold or rapidly evaporating.

IV. FORMULATION OF WORST-CASE SCENARIO:

For a toxic liquid, the worst-case scenario is defined as the quantity in the largest vessel or pipe is spilled instantaneously to form a liquid pool. The surface area of the pool shall be determined by assuming that the liquid spreads to 1-centimeter-deep unless passive mitigation systems are in place that serves to contain the spill and limit the surface area. The volatilization rate shall account for the highest daily maximum temperature occurring in the past three years, the temperature of the substance in the vessel, and the concentration of the substance if the liquid spilled is a mixture or solution. In simple terms, the worst-case scenario is the release of the largest quantity of a regulated substance from a single vessel or process line failure that results in the greatest distance to an endpoint. In broad terms, the distance to the endpoint is the distance toxic vapor cloud will travel before dissipating to the point that serious injuries from short-term exposures will no longer occur. The meteorological data are gathered from pharma industries.

Table 3 : The worst-case scenario for modeling the Glyceryl trinitrate storage vessel failure.

Worst case data	**During day time**	**During night time**
Atmospheric Data		
Wind speed	3.5 m/s	4.5 m/s
Wind direction	NE	NE
Cloud cover	0	0
Air temperature	320C	240C
Stability Class	E	F
Relative humidity	57%	61%
Source strength		
Leak type	Hole	Hole
Tank volume	150 m3	150 m3
Internal temperature	18.30C	18.30C
Chemical mass in tank	80%	80%
Hole diameter	50 mm	50 mm
Hole at a height in tank	10%	10%
Ground type	Concrete	Concrete
Ground temperature	Equivalent to Ambient temperature	Equivalent to Ambient Temperature

4.2 INPUT NEEDED FOR SOFTWARE SIMULATION: To do a simulation in ALOHA software, this project needs the following things which are site data, chemical data, atmospheric data and source of release data.

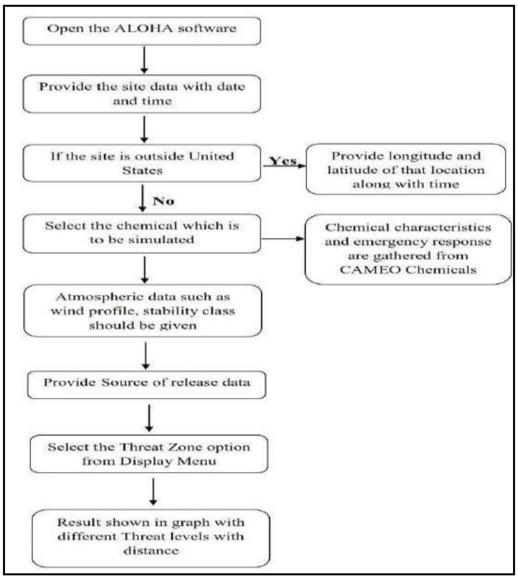


Figure 5: Flowchart for Working ALOHA software

V. RESULTS OF ALOHA SIMULATION:

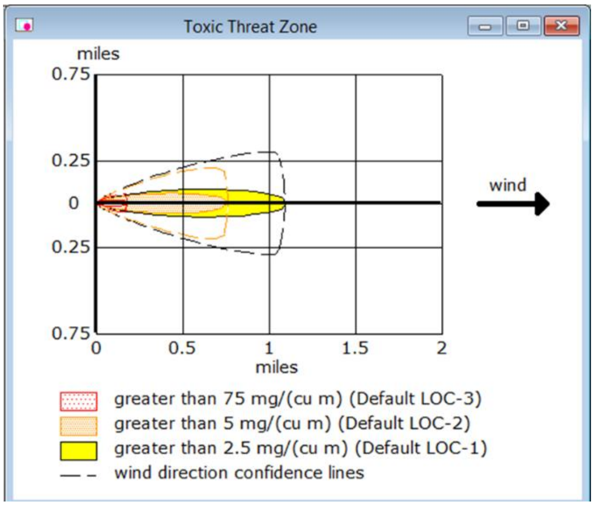


Figure 6: Release of Glyceryl trinitrate from the storage tank during Day Time

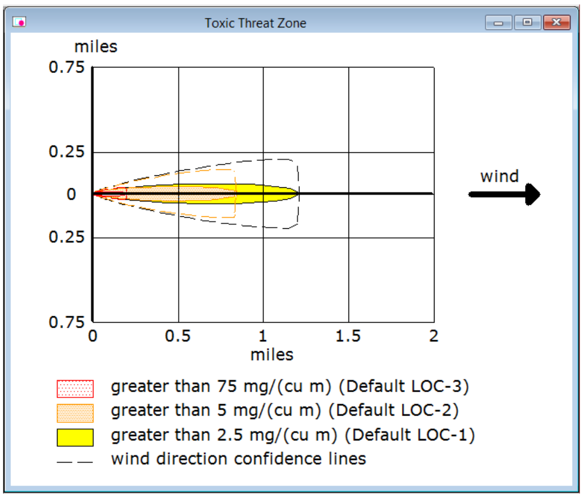


Figure 7: Release of Glyceryl trinitrate from the storage tank during night time

5.2 LOSS CALCULATION

After the calculation of threat zones distance from ALOHA software, the human health and safety loss should be calculated. Hosted and Stair suggested six categories of consequence Values under four hazard/threat categories. They recommended a total of 11 loss categories. These are loss of life in major accidents, loss of life in other accidents, acute personal injury, chronic disease, reduced functionality, acute pollution on external environment, continuous pollution on external environment, material damage, and loss of production (could include deferred and damaged production) the first 9 categories relate to four targets namely, human, environment, material, and production and are contributing the major share of potential losses as reported globally. The remaining losses such as loss of data information and loss of reputation are difficult to quantify and not available in most of the cases. Finally, the losses can be broadly categorized into production loss, assets loss, human health and safety loss and Environmental loss. In this project, only human health and safety loss is considered.

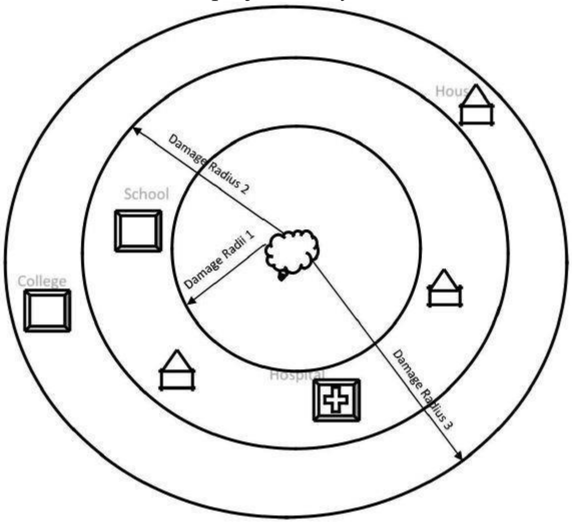


Figure 8: Damage radii of chemical dispersion

5.3 COST OF INJURIES AND LIFE:

Table 4: Compensation Amount according to Public Liability Act 1991

Sr. no.	Type of Damage/Injury	Compensation amount (Rs.)/each
1	Medical expenses only	12,500
2	Fatal accidents (in case along with Medical expenses)	25,000 + 12,500
3	Permanent partial disability & sickness	12,500
4	Total permanent disability	25,000
5	Temporary partial disability (at least 3 days hospitalized & above 16 yrs.)	1,000 /person for 3 months
6	Property Damage	6,000

Final cost for Red Zone

Type of damages in red zone-
Medical expenses = 12500
Fatal accident with medical = 25000
Permanent partial disability = 12500
Total permanent disability = 25000
Property damage = 6000
Total cost = 81000/-
Human density in Lalitpur = 242 person/km^2
Area of Red Zone = 0.26 km^2
Estimated cost of injury and life in red zone =
(Total cost of damage) X (Area of Zone)X(human density)
= 81000x.26x242
= 50,96,520/-

Final cost for Orange Zone

Type of damages in Orange zone-
Medical expenses = 12500
Fatal accident with medical = 25000
Permanent partial disability = 12500
Property damage = 6000
Total cost = 56000/-
Human density in Lalitpur = 242 person/km^2
Area of Red Zone = 4.67 km^2
Estimated cost of injury and life in Orange zone =
(Total cost of damage) X (Area of Zone) X (human density)

= 56000x4.67x242
= 6,32,87,840/-

Final cost for Yellow Zone

Type of damages in Yellow zone-
Medical expenses = 12500
Partial permanent disability = 12500
Property damage = 6000
Temporary partial disability (at least 3 days hospitalized & above 16 yrs.) = 1000
Total cost = 34000/-
Human density in Lalitpur = 242 person/km^2
Area of Red Zone = 9.83 km^2
Estimated cost of injury and life in red zone =
(Total cost of damage) X (Area of Zone) X (human density)
= 34000x9.83x242
= 8,08,81,240/-

The final cost of HSSL is Rs.14.92 crores (approx.) during day time and Rs. 16.10 crores (approx.) during night time. When calculating the loss, the cost of death is taken from the law, but the cost of value is costless where it can be said as the value of statistical life (VSL). In India, the value of statistical life is Rs.12 lakhs. When the VSL is considered, the loss will be Rs.179.04 crores (approx.) during day time and Rs.182.12 crores (approx.) but in this project the compensation cost is based on the law. And, the company workers also inside the red zone which will cause more life loss, compensation cost should be considered, and the experienced workers are one of the important assets of the company but the above said is not included. And there is also an indirect cost such as recruitment of new workers, experienced workers and training for them etc. The loss of reputation due to the accident is inevitable and irreparable which needs more time to change that bad reputation.

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