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No : AD/00756  
Defence Res. & Dev. Establishment  
Govt. of India, Min of Defence  
Jhansi Road, Gwalior - 474002

Date : 11 Aug., 2008

936/DRDE/8  
21/8

To  
The Principal Secretary  
Govt. of India  
Dept. of Chemical & Petrochemical  
Room No. 501, A Wing, Sashtri Bhawan  
New Delhi-110 011  
Fax No. 011-23387892

Kind attn. : Sh. Yashvir Singh, Dy. Secretary.

Refer our earlier letter No. AD/00756, dated 30.06.08. All the toxicity tests of the six samples are completed and the data is also analysed.

The conclusion remains same :

- (i) All the samples viz. Excavated waste, Lime sludge, Naphthol tar, Reactor residue, Semi processed pesticide and Sevin tar have very low mammalian toxicity;
- (ii) Based on the primary skin irritation test, all the six samples collected from 'Stored Toxic Wastes at the former UCII, Plant Site at Bhopal' are non-irritant.

The short report sent to you earlier is also sent along with this for your ready reference

20/8  
JS(BS)

(Dr. R. Vijayaraghavan)  
DIRECTOR

20/8

Copy to :

The Principal Secretary  
Bhopal Gas Tragedy  
Relief & Rehabilitation Dept.  
BHOPAL.  
Kind attn. : Sh. K.K. Dubey, Under Secretary, DGPR&R.

5 (MS)

Encl. : as above.

21/8/08  
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21/8/08  
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(iii)

**Preliminary Report "Acute Oral Toxicity Studies of Samples of 'Stored Toxic Wastes at the former UCIL Plant Site at Bhopal' in Rats"**

This study was conducted to assess the safety with special reference to the acute toxicity, if any of six samples (Excavated waste, Lime sludge, Naphthol tar (or Naphthol tar), Reactor residue, Semi processed pesticide and Sevin tar) collected from 'Stored Toxic Wastes at the former UCIL Plant Site at Bhopal'. All the six coarse samples were separately collected in polythene bags and brought to DRDE, Gwalior. The samples were grinded, homogenized and filtered using 40 mesh sieve and stored in glass bottles at room temperature.

Acute toxicity describes the adverse effects of a substance which result either from a single exposure or from multiple exposures in a short space of time (usually less than 24 hours). To be described as *acute* toxicity, the adverse effects should occur within 14 days of the administration of the substance. Toxicity studies of all the chemicals/materials is a prerequisite, before the material is allowed for human usage. This is essential for safety evaluation of the material. The rat was selected as a test system because it is a readily available laboratory rodent species. It has been historically shown to be a suitable model for toxicity assessment. The oral route represents inadvertent/ accidental route of administration specially during handling of the samples in humans.

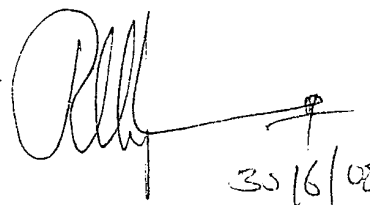
Briefly, each of the samples was separately triturated using ceramic mortar and pestle in 1% hydroxypropyl cellulose (HPC in distilled water). The required volume (not more than 1% of body weight) of freshly prepared suspension was fed orally to the rats using oral dosing needle. Three doses of each sample viz. 0.80, 1.60 and 3.20 g/kg of body weight to male rats and two doses (1.60 and 3.20 g/kg) to female rats (n=4 for each dose) were fed. The rats were observed for 14 days for development of any toxic symptoms and also for mortality.

**Results:** The median lethal dose (LD<sub>50</sub>) of the samples calculated following the moving average method of Gad and Weil (1989), considering that a dose of 6.40 g/kg body weight will kill all the rats, are as follow: (i) Excavated waste 4.525 g/kg in both sexes; (ii) Lime sludge 4.525 g/kg in both sexes; (iii) Naphthol tar male rats 3.80 g/kg and female rats 4.525 g/kg; (iv) Reactor residue 4.525 g/kg in both sexes; (v) Semi processed pesticide 4.525 g/kg in both sexes and (vi) Sevin tar male rats 2.69 g/kg and female rats 3.20 4.525 g/kg.

**The important finding of the study:** Oral LD<sub>50</sub> of four samples i.e. Excavated waste, Lime sludge, Reactor residue, Semi processed pesticide and Naphthol tar (in female rats) were found to be more than 4.5 g/kg. Sevin tar indicated more toxicity compared to other five samples. However, this can not be considered as highly toxic compound as LD<sub>50</sub> was 2.69 g/kg or more.

**Conclusion**

All the samples viz. Excavated waste, Lime sludge, Naphthol tar, Reactor residue, Semi processed pesticide and Sevin tar were found to be having very low mammalian toxicity.



30/6/08

(iii)

## Primary Skin Irritation Test of Samples of "Stored Toxic Wastes at the former UCIL Plant Site at Bhopal" in Rabbits

### Summary

This study was conducted to assess the safety with special reference to the primary skin irritation, if any, of six samples (Excavated waste, Lime sludge, Naphthol tar (or Naphthol tar), Reactor residue, Semi processed pesticide and Sevin tar) collected from 'Stored Toxic Wastes at the former UCIL Plant Site at Bhopal'. All the six coarse samples were separately collected in polythene bags and brought to DRDE, Gwalior. The samples were grinded, homogenized and filtered using 40 mesh sieve and stored in glass bottles at room temperature. Thereafter, administered as such percutaneously or dermally (on intact but hair clipped non-abraded and abraded skin) for a period of four hours in male rabbits.

Skin irritation testing in laboratory animals has not changed significantly since the method of Draize *et al.* (1944) even though several modifications of the basic procedures have been developed. The technique described by Draize *et al.* is successfully used to evaluate primary skin irritation properties of consumer products, drugs etc. The rabbits were selected as a test system because it is a readily available laboratory animal and also recommended for such type of studies. It has been historically shown to be a suitable model for primary skin irritation assessment. The percutaneous or dermal application (administration) represents the inadvertent route of administration/ contact of the samples in humans. The results of the study are believed to be of value in predicting the irritation of the samples in humans.

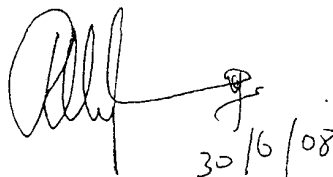
Briefly, each of the sample as such (0.5 g on each site) was applied on closely hair clipped non-abraded and abraded dorsal skin sites of rabbits. Thereafter, the animals were restrained for 4 hours so as to keep the sample(s) in direct contact with the skin. After the aforesaid duration the skin sites were carefully cleaned with moist cotton and after drying the sites were examined in clear day light following standard scoring procedure. The data was analyzed to determine Primary Skin Irritation Index (PSII).

Results: All the six samples did not induce the sign of irritation on the skin sites. Further, no noticeable change in clinical signs and gross motor activity was observed in any of the rabbits either during the period of treatment with the sample(s) or up to fourteen days. Body weight gain, feed and water consumption of all the animals grossly observed for a period of 14 days post treatment and compared to that of normal animals, did not show significant change.

**The important finding of the study:** The percutaneous (dermal) application of any of the six samples to hair clipped skin sites (non-abraded and abraded) of rabbits for a duration of 4 hours did not cause change compared to that of control skin sites. Further, no treatment related alterations were observed in gross loco-motor activity, feed intake, water intake and body weight up to 14 days.

### Conclusion

Based on the primary skin irritation test, all the six samples (Excavated waste, Lime sludge, Naphthol tar, Reactor residue, Semi processed pesticide and Sevin tar) collected from 'Stored Toxic Wastes at the former UCIL Plant Site at Bhopal' were found to be non-irritant to the rabbit's skin.



30/6/08



To

The Joint Director  
Bhopal Gas Tragedy Relief and Rehabilitation Department  
Govt. of Madhya Pradesh  
Jabalpur.  
Fax: 0761-2678493

Kind attn: Shri K.K. Dubey, Dy. Secy.

Ref: Your letter No. F.5-24/2009/47, dtd. 17.11.09

1. All the samples viz. Excavated waste, Lime sludge Napthol tar Reactor residue, Semi processed pesticide and Sevin tar have very low mammalian toxicity based on animal experimentation carried out in DRDE, Gwalior.
2. In other words, for a 70 kg man, there will not be any death even if he takes 200 gm by oral route. For Sevin tar, there will not be any death even if he takes 100 gm by oral route. This toxicity rate is lesser than ethyl alcohol, table salt (sodium chloride) and many of the commonly used drugs.
3. As per your plan, that is going to be followed on 03.12.09, there will not be any untoward, adverse or toxic effect to the public.

(Dr. R. Vijayaraghavan)  
Director



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: [director@drde.8m.com](mailto:director@drde.8m.com)

No: AD/00756  
Defence Res. & Dev. Establishment  
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