TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 2/3/81 OUT 3/9/81

Reviewed by James E. Wilson, Jr. Date 3/5/81

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Type Product(s): I, (D), H, F, N, R, S

Data Accession No(s). 243447

Product Mgr. No. 32 (Castillo)

Product Name(s) Lysol Brand Pine Action

Company Name(s) Lehn & Fink Products Co.

Submission Purpose New Product

Chemical & Formulation Liquid

Active Ingredient(s):	%
Pine Oil	15.00
Isopropanol	11.70
O-Phenylphenol	0.78

300.0 Introduction

300.1 Uses

Product is used to disinfect non-porous hard surfaces and laundry.

300.2 Background

None

301.0 Data Summary

301.1 Brief Description of Studies

a. Acute Oral Toxicity in Rats. Report by M. B. Research Laboratories, Inc. submitted to Lehn & Fink Products Co., Montvale, NJ 07645, dated July 31, 1980. (Accession No. 243447).

b. Acute Dermal Toxicity Study in Rabbits. Report by ...(same as above).

c. Eye Irritation Study in Rabbits. Report by ...(same as above).

d. Dermal Irritation Study in Rabbits. Report by ...(same as above).

301.2 Study Summaries

a. Acute Oral

1. Method

Ten Wistar rats, 5 male and 5 female, were fed 5 g/kg of the test material orally by syringe and dosing needle. The animals were observed at 1,2, and 4 hours after dosing and twice daily thereafter for 14 days. Untoward signs and mortality were recorded. At the end of 14 days the survivors were sacrificed and all animals were examined for gross pathology. Body weights were recorded on days 0, 7, and 14.

2. Results

No signs of toxicity, mortality or gross pathology were observed.

3. Conclusion

The oral LD_{50} of the chemical is greater than 5.0 g/kg.

b. Acute Dermal

1. Method

The trunks of 5 young adult New Zealand white rabbits were clipped free of hair. The exposed area was further prepared by abrading the area. A dose of 2.0 ml/kg was applied to the back of each rabbit. The test material remained on the backs for 24 hours after which, the exposed area was wiped free of any residual material. The rabbits were observed for 14 days and then necropsied.

2. Results

Grade 2 erythema was found on day 1 which intensified to grade 4 by day 7 and persisted at that degree through day 14. On day 7, 8/10 rabbits showed moderate to severe eschar formation. Edema scores ranged from 2-4 on day 1, decreased to 1-3 on day 7, and 1 on day 14. No mortality or gross pathology was observed.

3. Conclusion

The dermal LD_{50} of the product is greater than 2 g/kg.

c. Eye Irritation

1. Method

Nine New Zealand white rabbits were selected for use in this study after their eyes had been examined for defects with fluorescein dye and a cobalt blue light. One-tenth of an ml of the test material was placed into the conjunctival sac of one eye of each rabbit. The lids were held together briefly. Six of the eyes were not rinsed. Three were rinsed for 1 minute, 20-30 seconds after instillation using lukewarm tap water. Reactions were graded at 1,2,3,4,7,10,14, and 21 days after instillation. Fluorescein stain was also used to observe damage.

2. Results

In the unwashed group, corneal opacity persisted through the 4 day reading in 5/6 and through the 7 day reading in 1/6. The scores ranged from 1-4. Iritis, grade 1, was observed in all rabbits. The persistence was identical to that of the opacity. Mild to moderate conjunctival irritation was noted but cleared within 10 days. Irritation in the washed group was generally identical to that found in the unwashed group. No effects of any kind were present in any animals on day 14.

3. Conclusion

The chemical causes moderate transient corneal opacity and iritis which clears in 14 days.

d. Skin Irritation

1. Method

Six rabbits were clipped free of dorsal fur. Four test areas were selected on each animal and 2 of those areas were abraded. One-half ml of the test material was placed on each site. The areas were covered with gauze patches and occluded for 24 hours. Reaction were evaluated and recorded on days 1,3,7,14, and 21.

2. Results

At 24 hours the erythema scores ranged from 1-2, with an average slightly greater than 1.5. For the same period, the edema scores range was 1-3 with an average of slightly more than 2.0. Scores for erythema reached their peak at the 7 day reading when they averaged 3.5. Edema scores peaked at 3 days averaging 3.0. At 21 days all sites had returned to normal condition in appearance.

3. Conclusion

The chemical causes moderate transient irritation when applied to the skin of rabbits.

302.0 Recommendation

302.1 Safety Supported by Data

Based on the data submitted the product should be placed in the following toxicity categories:

Acute Oral	- 4
Acute Dermal	- 3
Eye Irritation	- 2
Skin Irritation	- 3

302.2 Safety Not Supported by Data

None

302.3 Additional Data Required

None

302.4 Other Considerations

A dermal corrosion study was also submitted. Since this study is required by D.O.T. and not E.P.A., the study was not reviewed.

303.0 Labeling

Revise the precautionary labeling to read according to S-76 B.