331A

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

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Reviewed by James E. Wilson, Jr. Date 8/25/81

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

Data Accession No(s). 244350

Product Mgr. No. 31 (Lee)

Product Name(s) Bardac 2250

Company Name(s) Lonza, Inc.

Submission Purpose Submission with data

Chemical & Formulation Liquid concentrate

Active Ingredient(s):	%
Didecyl dimethyl ammonium chloride	50.0
Ethanol	10.0

300.0 Introduction

300.1 Uses

Product is used in wood preservatives to prevent fungal rot in wood used above ground.

300.2 Background Information

None

301.0 Data Summary

301.1 Description of Studies

a. Acute Oral LD_{50} in Rats. Report by Consumer Product Testing Co., Inc., submitted to Lonza, Inc., Fair Lawn, NJ 07410, dated November 13, 1980. (Accession No. 244350)

b. Acute Dermal LD_{50} in Rabbits. Report by Consumer Product Testing Co., Inc., submitted to Lonza, Inc., Fair Lawn, NJ 07410, dated June 13, 1980. (Accession No. 244350)

c. Primary Dermal Irritation in Rabbits. Report by Consumer Product Testing Co., Inc., submitted to Lonza, Inc., Fair Lawn, NJ 07410, dated June 13, 1980. (Accession No. 244350)

d. Primary Ocular Irritation in Rabbits. Report by Consumer Product Testing Co., Inc., submitted to Lonza, Inc., Fair Lawn, NJ 07410, dated June 13, 1980. (Accession No. 244350)

301.2 Study Summaries

a. Acute Oral LD_{50}

1. Method

Five groups of Wistar albino rats, consisting of 5 males and 5 females per group, were fed doses ranging from 0.13 to 1.00 g/kg of the test material. Observations were made at 1, 3, 6, and 24 hours post-dosage and once daily thereafter for a total of 14 days. Body weights were recorded on days 1, 7, and 14. All animals were subjected to gross necropsy and findings recorded. The test material was prepared as a 10% gravimetric aqueous suspension.

2. Results

The mortality associated with each dose is presented in the following chart:

Dose (g/kg)	No. Dead/No. Dosed (M/F)
0.13	0/5:3/5
0.50	3/5:2/5
0.63	3/5:2/5
0.79	2/5:4/5
1.00	5/5:3/5

2. Conclusion

The calculated LD_{50} of the chemical is 0.450 (0.285-0.711) g/kg in rats.

b. Acute Dermal LD_{50}

1. Method

Thirty-six New Zealand white rabbits were prepared by clipping the dorsal hair. One-half of the animals were further prepared by abrading the exposed area. Six males and 6 females were used in all groups. The dose levels used were 2.00, 5.00, and 8.00 g/kg. The test substance was administered to the site in one application, after which the site was occluded for 24 hours. After 24 hours the residual material, if any, was wiped from the skin. Animals were observed for toxic signs at 1, 3, 6, and 24 hours post-dosage and once daily thereafter for a total of 14 days. Body weights were recorded on days 1, 7, and 14. All sacrificed animals as well as non-survivors were subjected to gross necropsy after the 14-day observation period.

2. Results

The mortality is listed in the chart below:

Dose Level (g/kg)	No. Dead/No. Dosed (M/F)
2.00	1/6:2/6
5.00	2/6:2/6
8.00	5/6:5/6

Dermal irritation was severe.

3. Conclusion

The dermal LD_{50} of the chemical is 4.30 (3.21-5.76) g/kg based on the data submitted.

c. Primary Dermal Irritation

1. Method

Six New Zealand white rabbits received a single dermal application of 0.5 ml of the test material on four sites, two abraded and two intact. After application, the areas were covered with a gauze patch and occluded for 24 hours. The residual chemical was wiped from the skin after 24 hours. Reactions were examined and recorded 24 and 72 hours and 7 days after treatment.

2. Results

After 24 hours, scores for edema and erythema were grade 2 and 3 respectively, with blanching at all sites. The scores at 72 hours for edema and erythema were 4 with blanching and crust formation.

3. Conclusion

The chemical is a severe skin irritant which causes damage to both intact and abraded skin. The irritation index is 6.5

d. Eye Irritation

1. Method

The eyes of nine New Zealand white rabbits were examined before the test using fluorescein stain. One-tenth gram of the undiluted liquid was instilled into the conjunctival sac of one eye of each rabbit. The lids were gently held together for 1 second and then released. The eyes of three rabbits were washed with lukewarm water 20 to 30 seconds after instillation. Six eyes remained unwashed. All eyes were examined 1, 2, 3, 4, and 7 days after treatment.

2. Results

Corneal opacity was present from day 1 through the final reading on day 7. The grade was 4. Iritis, grade 2, was observed after 24 hours and persisted in all rabbits through day 7. Irritation to the conjunctivae was severe. All scores were maximum throughout the observation period.

3. Conclusion

The chemical is an extremely severe irritant when applied to rabbit eyes. The opacity produced is not reversible in 7 days.

302.0 Recommendations

302.1 Safety Supported by Data

Based on the data received, the toxicity categories are:

Acute Oral	2
Acute Dermal	3
Skin Irritation	1
Eye Irritation	1

302.2 Safety Not Supported by Data

None

302.3 Other Considerations

We note that identical data was submitted for two formulations. Which product does the data represent?

302.4 Additional Data Required
None

303.0 Labeling

Expand the statement to read "Harmful or fatal if swallowed."

The statement "Protect eyes and skin when handling" should be revised to read "Wear goggles or face shield and rubber gloves when handling."

304.0 CRP Status

This is a product is intended for industrial, institutional and agricultural uses and not subject to special packaging requirements.