TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 5/25/83 OUT 7/1/83

WEL 6-30-83

Reviewed by James E. Wilson, Jr. Date 6/27/83

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

Data Accession No(s). 250353

Product Mgr. No. 31 (Lee)

Product Name(s) 5772

Company Name(s) Dow Corning Corporation

Submission Purpose New Application

Chemical & Formulation Liquid Concentrate

Active Ingredient(s):	%
3-(Trimethoxysilyl)propyidimethyloctadecyl ammonium chloride	72.0

300.0 Introduction

This product is used to impart a bacteriostatic and fungistatic coating to a variety of surfaces.

301.0 Data Summary

301.1 Brief Description of Studies

a. Acute Oral Toxicity in Rats. Report by Dow Corning, Health & Environmental Sciences, Toxicology Dept., dated March 23, 1983. (Accession No. 250353)

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

c. Primary Dermal Irritation in Rabbits. Report by...(Same as above)...Dated March 15, 1983.

d. Primary Eye Irritation in Rabbits. Report by...(Same as above)... April 7, 1983.

301.2 Study Summaries

a. Acute Oral

1. Method

Five gm per kg body weight of the test material was administered orally to 5 male and 5 female rats. The rats were observed for 14 days for mortality and signs of toxicity. At the end of the observation period all survivors were given a gross necropsy examination. Body weights were recorded on days 7 and 14.

2. Results

No mortality or signs of toxicity were reported. Body weight gains were in the normal range. Gross necropsy examinations were unremarkable.

3. Conclusion

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

b. Acute Dermal

1. Method

Five male and 5 female rabbits were clipped free of dorsal fur. The exposed area was abraded prior to the application of a single dose of the test material equal to 2.0 g/kg. The area was covered for 24 hours after which the coverings were removed and the residual material was wiped fromm the skin. All animals were observed for 14 days and body weights were taken on days 7 and 14. Gross necropsy examinations were performed on all animals.

2. Results

No deaths or signs were reported. Gross pathology findings were unremarkable.

3. Conclusion

The acute dermal LD_{50} of the chemical is greater than 2.0 g/kg.

c. Dermal Irritation

1. Method

Six albino rabbits received a single dermal application of 0.5 ml of the test material on one intact site. After application the areas were covered with a gauze patch and occluded for 4 hours. After the exposure period the residual material, if any, was removed by washing. Reactions were examined and recorded after 1, 24, 48 and 72 hours.

2. Results

Mean scores were 2.8 and 2.5 for erythema and edema, respectively, after 24 hours. By the 72-hour reading erythema scores averaged 3.0 and edema average scores dropped to 1.3.

3. Conclusion

The product is a moderate skin irritant.

d. Eye Irritation

1. Method

Six rabbits were used in the study. Fluorescein stain was used for screening and during the test to show corneal injury. One tenth ml of the test material was placed in each eye. Three of the eyes were rinsed 4 seconds after installation and 2 were rinsed after 30 seconds; both groups were washed for 5 minutes. All eyes were examined 1, 24, 58 and 72 hours and 7, 14 and 21 days after installation. The stain was used at all times other than the one hour reading.

2. Results

Iritis, corneal opacity and conjunctival irritation were present in all eyes beginning with the 1-hour reading. Iritis cleared in the 4 second wash group by 21 days. Moderate to severe opacity persisted through the 21-day period. Necroses and/or ulceration were present in all eyes after 21 days.

3. Conclusion

The product is corrosive to the rabbit eye.

302.0 Recommendations

The data are adequate to place the product in the following toxicity categories:

Acute Oral	- 4
Acute Dermal	- 3
Skin Irritation	- 3
Eye Irritaton	- 1

We prefer that the scores for dermal and eye irritation be assigned to individual animals and not grouped as they were in this data package.

All eye studies should include need one group of six eyes which are not rinsed. There is little need to repeat this study since we are certain that the product will cause corneal opacity lasting for more than 21 days. The word "corrosive" will be required.

303.0 Labeling

a. Add the word "Corrosive" and the statement "Causes severe eye damage and skin irritation."

b. The following statements must be added to the label: "Methanol may cause blindness," and "Vapor harmful."

c. Delete the word "prolonged" from the statement "Avoid prolonged breathing of vapor."

The following comments apply to the bulletin:

a. Under Handling, delete 1) the phrase "in amounts incidental to industrial handling," and 2) the word "undiluted" from the statement "Direct contact of the undiluted...."

b. The references to skin irritation should be revised. Data show that a single exposure to intact skin produces moderate irritation. Statements in the bulletin should reflect that finding.

c. The words "repeated" and "prolonged" should be deleted. The label statement reads "Do not get in eyes, on skin or on clothing." Moreover, instructions are given as to the appropriate action if the product contacts the skin. Therefore, these words are unnecessary and confusing.

304.0 CRP Status

Due to the use pattern the product is not subject to special packaging.

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