TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 7/15/81 OUT 10/9/81

Reviewed by James E. Wilson, Jr. Date 10/6/81

EPA Reg. No. or File Symbol 1677-ON (90)

EPA Petition or EUP No.

Date Division Received 6/15/81

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

Data Accession No(s). 245447

Product Mgr. No. 32 (Castillo)

Product Name(s) Cut Bac

Company Name(s) Economics Laboratory, Inc.

Submission Purpose New Product with Data

Chemical & Formulation

Active Ingredient(s):	%
Phosphoric Acid	22.5
Citric Acid	19.5
Alkanoic (C_8 59%, C_{10} 41%) Acid	6.8

300.0 Introduction

300.1 Uses

The product is used to sanitize dairy and food processing equipment.

301.0 Data Summary

301.1 Brief Description of Studies

a. Acute Oral Toxicity in Rats. Report by Raltech Scientific Services, Inc., submitted to Economics Laboratory, Inc., St. Paul, MN 55102, dated April 20, 1981. (Accession No. 245477)

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

c. Primary Dermal Irritation. Report by ... (same as above)....

d. Primary Eye Irritation in Rabbits. Report ... (same as above).....

301.2 Study Summaries

a. Acute Oral

1. Method

A group of 10 Sprague-Dawley albino rats, 5 male and 5 female, were given 5.00 g/kg of the test material via intubation. Additional dose levels of 1.64, 2.05, 2.56 and 3.20 were tested in females and levels of 1.05, 1.64, 2.05 and 3.20 were tested in males. Each of these groups contained 8 rats of each sex per level. Animals were observed for signs at 1, 2, and 4 hours after treatment and daily thereafter for 14 days. Body weights were taken on days 0, 7, and 14. All animals which died during the study or were sacrificed on day 14 were subject to a gross necropsy examination.

2. Results

The mortality is presented in the table below:

	Number Dead/No. Dosed	
Dose (g/kg)	M	F
1.05	0/8	---
1.64	2/8	0/8
2.05	2/8	2/8
2.56	---	4/8
3.20	6/8	7/8
5.00	5/5	5/5

Decreased activity, lacrimation, ataxia and muscle weakness were reported. Necropsy findings were unremarkable.

3. Conclusion

The oral LD_{50} of the product is 2.55 (2.08-3.40)g/kg in male rats and 2.55 (2.24-2.95) g/kg in female rats.

b. Acute Dermal

1. Method

Ten New Zealand albino rabbits, 5 male and 5 female, were clipped free of dorsal fur. Each rabbit had the exposed skin abraded. The test material was applied under an impervious band at a dose of 2.0 g/kg. After 24 hours, the band was removed and the residue wiped from the skin. Body weights were recorded on days 0, 7, and 14. Observations were made daily for toxic signs, dermal reactions and mortality. All animals were subjected to gross necropsy.

2. Results

No deaths or untoward signs were recorded. Edema and erythema were moderate with subcutaneous hemorrhages, blanching and necrotic areas.

3. Conclusion

The dermal LD_{50} is greater than 2.0 g/kg.

c. Dermal Irritation

1. Method

Six New Zealand albino rabbits, 3 males and 3 females, were clipped free of dorsal fur. Four test sites were selected on each animal. One-half (2) of the sites were abraded and two left intact. A single application of 0.5 ml of the test material was placed on each site. The area was covered with gauze pad and an impervious material for 24 hours. After 24 hours the coverings and gauzes were removed and the area was wiped free of any remaining material. Each site was scored 24 and 72 hours and 4 and 7 days after the initial application.

2. Results

In the first 24 hours, blanching and areas of subcutaneous hemorrhages noted in all of the rabbits. Erythema and edema scores were in the moderate range at the 24 and 72 hour readings. Subcutaneous hemorrages were found in five animals after 72 hours, four at 96 hours, and three at 7 days. The irritation index was 5.9.

3. Conclusion

The chemical is corrosive to the skin of rabbits.

d. Eye Irritation

1. Method

The right eyes of nine New Zealand albino rabbits were screened for defects using a 0.2% sodium flourescein solution and an ultraviolet lamp. The nine rabbits were divided into two groups, one with six rabbits whose eyes were rinsed with warm water 30 seconds after instillation. Each rabbit had 0.1 ml of the test material instilled into the right eye. Readings were made 1, 2, 3, 4 and 7 days after treatment. The ultraviolet light and stain were used on days 3 and 7 to reveal possible corneal injury.

2. Results

Vocalization was heard from one rabbit immediately after instillation. Opacity, iritis and conjunctival irritation were moderate after 24 hours. Conjunctival irritation grade 2-4 persisted in all eyes through the 48-hour reading. A red or purulent discharge was noted in all eyes after 48 hours. No readings were made after 48 hours.

2. Conclusion

The product is corrosive to the eyes of rabbits.

302.0 Recommendations

302.1 Toxicity Supported by Data

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

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

302.2 Toxicity Not Supported by Data

None

302.3 Other Considerations

None

303.0 Labeling

Add the following statements to the precautionary labeling: "Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

The preferred heading is "Statement of Practical Treatment" rather than "First Aid."

304.0 CRP Status

The label states "For Industrial or Commercial Use Only," therefore the product is not subject to CRP. However, it is subject based on toxicity.

Page_____ is not included in this copy.

Pages 6 through 7 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

✓ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.