7-25-85

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 07/05/85 OUT 07/17/85

Reviewed by James E. Wilson, Jr. Date 07/15/85

EPA Reg. No. or File Symbol 51267-R

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Date Division Received 07/05/85

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

Data Accession No(s) 258529

Product Mgr. No. 31 (LEE)

Product Name(s) Bio-Clean

Company Name (s) Bioserve, Inc.

Submission Purpose Resubmission

Chemical & Formulation Liquid

Active Ingredient (s):	%
n-Alkyl dimethyl ethylbenzyl ammonium chlorides	0.5
n-Akyl dimethyl benzyl ammonium chlorides	0.5
Bis(tributyltin)oxide	0.1

BACKGROUND

A review dated April 15, 1984, discussed the data received to determine the acute oral and inhalation and skin irritation hazards associated with this product. Those data were found to be deficient in certain respects.

RECOMMENDATIONS

Based on the data contained in the two submissions, the product should be placed in the following toxicity categories:

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

LABELING

The First Aid section should be deleted along with the If Swallowed section under the Statement of Practical Treatment. Also add "If on Skin: Wash with plenty of soap and water. Get medical attention if irritation persists." Change the word "Warning" on the side panel to "Caution." Delete the sentence "Distasteful if swallowed." Revise the statement "Causes mild eye irritation" to read "Causes eye and skin irritation."

CRP STATUS

Product does not require special packaging.

DATA REVIEW

Reports by Leberco Laboratories, submitted to Bioserv, Inc., Boca Ration, FL 33432. (Accession No. 258529)

Acute Oral

Discussion - The original review concluded that the acute oral LD_{50} was greater than 5.0 g/kg since one animal died at that dose. The rat that died was a female; one female lost weight and all others gained weight doing the observation period. Slight hemorrhages were noted in the lungs of one female and 4 males; no other gross pathology was reported.

Acute Dermal

Report dated June 21, 1984.

Method - 40 CFR 158-135, part 81-2, abraded skin.

Results - Erythema was mild to moderate which cleared on day 14. All rabbits loss weight except two males. No deaths or gross necropsy lesions were reported.

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

Acute Inhalation

To complete the information contained in the first study the following data were submitted; chamber temperature 21'C, humidity 55%, particle size 0.1 to 7 microns, delivered with a glass nebulizer and the acutal chamber concentration was not measured.

Skin Irritation

The individual scores were submitted with the most recent correspondence. There was almost no difference in the degree of irritation seen on intact sites when compared with abraded sites.

Eye Irritation

Report dated May 30, 1984.

Method - The eyes of six New Zealand white rabbits were examined before the test. One-tenth ml of the test material was instilled into the conjunctival sac of one eye of each rabbit. Three of the eyes were rinsed. All eyes were examined on days 1, 2, 3, 4 7 after instillation.

Results - No corneal opacity or iritis was observed. Conjunctival irritation was mild after 24 hours and cleared in three days in non-rinsed eyes and in two days in rinsed eyes.

Conclusion - The product is a mild irritant to ocular tissue.