4-26-84

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 03/15/84 OUT 04/26/84

Reviewed by James E. Wilson, Jr. Date 04/25/84

EPA Reg. No. or File Symbol 51267-R

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

Data Accession No(s) ~~252561~~ 252651

Product Mgr. No. PM 31 (LEE)

Product Name Bio-Clean

Company Name Bioserv,Inc.

Submission Purpose New Application

Chemical & Formulation

Active Ingredient(s)	%
Tri-n-butyl tin oxide esters	0.10
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12} $C_{11}8$) dimethyl benzyl ammonium chlorides	0.50
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides	0.50
[redacted]	

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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BACKGROUND

Bioserv, Inc. is submitting actue oral, acute inhalation and skin irritation studies to partially satisfy the data base for the subject product which is a surface deodorizer-disinfectant for use food processing plants and institutions.

RECOMMENDATIONS

All of the studies were deficient in some respect. The most serious discrepancies were found in the inhalation study. Actual chamber concentrations, humidity and temperature in addition to body weights and signs of toxicity were not reported. The study should be repeated if the registrant desires an acceptable study to be placed on file for this product. Based on the intended use pattern an inhalation study does not appear to be required.

The acute oral study did not include body weights, signs of toxicity or gross nersopsy findings. Individual irritation scores were not reported in the primary skin iritation study.

It is recommended that the above items be resolved prior to accepting the acute oral and primary skin irritation studies. It should also be noted that acute dermal nor eye irritation data were submitted.

All comments with regard to labeling should be withheld until the data base is complete.

DATA REVIEW

Acute Oral

Report by Leberco Laboratories, submitted to Bioserv, Inc. Boca Ration, FL 33432, dated April 21, 1983. (Accession No. 252651)

Method - Five male and five female rats were dosed with the test material at 5 ml/kg body weight. The animals were observed for 14 days following dosing and gross necropsy examinations were performed on internal organs. Body weights were recorded at the beginning and at the end of the study.

Results - One animal died during the observation period. No signs of toxicity actual body weights or gross necropsy finding were reported.

Conclusion - The actue oral LD_{50} is greater than 5.0 ml/kg.

Acute Inhalation

Report by Leberco Laboratories, submitted to Bioserv,Inc. Boca, Ration, Fl 33432, dated April 20, 1983 (Accession No.252651).

Method - Five male and five female rats were placed in a chamber with a volume of approximately 200 liters. A total weight of 15.6 g of the test material was aerosolized into the chamber over a 4 hour period with an air flow of 10 liters per minute which resulted in a concentration of 6.5 mg per liter. Animals were observed for 14 days.

Results - No signs of toxicity, mortality or gross pathology were noted.

Conclusion - No conclusions can be drawn from this study. The method did not follow guideline procedures. The body weight, chamber humidity, and temperature, actual concentrations and signs of toxicity were not reported.

Skin Irritation

Report by Leberco Laboratories, submitted to Bioserv, Inc. Boca Ration, Fl. 33432, dated April 12, 1983. (Accession No. 252651)

Method - Two areas, one intact and one abraded, were identified on six rabbits. One-half ml of the test material was placed on each site for 24 hours. Irritation was evaluated 24 and 72 hours after application.

Results - The average scores were 2 for erythema after 24 hours; for edema the average scores were 1 for both readings.

Conclusion - The product is a moderate skin irritation.