4-10-86

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 02/28/86 OUT 04/10/86

Reviewed by James E. Wilson, Jr. Date 04/09/86

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

Data Accession No(s) 261413, 14, 15

Product Mgr. No. 32 (Kempter)

Product Name(s) Tek-Trol Disinfectant Cleaner Concentrate

Company Name (s) Bio-Tek Industries, Inc.

Submission Purpose New Application

Chemical & Formulation Liquid

Active Ingredient(s):	%
o-Phenylphenol	12.0
o-Benzyl-p-chlorophenol	10.0
p-tert-Amylphenol	4.0

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BACKGROUND

This product will be used as an disinfectant cleaner, sanitizer and deodorizer.

RECOMMENDATIONS

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

Acute Oral	- 3
Acute Dermal	- 3*
Acute Inhalation	- 4 (1:256 dilution)
Skin Irritation	- 1*
Eye Irritation	- 1*

*Based on the product pH of 12.1. The use dilution (1:256) did not irritate the skin.

LABELING

No changes required.

CRP STATUS

Product does not require special packaging.

DATA REVIEW

Reports by American Biogenics Corporation, submitted to Bio-Tek Industries, Inc., Atlanta, GA 30318.

Acute Oral

Report dated October 9, 1985. (Accession No. 261413).

Method - Five male and five female rats per group were fed doses of 1.995, 2.512, 3.162, 3.981 and 5.00 g/kg of the test material via gastric gavage. The animals were observed for signs of toxicity and mortality for 14 days. Body weights were taken on the day of dosing and weekly thereafter. All animals were subjected to gross necropsy examination at time of death or after sacrifice.

Results - No deaths occurred at 1.995 and 2.512 g/kg; one male and two females died at 3.162 and 3.981 g/kg and all died at 5.00 g/kg. Salivation, lacrimation, lethargy, ataxia, irregular slow breathing, loose stools and staining were the signs observed. Distention and signs of irritation were noted in the stomachs and intestines of all animals.

Conclusion - The acute oral LD_{50}s were calculated to be 3.720(2.878-4.807) g/kg and 3.610 (2.868-4.536) g/kg for male and female rats respectively and 3.178(3.118-4.433)g/kg for combined sexes.

Acute Inhalation

Report dated October 4, 1985. (Accession No. 261414)

Method - Five male and five female rats were placed in a 500 liter chamber to test the effects of the aerosolized test material diluted 1:256 with water. Actual concentrations were measured during the 4-hour exposure period. Particle size distribution was determined Airflow, temperature and humidity of the chamber were continuously monitored. The animals were observed during the exposure period for 14 days after exposure. All animals were weighed on the day of dosing and weekly thereafter.

Results - The average gravimetric concentration of the chamber was 3.79 mg/l and the nominal concentration was 35.72 mg/l. The mass median diameter of particles was 2.48u. No deaths occurred. The signs of toxicity reported were irregular respiration, tremors and damp fur. Body weight gains were normal in males and decreased in females during the first week. Gross necropsy findings were unremarkabale.

Conclusion - The acute inhalation LC_{50} of the product is greater than 3.79 mg/l (maximum attainable concentration) during a 4-hour exposure.

Skin Irritation

Report dated October 23, 1985. (Accession No. 261415).

Method - Six white rabbits received a single dermal application of 0.5 ml of a 1:256 dilution of the test material on one intact site on each animal. After application the area was covered with a gauze patch and occluded for 4 hours. The residual chemical was wiped from the skin. Reactions were examined and recorded 4.5, 24, 48 and 72 hours after treatment.

Results - No other irritation was reported.

Conclusion - The product tested is not a skin irritant.