7-15-85

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 06/12/85 OUT 07/15/85

Reviewed by James E. Wilson, Jr. Date 07/12/85

EPA Reg. No. or File Symbol 8622-EL

EPA Petition or EUP No.

Date Division Received 05/30/85

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

Data Accession No(s) 258165

Product Mgr. No. 32 (Castillo)

Product Name(s) Halobrom, Inc,

Company Name (s) Ameribrom, Inc.

Submission Purpose New Application

Chemical & Formulation

Active Ingredient (s):	%
Bromo-chloro-5,5-dimethylhydantoin	96.0

BACKGROUND

This product will be use for reformulating purposes only.

RECOMMENDATIONS

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

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

*Because of the corrosion produced in the skin irritation study the acute dermal and eye irritation studies were not done.

LABELING

When a product is corrosive, usually dilution is a safer first aid treatment than emesis. A medical advisor should be consulted. A Note to Physician section should be included.

CRP STATUS

Product does not require special packaging.

DATA REVIEW

Reports by Dead Sea Bromine Company, Ltd., submitted to Ameribrom,Inc., New York, NY 10001 dated December 2, 1985. (Accession No. 258165)

Acute Oral

Method - After a preliminary study was done using 2 rats per sex to determine the range the main study was done using five male and five female rats per group at doses of 0.316,0.464, 0.680, 1.00 and 1.47 g/kg of the test material. 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 a gross necropsy examination at time of death or after sacrifice.

Results - The mortality chart appears below.

Dose (g/kg)	Mortality (M:F)
0.316	0/5:0/5
0.464	0/5:0/5
0.680	1/5:1/5
1.000	2/5:4/50
1.470	5/5:5/5

Hunched posture, salivation and decreased motor activity were the most freqently reported signs. Gross necropsy examinations revealed fluid in the stomach and hemorrhages and erosion of the stomach and intestine mucosa. Findings in survivors were unremarkable.

Conclusion - The acute oral LD_{50}s were calculated to be 1.037 (0.765-1.309) and 0.860(0.619-1.101) g/kg for male and female rats respectively and 0.929(0761-1.097) g/kg for combinded sexes.

Skin Irritation

Method - Six rabbits received dermal applications of 0.5 ml of the test material on one intact site. After application the area was covered with a gauze patch and occluded for 4 hours. Reactions were examined and recorded 24, 48 and 72 hours after treatment.

Results - Maximum scores for edema were reported at all observations; eschar was observed at all sites one hour after patch removal.

Conclusion - The product is a corrosive to the skin.