5-9-83

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 4/25/83 OUT 5/9/83

Reviewed by James E. Wilson, Jr. Date 5/4/83

EPA Reg. No. or File Symbol 5785-AE (62) and 5785-AG

EPA Petition or EUP No. _____

Date Division Received 3/18/83

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

Data Accession No(s). 250078, 79, 80, 81

Product Mgr. No. 32 (Castillo)

Product Name(s) Bromo-Tabs

Company Name(s) Great Lakes Chemical Corp.

Submission Purpose New Application

Chemical & Formulation Tablet

Active Ingredient(s):	%
1-Bromo-3-chloro-5,5-dimethylhydantoin	25.8

300.0 Introduction

The Great Lakes Chemical Corporation is submitting a skin irritation study on the subject product. In addition, acute oral, acute dermal and skin irritation studies were submitted on the technical product Dihalo (EPA Registration No. 1729-125) which contains 96% of the active ingredient.

Eye irritation data were not submitted. The registrant feels that if the skin irritation produced was severe, the eye irritation would also be severe (Category I) and will label the product accordingly.

A cursory review of the technical studies indicate that the acute oral LD_{50} is approximately 1.3 g/kg and the acute dermal LD_{50} is greater than 2.0 g/kg. Dermally, this formulation produced severe irritation and corrosion. These studies will not receive a complete review at this time.

301.0 Data Summary

301.1 Brief Description of Study

Primary Dermal Irritation in Rabbits. Report by Wil Research Laboratories, Inc., submitted to Great Lakes Chemical Corporation, West Lafayette, IN 47906, dated March 14, 1983 (Accession No. 250078).

301.2 Study Summary

a. Method

Six rabbits were clipped of dermal fur. Four sites were selected on each animal and two sites were abraded. One-half gram of the test material was moistened with physiological saline and placed on each site and covered for 24 hours. After the exposure period, the bandages were removed and any residual material remaining was wiped away with a moist towel. The degree of irritation was evaluated 24 and 72 hours, and 4, 7 and 14 days after exposure.

b. Results

Moderate to severe irritation was found after 24 hours with subcutaneous hemorrhages, blanching, eschar and necrotic areas. The same signs and degree of irritation were found after 72 hours. The dermal irritation score after 72 hours was 5.9. After 7 days most of the areas were denuded with most of the previously mentioned signs. The dermal irritation scores were 3.5 and 0.3 for 7 and 14 days respectively.

c. Conclusion

The chemical produces severe irritation and necrosis when applied to the skin of rabbits.

302.0 Recommendations

Based on extrapolations using the technical formulation data and the data in the use formulation, it is recommended that the product be placed in the following toxicity categories:

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

303.0 Labeling

Revise the statement "Causes irreversible eye damage..." to read "Causes irreversible eye damage and skin burns."

This product is a strong irritant. The registrant should be advised to consult his medical advisor for assurance that dilution and emesis is the desired way to treat a person who has ingested the product.

304.0 CRP Status

Based on toxicity, the product requires special packaging; however, it is intended for industrial use which exempts it from these requirements.