3-17-88

TECHNICAL SUPPORT SECTION TOXICITY REVIEW - I

Disinfectants Branch

IN 07/01/87 OUT 03/14/88

Reviewed by James E. Wilson, Jr. 3/17/88 Date 03/08/88

EPA Reg. No. or File Symbol 33753-T

EPA Petition or EUP No. None

Date Division Received 06/17/87

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

Data Accession No(s) 402371-03,04

Product Mgr. No. 31 (Lee)

Product Name(s) Myacide S-2

Company Name (s) The Boots Company PLC

Submission Purpose Resubmission-Tox Data

Chemical & Formulation Liquid

Active Ingredient (s):	%
2-Bromo-2-nitropropane-1,3-diol	40.8

BACKGROUND

The registrant is submitting the requested acute oral and dermal studies to support the safety of the subject product. The eye and skin irritation stuides were waived based on the data indicating a 2.0% formulation is mildly irritating to the eye while a 5.0% formulation is moderately irritating (Tox. cat. 2).

RECOMMENDATIONS

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

Acute Oral	- 2
Acute Dermal	- 3
Skin Irritation	- 1*
Eye Irritation	- 1*

* Based on extrapolation from previously submitted data.

LABELING

Delete 'milk' from the "If Swallowed" section of the statement of Practical Treatment Section.

CRP STATUS

Special packaging is not required based on area of intended use.

DATA REVIEW

Report by the Boots Company PLC, Research Department, Nottingham, England.

Acute Oral

Report dated May 22, 1987. (MRID No. 402371-03.

Method - The test material was fed to 6 groups of rats at 0.05, 0.1, 0.2, 0.4, 0.8 and 1.6 ml/kg; control group was also used. All groups contained 5 male and 5 female rats. Each rat received one oral dose via gastric gavage. Animals were observed for 6 hours on the day of dosing and twice daily thereafter for 14 days. Body weights were taken on days 0 through 7 and on day 14. Gross necropsy examinations were performed on all animals.

Results - Signs began appearing within 1/2 hour after dosing. The untoward reactions included stained coats, excitability, digit swelling and/or lesions, pilocrection, diluted pupils, noisy respiration and urine stains. Ataxia, hunched posture, inactivitly, lethargy and sedation were seen at doses of 0.2 ml/kg and above. All males died at 0.8 and 1.6 ml/kg, two males died at 0.2 and 0.4 ml/kg, one female died at doses of 0.4 and 0.8 ml/kg and all died at 1.6 ml/kg. Gross necrospy examinations of decedents revealed severe irritation of the g.i tract, changes in the g.i. tract, changes in the spleen and thymus congestion in the liver of males and dilated, debris-filled kidney tubules. Findings in survivors were generally unremarkable.

Conclusion - The acute oral LD_{50} of the product is greater than ~~0.8~~ 0.4 and less than 0.8 ml/kg.

Acute Dermal

Report dated April 8, 1987. (MRID No. 402371-04).

Method - Ten male and ten female rats were clipped of dorsal hair. One group received the test material and one received the blank formulation. Both materials were diluted to deliver 0.8 ml/kg for each 0.5 ml/100 kg body weight. After application each area was occluded for 24 hours. When the dressings were removed the areas were washed. Animals were observed for 14 days and gross necropsy examinations were made at time of death or after sacrifice.

Results - No deaths occurred. Staining was seen around the area of application. Some inactivity, lacrimation and salivation was observed. These signs disappeared in both groups in two days. Bald areas and sores were found at the application sites; lesions healed in the blank group by day 10 and persisted in the test group through the observation period. Body weight gains were in the normal range and gross necropsy findings were unremarkable.

Conclusion - The acute dermal LD_{50} is greater than 5.0 ml/kg in rats.