9-11-84

Date: September 11, 1984

005475

Subject: EPA File Symbol 516-TR
Cuprinol Stain and Wood Preservative

From: Deloris F. Graham
FHB/TSS E 9/12/84

To: Henry Jacoby
Product Manager (21)

Applicant: Darworth Company
P.O. Box K
Tower Lane
Avon, CT 06001

Active Ingredient:
Bis (tributyltin) oxide 0.30%
Chlorothalonil 0.70%
Inert Ingredient 99.00%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies. Studies conducted by Bioassay Corporation. Data under accession numbers 252618, 252617, 252616, 252615. Method of support not indicated.

Recommendations:

1. FHB/TSS finds the Eye Irritation and Primary Skin Irritation Studies acceptable to support conditional registration of this product.

2. However, the Acute Oral and Acute Dermal are not acceptable, because at least 5 animals per sex per dose must be used.

3. Acute Inhalation and Dermal Sensitization studies were not submitted and these studies or information to support waiver of said studies must be submitted.

Label:

1. Upon submissions of Acute Oral, Acute Dermal, Acute Inhalation and Dermal Sensitization Studies, appropriate precautionary labeling can be determined.

Review:

1. Acute Oral Toxicity Study: Bioassay Systems Corporation; Project Number 10656; May 7, 1981.

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Procedure: An Acute Oral range-finding study using 1 M and 1 F animal per dose was submitted. The doses used were 50, 156, 500, 1580 and 5000 mg/kg. Observations made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities reported, clinical signs or abnormalities at necropsy reported.

Study Classification: Core Supplementary Data. At least five animals per sex per dose must be used.

2. Acute Dermal Toxicity Study: Bioassay Systems Corporation; Project No. 10656; June 3, 1981.

Procedure: In this range-finding study, 1 M and 1 F per each of 5 dose levels were used. Dose levels used were 20, 63, 200, 630 and 2000 mg/kg. Treated areas were placed under occlusive wrap for 24 hour exposure. Observations made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities or abnormalities at necropsy reported. Erythema and edema noted days 1 through 5, but had cleared by day 6.

Study Classification: Core Supplementary Data. At least 5 animals per sex per dose must be used.

3. Skin Irritation Study: Bioassay Systems Corporation; Project No. 10656; June 1, 1981.

Procedure: Six rabbits recieved 0.5 ml of the test material at abraded and intact skin sites under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 slight erythema (scores of 1) and 1/6 edema (score of 1). Irritation had deased by 72 hours. Primary Irritation Score reported to be 0.416.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

4. Eye Irritation Study: Bioassay Systems Corporation; Project No. 10656; May 29, 1981.

Procedure: Nine rabbits recieved 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed for one minute with lukewarm water 20-30 seconds after treatment. Observations made 24, 48 and 72 hours, and 4 and 7 days after treatments. Observations made every 3 days thereafter if injury persisted, for at least 21 days.

Results: At 24 hours, 5/6 animals of the unwashed group and 1/3 of the washed group had hyperemia (5/6=1) (1/3=1) and chemosis (5/6=1) (1/3=2); 1/6 discharge (1/6-2). All irritation had cleared by 72 hours. No corneal opacity or iris irritation reported in any animal throughout the study.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

TBTO Scientific Reviews

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