Date: September 11, 1984

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

From: Deloris F. Graham
FHB/TSS

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 252616, 252617, 252616,
252618. 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 10556; May 7, 1981.
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.


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 received 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 ceased 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 received 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
The material not included contains the following type of information:

- Identity of product inert ingredients
- Identity of product impurities
- Description of the product manufacturing process
- Description of product quality control procedures
- Identity of the source of product ingredients
- Sales or other commercial/financial information
- A draft product label
- The product confidential statement of formula
- Information about a pending registration action
- FIFRA registration data
- The document is a duplicate of page(s) ________
- The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.