

8-15-80

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TAX 31
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DATE August 15, 1980

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SUBJECT: EPA File Symbol 518-AO
Cuprinol Stain and Wood Preservative

FROM: Sherrell A. Sterling *SAW*
FHB/TSS *8-24-80 F 9/5/80*

TO: Henry Jacoby
Product Manager (21)

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

Active Ingredients:

Bis(Tri-n-butyl-tin)oxide 0.5%
Tetrachloroisophthalonitrile..... 0.7%
Inert Ingredients.....98.8%

Background: An acute oral study was submitted for this product which is a combination of two already registered active ingredients. Information was also submitted by Dr. Steven D. Cohen of the University of Connecticut which states that the combination of these two actives would not have synergistic effects in his expert opinion. The method of support for this application for conditional registration is "cite-all."

The Acute Oral study was conducted by Bioassay Systems Corporation of Woburn, Massachusetts. An accession number has not been assigned to the data.

Comments: While Acute Dermal, Acute Inhalation, Eye and Skin Irritation studies were not conducted on this formulation, sufficient data were available to assess the hazard of this product. The Acute Oral toxicity was sufficiently close to the hazard from TBTO to

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show similarity. The letter submitted by an "expert" supported the idea that the toxicity of the combined chlorothalonil and TBTO formulation would be no worse than the toxicity of these active ingredient separately.

Recommendations:

1. The Acute Oral study is considered adequate to support conditional registration of this product; however, the test formulation must be identified in greater detail. A statement must be submitted which identifies "mixture of tri(n-butyltin)oxide and tetrachloroisophthalonitrile Darworth Company No. 9708-1" as the formulation. At least, please submit the percentages of the active ingredients.
2. At this time, additional data are not necessary since the hazard potential has been sufficiently defined. However, additional testing may be required in the future.
3. FHB/TSS has no objection to the conditional registration provided that a more detailed description of the test substance is submitted and the following labeling revisions are made.

Labeling Recommendations:

1. Based on eye hazard potential, the appropriate signal word is DANGER. The signal word must be changed to DANGER on both the front and side panels.
2. The preferred placement of the "Keep out of reach of children" statement is above the signal word.
3. The "Hazards to Humans and Domestic Animals" section must be revised to the following (or similar) statement:

"DANGER. Corrosive, causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. May be fatal if swallowed. Do not breathe vapors or spray mist. May be absorbed through skin."

The statement [REDACTED] may remain on the labeling, however, an appropriate place for this statement is in the proximity of the ingredient statement.

INFORMATION WHICH MAY REVEAL AN INERT INGREDIENT IS NOT INCLUDED

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4. The "First Aid" section must be changed to the following (or similar) statement:

If swallowed, immediately drink 1 or 2 glasses of milk. If milk is not available, drink 1 or 2 glasses of water. Then induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. Get medical attention.

If contact with eyes, flush with water for 15 minutes. Get medical attention.

If contact with skin, immediately remove any contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation persists. Wash clothing before reuse."

Please note that the heading for this section must be revised to "Statement of Practical Treatment."

5. The referral statement which appears on the front panel must be revised to "See back panel for additional precautionary statements."
6. The following statement must be added to the "Environmental Hazards" section:
- "Do not contaminate water by cleaning of equipment or disposal of wastes."
7. The general restrictions area under the "Directions for Use" must bear the statement:
- "This product must be applied out-of-doors to wood intended only for exterior use."

Review

1. Acute Oral LD50 Determination (FIFRA DESIGN) on Sample No. 9708-1; Bioassay Systems Corp. Project No. 10230; July 2, 1980

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Procedure: Groups of 10M (200.0-257.6g) and 10F (194.4-235.9g) Sprague-Dawley rats received oral dosages of 75 mg/kg, 150 mg/kg, 300 mg/kg, 600 mg/kg and 1200 mg/kg of "Darworth Co. No. 9708-1" by gavage. "Darworth Co. No. 9708-1" was identified as a mixture of TBTO and chlorothalonil. A dosage of 1200 mg/kg of sterile deionized water was administered to a group in similar fashion. Animals were observed for 14 days post-exposure. Necropsies were performed on all animals.

Results: Mortalities were: none at 75 mg/kg; 5M and 4F at 150 mg/kg; 6M and 7F at 300 mg/kg; 10M and 7F at 600 mg/kg; 10M and 10F at 1200 mg/kg of the test substance. Symptoms included: lacrimation, nasal and oral discharge, diarrhea, lethargy, weight loss and paralysis of hind limbs. Necropsy revealed gastrointestinal tracts filled with gas, fluid. The LD₅₀ for M was 198 mg/kg with a 95% confidence range of 143-275 mg/kg. For F, the LD₅₀ was 223 mg/kg with a 95% confidence range of 139-353 mg/kg.

Study Classification: Core ^{Minimum} ~~Guideline~~ Data. Formulation tested must be clearly identified.

Toxicity Category: II - WARNING.

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