

US EPA ARCHIVE DOCUMENT

Date: July 26, 1983

Subject: EPA File Symbol: 3095-GI
PIC Mildew Stop

From: Deloris F. Graham *DFG 8/2/83*
FHB/TSS *E 8/4/83*

005133

To: Henry Jacoby
Product Manager (21)

Applicant: PIC Corporation
23 South Essex Avenue
Orange, NJ 07050

Active Ingredient:
Biphenyl.....95%
Inert Ingredients.....5%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation, Primary Skin Irritation and Acute Inhalation data. Studies conducted by Younger Laboratories. Data not accessioned. Method of support not indicated.

Recommendation:

(1) FHB/TSS finds these Eye Irritation and the Primary Skin Irritation studies acceptable to support conditional registration of this product. However, for future submission, please note:

(a) In the Eye Irritation Study, 9 animals (6 with treated unwashed eyes and 3 with treated washed eyes) must be used. *Individual score for conjunctive redness, chemosis and discharge must be submitted.*

(2) FHB/TSS finds the Acute Oral, Acute Dermal and Acute Inhalation studies unacceptable to support conditional registration of this product.

(a) At least 5 animals per sex per dose must be used in each of the previously mentioned studies.

Label:

(1) Labeling comments reserved until acceptable Acute Oral, Dermal and Inhalation studies are submitted.

Review:

(1) Acute Oral Toxicity Study: Younger Laboratories; Project No. Y-76-263; August 4, 1976.

Procedure: Four groups, two groups consisting of two males and three females and two groups consisting of three males and two females, received one of the following doses: 2,000, 2,510, 3,160 and 3,980 mg/kg. Observed for 14 days. Necropsy performed on all animals.

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Results: At 2,000 mg/kg, 1/3 M died; at 2,510 mg/kg, 1/2 M and 2/3 F died; at 3,160 mg/kg, 1/3 M and 2/2 F died; at 3,980 mg/kg, 2/3 M and 3/3 F died. Toxic signs included increasing weakness, ocular discharge, collapse and death. Necropsy revealed hemorrhagic areas of the lungs, slight liver discoloration and gastrointestinal inflammation. LD₅₀ was 2,400 mg/kg with 95% confidence limits between 2,180 and 2,640 mg/kg.

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

(2) Acute Dermal Toxicity Study: Younger Laboratories Project No. Y-76-263; August 4, 1976.

Procedure: Two groups, one group consisting of one female and the other group consisting of one male and one female, received one of the following doses: 5,010 or 7,940 mg/kg. Observed for 14 days. Necropsy performed.

Results: At 7,940 mg/kg, 1/1 M died. Toxic signs included reduced appetite and activity, increasing weakness, collapse and death. Necropsy revealed lung and liver hyperemia, slightly enlarged gall bladder, and gastrointestinal inflammation. LD₅₀ greater than 5,010 mg/kg.

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

(3) Eye Irritation Study: Younger Laboratories; Project No. Y-76-263; August 4, 1976.

Procedure: Six New Zealand rabbits received 100 mg each of the test material. Observations made at 1, 24, 48, 72, 120 and 168 hours after treatment.

Results: At 24 hours, no corneal opacity or iris irritation present. Conjunctive irritation present in 6/6 animals (cumulative scores, 1/6 = 10, 5/6 = 12). Irritation had ceased by 72 hours.

Study Classification: Core Minimum Data. 9 animals (6 with treated unwashed eyes and 3 with treated washed eyes) must be used. Individual score for conjunctive redness, chemosis and discharge must be submitted.

Toxicity Category: III - CAUTION

(4) Primary Skin Irritation Study: Younger Laboratory; Project No. Y-76-263; August 6, 1980.

Procedure: Six New Zealand rabbits received 0.5 g of the test material at intact and abraded skin sites for 24-hour exposure period. Observations made at 4, 24, 48, 72 and 168 hours.

Results: At 24 hours, 6/6 had erythema (6/6 = 1) and no edema. At 72 hours, erythema had ceased. Irritation Score = 0.3. Slight defatting effect, skin flaked off.

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Study Classification: Core Guideline Data.

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Toxicity Category: IV - CAUTION

(5) Acute Inhalation Toxicity Study: Younger Laboratory; Project No. Y-76-263; August 4, 1976.

Procedure: Six Sprague-Dawley male rats were exposed for 6 hours to a 0.2 mg/l concentration. Observations made for 14 days. Necropsy performed. Chamber temperature 27°C and chamber humidity was 85%.

Results: No mortalities. No toxic signs. No abnormalities at necropsy.

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

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Biphenyl toxicology review

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