Date: July 26, 1983

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

From: Deloris F. Graham 8/2/83 005133
FHB/TSS
E 8/4/83

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, recieved 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.

174

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. LD_{50} 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, recieved 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. LD_{50} 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 (cummulative 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.

2

005133

Study Classification: Core Guideline Data.

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.

Biphenyl toxicology review

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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

X 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.
