4-1-83

005455

Date: April 1, 1983

Subject: EPA Registration Number: 3214-0
Mildewdisk

From: Delores J. Grohen
FHB/ISB E 4/1/83

To: Henry Jacoby
Product Manager (21)

Applicant: Vapor Products
P.O. Box 8395
Orlando, Florida 32856

Active Ingredients:
Biphenyl 95%
Inert Ingredients 5%

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

Recommendations:
(1) FHB/ISB finds the Acute Oral, Eye Irritation and Primary Skin Irritation Studies acceptable to support conditional registration of this product. However for future submissions please note;

(a) In the Acute Oral Study, 5 animals per sex per dose must be used;

(b) In the Eye Irritation Study, 9 animals (6 with treated unwashed eyes and 3 with

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treated waders eyes must be used.

(2) The Acute Dermal Toxicity is unacceptable to support conditional registration of this product. Only one animal was used for the 5,010 mg/kg dose and only two for the 7,940 mg/kg dose for this study. Five animals per sex per dose must be used.

(3) The Acute Inhalation Study is unacceptable also, since only male animals were used and actual concentrations not indicated. 5 animals per sex per dose must be used and LC50 and 95% confidence limits submitted based on actual concentrations.

Label:
(1) Labeling comments reserved until acceptable Dermal and Inhalation Studies are submitted.

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

Procedure: 4 groups consisting of 5 rats each received one of the following doses orally: 2,000; 2,510; 3,160 or 3,980 mg/kg. Each group consisted of male and female animals. Observations made for 14 days after treatment. Necropsy performed on all animals.

Results: At 2,000 mg/kg, 1/3 M + 0/2 F died; at 2,510 mg/kg, 1/2 M + 3/3 F died; at 3,160 mg/kg, 1/3 M + 2/2 F died; at 3,980 mg/kg, 2/2 M + 3/3 F died. Toxic signs observed included reduced appetite and activity, 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 (2,180 - 2,640 mg/kg, 95% confidence limits).

Study Classification: Core Minimum Data. 5 animals per sex per dose must be used.

Toxicity Category: III - CAUTION.

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

Procedure: 2 groups, one group consisted of 1F received 5,010 mg/kg dose and the other group consisted of 1M and 1F received a 7,940 mg/kg. Animals were exposed for 24-hours. Observation were made for 14 days after treatment. Necropsy performed on all animals.

Results: At 7,940 mg/kg, 1/1M 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 5 animals/per sex per dose must be used. Test sites must have abraded skin.

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

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

Results: No corneal opacity or iris irritation present. At 24 hours, 6/6 had conjunctive irritation with a cummulative score of 8. Irritation had cleared by 72 hours.

Study Classification: Core Minimum Data. 9 animals (6 with abraded unwashed eyes and 3 with abraded washed eyes must be used. Individual scoring of conjunctive irritation

(redness, chemosis and discharge) must be submitted

Toxicity Category: III - CAUTION

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

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

Results: At 24 hours, 4/6 had erythema (4/6=1), and no edema. At 72 hours erythema had cleared. Irritation Score was 0.3. Slight defatting effect - 2+ in flaked epp. There was no injury in depth reported.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

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

Procedure: 6 Sprague-Dawley male rats were exposed to a 0.2 mg/L concentration for 6 hours. Chamber temperature 21°C, and chamber humidity 85%. Observations made for 14 days after exposure. Necropsy performed on all animals.

Results: No toxic signs, no mortalities and no abnormalities at necropsy.

Study Classification: Core Supplementary Data. 5 animals per sex per dose must be used. LC50

and 95 % confidence limits must be submitted. Actual measured concentration, not nominal concentrations, must be used.

Biphenyl toxicology review

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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

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