DATE: April 27, 1981

SUBJECT: EPA Registration Number: 4581-308
Deccoscald-EC 282(DPA): Caswell#_____

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FROM: Deloris F. Graham DFG 4/29/81
FHB/TSS

TO: Robert Taylor
Product Manager (25)

Applicant: Pennwalt Corporation
Decco - Tiltbelt Division
1713 South California Avenue
Monrovia, California 91016

Active Ingredients:
Diphenylamine 25%
Inert Ingredients 75%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies. These studies were conducted by Applied Biological Sciences Laboratories, Inc. Data are under Accession Number 244761. Method of support not indicated.

Recommendation:

(1) FHB/TSS finds these studies acceptable to support a conditional registration of this product.

(2) An Acute Inhalation Study was not submitted and one must be submitted or justification as to why this study is not necessary for this product.

Label:

(1) The appropriate signal is CAUTION

(2) Precautionary statements similar to the following must appear on label:

"Harmful if swallowed. Avoid breathing spray mist. Avoid contact with skin, eyes and/or clothing."

"In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists."

(3) Under the heading "Environmental Hazards" the statement "Keep out of lakes, streams or ponds." must be revised to read "Do not apply directly to any body of water."

(4) Please see labeling procedures and formats enclosed for your convenience.

Review:

(1) Acute Oral Toxicity Study: Applied Biological Sciences Laboratories, Inc.; ABSI #17040; February 3, 1981.

Procedure: 5M and 5F Sprague-Dawley rats weighing between 200-300 grams received a 5g/kg dose orally. Observations were made for 14 days. Necropsies were performed on all animals.

Results: 2/10 animals died. Symptoms observed were lethargy, ruffled fur, diarrhea.

By day 7, animals appeared normal. Necropsy of the two animals that died during study revealed distended stomach, transparent, distended and hyperemic intestines and dark kidneys. Necropsy of the other animals at termination of study revealed dark, congested spleens and pelvic hyperemia in the kidneys. LD50 greater than 5g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity Study: Applied Biological Science Laboratories, Inc.; ABSI # 17040; February 20, 1981.

Procedure: 5M and 5F New Zealand white rabbits received a 2g/kg dose of the test material at abraded skin sites. The treated areas were placed under occlusive wrap for 24 hour exposure. Observations made for two weeks. Necropsies were performed on all animals.

Results: No mortalities. Slight lethargy observed. Slight erythema persisted for 4 or 5 days. By day 7 all animals exhibited flaking skin which persisted until the end of the two week osbervation period. Necropsy revealed-consolidated lungs; congested spleen; medulla hyperemia in the kidneys; slightly mottled lungs; white nodules in the liver, lungs filled with thick, white, pus-like material. LD50 greater than 2g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

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(3) Eye Irritation Study: Applied Biological Sciences Laboratories, Inc., ABSI #17040; February 20, 1981.

Procedure: Nine white rabbits received a 0.1 ml dose of the test material in one eye of each rabbit. Animals were divided into two groups. Group A consisted of 6 rabbits with treated unwashed eyes and Group B consisted of 3 rabbits with treated washed eyes. Observations made at 24, 48 and 72 hours and at 4 and 7 days.

Result: No corneal opacity or iris irritation. Slight conjunctive redness, chemosis and discharge at day 1, but irritation clear by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(4) Dermal Irritation Study: Applied Biological Sciences Laboratories, Inc.; ABSI# 17040; January 12, 1981.

Procedure: Six New Zealand white rabbits receive a 0.5 ml dose of the test material at 2 abraded and 2 intact sites per animal. The treated areas were placed under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours.

Results: No irritation present at 24 or 72 hours after treatment.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

Diphenylamine 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.
