BP-1141
TXR-5465

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Date: March 31, 1983

Subject: EPA File Symbol: 19713-RTA
Dretd Malerate 96% Technical

From: Deloid F. Graham
TH3/TSB E 4/1/83

To: Richard Mountfort
Product Manager (23)

Applicant: Dretel Chemical Company
P.O. Box 9306
Memphis, TN 38109

Active Ingredients:
S-Ethyl hexahydro-1H-azepine-1-carbothioate 96.0%
Inert Ingredients 4.0%

Background: Submitted Acute Oral, Eye Irritation and Skin Irritation. Studies conducted by Pharmatox Forschung Beratung GmbH. Data under accession numbers: 247457, 247458 and 247459. Cite-all method of support.

Recommendations:
(1) TH3/TSB finds these data acceptable to support conditional registration of this product. However for future submissions, in the Eye-Irritation Study, 9 animal (6 with treated unwashed eyes and 3 with treated washed eyes) must be used.

(2) An Acute Dermal Study was not submitted and one must be submitted and/or cited as a

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justification as to why this study is not necessary.

Label:

(1) Labeling comments reserved until an Acute Dermal Toxicity Study is submitted.

Reviewer:

(1) Acute Oral Toxicity Study: Pharmatex; Study # 1-4-175-79; December, 1976; EPA Accession # 247457.

Procedure: 5 groups consisting of 5M and 5F rats weighing between 120 to 140g recieved one of the following doses: 400, 504, 635, 800 and 1008 mg/kg Necropsy performed on all animals. Observations made for 14 days after treatment.

Results: at 400 mg/kg, 1/5F died; at 504 mg/kg, 1/5M 4/5F died; at 635 mg/kg, 4/5M + 3/5F died; at 800 mg/kg, 5/5M + 4/5F died; at 1008 mg/kg 5/5M + 5/5F died. Symptoms observed included apathy, reduced frequence of respiration and diminished readiness for righting reflexing. Necropsy revealed changes in the cranium respectively in the thorax cavity and hyperemia looking gastro-intestinal tract. LD50 was 549 mg/kg (482 to 626 mg/kg, confidence limits).

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Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(2) Eye Irritation Study: Pharmatox; Study # 1-3-258-80; August, 1980.

Procedure: Six New Zealand rabbits received 0.1g of the test material in one eye each. ——— Observations were made at 1, 2, 4 and 8 hours after treatment, then at 1 to 7 days.

Results: At 24 hours, 4/6 had conjunctival redness (4/6=2, 2/6=3), chemosis (3/6=1, 2/6=3, 1/6=4) and 5/6 discharge (2/6=1, 1/6=2, 2/6=3); no corneal opacity or iris irritation present. At day 4, 3/6 had conjunctival redness (3/6=1). All irritation had cleared by day 7.

Study Classification: Core Minimum Data. 9 animals (6 with treated unabraded eyes and 3 with treated abraded eyes) must be used.

Toxicity Category: III - CAUTION.

(3) Skin Irritation Study: Pharmatox; Study # 1-3-257-80; August, 1980.

Procedure: Eight New Zealand rabbits received 0.5g of the test at abraded and intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours after treatment.

Results: At 24 hours, 5/8 had erythema (5/8=1, no edema present. At 72 hours, irritation had cleared. Primary irritation index was 0.31.

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Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION