PC 35617
TXR-5470
3-28-83

005470

Date: March 28, 1983

Subject: EPA File Symbol: 48234-R
Regalstar

From: Delores F. Graham
THB/IBS

E 3/29/83

To: Richard Mountfort
Product Manager (23)

Applicant: Regal Chemical Company
P.O. Box 900
13960 Highway 9
Alpharetta, Georgia 30201

Active Ingredient:
Oxadiazon 2-tert-butyl-4-(2,4 dichloro-5-isopropoxyphenyl)-2-1,3,4-oxadiazolin-5-one 1.0%
Benefin N-Butyl-N-ethyl-2,6-dinitro-4-trifluoro-p-toludine 0.5%
Inert Ingredients 98.5%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies. Studies conducted by Basearch, Incorporated. Data under accession number 249519. Alternate method of support.

Recommendation:
(1) THB/IBS finds these data acceptable to support conditional registration of this product.

(2) An Acute Inhalation Study was not submitted and

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one must be submitted and/or cited.

(2) The appropriate signal word is DANGER.

Label:

(1) The precautionary statements must be worded similar to the following: "DANGER. Causes irreversible eye damage. Avoid contact with eyes skin and clothing. If in eyes, flush with plenty of water and get medical attention immediately. If ~~on skin or clothing~~ wash with plenty of soap and water and get medical attention if irritation persists."

(2) When precautionary statements appear on side panels, a referral statement on the front panel similar to the following must be used: "See side panel for additional precautionary statements."

Review:

(1) Acute Oral Toxicity Study; Bioresearch, Inc.; Project No. 82-3467A; February 1, 1983.

Procedure: 5M and 5F rats received 5g/kg of the test material orally. Observations were made frequently on days of dosing, then twice daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. No toxic signs. Necropsy revealed mottled kidneys in 1/5F, LD50 greater than 5g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Bioresearch, Incorporated Project No. 82-3467A; February 1, 1983.

Procedure: 5M and 5F New Zealand rabbits weighing between 2.0 and 3.0 Kg received 2g/Kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure period. Observations were made frequently on the day of dosing and twice daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. No toxic signs. Necropsy revealed slightly enlarged spleen in 1 SF. LD50 greater than 2g/Kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(3) Primary Skin Irritation Study: Biosearch, Incorporated; Project No. 82-3467A; February 1, 1983.

Procedure: Six New Zealand rabbits received 0.5g of the test material at two abraded and two intact skin sites per rabbit under occlusive wrap for 24 hour exposure. Observations made at 24 and 72 hours after exposure.

Results: No irritation noted. Primary Irritation Score was zero.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(4) Eye Irritation Study: Biosearch, Incorporated; Project No. 82-3467A, February 1, 1983.

Procedure: Nine rabbits received 0.1ml of the test material in one eye each. The treated

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eyes of three of the rabbits were washed for 30 seconds post treatment. Observations were made at 1 hour, 1, 2, 3, 4, 7, 14 and 21 days after treatment.

Results: At day 1, 4/6 animals of the washed group had corneal opacity (4/6=5); 4/6 had iris irritation (6/6=5), redness (4/6=3, 2/6=4), chemosis (2/3=3, 4/6=4) and discharge (4/6=3). At day 2, 4/6 animals had died. At day 4, 3/6 redness (2/6=1, 1/6=2); 4/6 chemosis (4/6=1). At day 7, 2/6 redness (2/6=1); 3/6 chemosis (3/6=1). At day 14, 3/6 redness (3/6=1) and 4/6 chemosis (4/6=1). At day 21, 2/6 redness (2/6=1) and 3/6 chemosis (3/6=1).

At day 1, 3/3 animals of the washed group had conjunctive redness (2/3=2, 1/3=3), chemosis (2/3=2, 1/3=3) and discharge (2/3=1, 1/3=2). At day 4, 2/3 redness (2/3=1, 1/3=2), chemosis (3/3=1) and 1/3 discharge (1/3=1). At day 7, 3/3 redness (2/3=1, 1/3=2), chemosis (3/3=1) and 1/3 discharge (1/3=1). At day 14, 3/3 redness (2/3=1) and chemosis (3/3=1). At day 21, 2/3 redness (2/3=1) and 3/3 chemosis (3/3=1).

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER.

PAGES 5 THROUGH 7 ARE NOT INCLUDED WITH THIS REVIEW. THOSE PAGES CONSISTED OF DRAFT LABELING.