KAB-1532
TXP-6344

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

OCT - 5

MEMORANDUM

SUBJECT: EPA File Symbol 19713-RTR
Drexel Simazat 4L

FROM: Deloris F. Graham DFG 10/14/87 E 10/14/87
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Drexel Chemical Company
2487 Pennsylvania Street
Memphis, TN 38109

ACTIVE INGREDIENTS:	
Atrazine	20.76%
Related Compounds	0.66%
Simazine	21.41%
INERT INGREDIENTS:	57.17%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Skin Irritation and Dermal Sensitization Studies to support conditional registration of this product. Studies conducted by Hill Top Research, Inc. and Bio/dynamics, Inc. Data under EPA MRID Nos. 402294-02 thru -07. Method of support not indicated.

RECOMMENDATIONS:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.

2. The appropriate signal word is CAUTION.

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LABEL:

1. In statement of practical treatment, the "syrup of ipecac" statement should be deleted.

2. The precautionary statement "Harmful if swallowed" is correct. The word "fatal" in the statement submitted should be deleted.

REVIEW:

(1) Acute Oral Toxicity Study: Hill Top Research; Study No. 87-0170-21(A); March 4, 1987; EPA MRID No. 402294-02.

PROCEDURE:

Four groups consisting of five male and five female rats each were dosed with one of the following dosages: 1.25, 2.5, 5.0 or 10.0 g/kg of the test material. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 2.5 g/kg, 3/5 M and 2/5 F died; at 5.0 g/kg 1/5 M and 4/5 F died; at 10.0 g/kg; 5/5 M and 5/5 F died. Toxic signs reported included reddish-brown colored stains around the muzzles, eye squinting, depression, scruffy hair coat, one animal appeared comatose, hunched posture, fecal stains, loose mucoid feces, dried urine stains, rats appeared thin, piloerection, comatose with muscle twitching, sensitive to touch, rapid respiration, yellow haircoat, alopecia on underside. Necropsy report revealed lungs reddened, liver and kidneys pale, kidneys congested, stomachs enlarged and filled with thick, white milky sample like material; reddened spleen, darkened spleen, small intestines yellowish-red in color; pancreas reddened, stomach distended with gas; darkened liver; spleen small in size. LD_{50} for males and females combined reported to be 3.6 g/kg with 95% confidence limits between 2.6 and 5.0 g/kg.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(2) Acute Dermal Toxicity Study: Hill Top Research; Study No. 87-0170-21(B); February 18, 1987; EPA MRID No. 402294-03.

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PROCEDURE:

Five male and five female rabbits with intact skin sites each received 2.0 g/kg of the test material under occlusive wrap for 24 hour exposure period. One animal (#6-566) was underdosed by 0.5 ml. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

One out of five female rabbits died. Clinical and dermal irritation signs reported included lacrimation, mild atonia, mild coriaceousness, moderate desquamation, mild to moderate edema, mild to extreme erythema, fecal stains, ataxic behavior and emaciation. Necropsy report revealed blood-like material apparent around the nose and mouth; abdominal region distended and greenish in color; lungs reddened with some dark areas; liver exhibited white spots; gall bladder appeared darkened; spleen appears black in color; stomach filled with light green mucoid material. LD_{50} reported to be greater than 2.0 g/kg.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(3) Acute Inhalation Toxicity Study: Bio/dynamics, Inc.; Project No. 87-7973; April 15, 1987; EPA MRID No. 402294-04

PROCEDURE:

Five male and five female rats were exposed for four hours. 0.97 mg/l average analytical exposure of Simazat (a 1:1 dilution of the test material in distilled water). Average mass median aerodynamic diameter reported to be 2.6 and geometric standard deviation 4.3. Chamber temperature and relative humidity reported to be 73 to 74°F and 100% respectively. Observations made for 14 days postexposure. Necropsy performed on all animals.

RESULTS:

No mortalities reported. Toxic signs reported included labored breathing, dried brown material on facial area, matted coat, yellow ano-genital staining, soft stool, dried white material on fur, red nasal discharge, matted coat, ano-genital staining, dried white material on fur.

STUDY CLASSIFICATION: Core Guideline Data

Toxicity Category: III - CAUTION

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(4) Eye Irritation Study: Hill Top Research, Inc.; Study No. 87-0170-21(D); January 30, 1987; EPA MRID No. 402294-05.

PROCEDURE

Six rabbits received 0.1 ml of the test material in one eye each. All eyes were washed with physiological saline 24 hours after treatment. Twenty-four hour reading was made prior to washing. Observations made for 72 hours posttreatment.

RESULTS:

At 24 hours, 2/6 rabbits had corneal opacity (2/6=5) and 1/6 erythema (1/6=1). Irritation and corneal opacity had cleared by 72 hours.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(5) Skin Irritation Study: Hill Top Research, Inc.; Study No. 87-0170-21(C); February 1, 1987; EPA MRID No. 402294-06.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 ml of the test material under occlusive wrap for four hour exposure period. Observations made for 72 nours posttreatment.

RESULTS:

At 24 hours posttreatment, 2/6 rabbits had slight erythema (2/6=1) and no edema. At 72 hours erythema had cleared. Primary Irritation Index reported to be 0.5.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: IV - CAUTION

(6) Dermal Sensitization Study: Hill Top Research, Inc.; Study No. 87-0170-21(E); March 5, 1987; EPA MRID No. 402294-07.

PROCEDURE:

During primary irritation phase two male and two female guinea pigs with four test sites each were treated with one of the following at one test site each: 10%, 25%, 50% and 100% w/v test material in distilled water. Based on the

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results of this study, the 50% w/v in distilled water was the concentration selected for induction phase and 10% w/v for challenge phase.

Using the Buhler Patch Test twenty guinea pigs (10 M, 10 F) received three (one per week) applications of the test material (50% w/v in distilled water) during induction phase. Each application exposed for six hours. Two weeks after last induction phase application, a challenge dose of the test material (10% w/v in distilled water) was applied to test group and a naive control group (5 M, 5 F guinea pigs). Observations made at 24 and 48 hours after each application.

RESULTS:

In the primary irritation phase, the 100% concentration produced slight erythema (score of 1) at 24 hours posttreatment and trace erythema (scores of ± to 1) at 48 hours, the 50% concentration produced trace irritation (±) at 24 and 48 hours; the 25% concentration produced ± irritation at 24 hours and 0 to ± at 48 hours; the 10% concentration produce ± irritation in one animal at 24 hours only.

At challenge test group had ± irritation in 7/20 animals at 24 hours posttreatment and no irritation at 48 hours; naive control group had ± irritation in 3/10 animals at 24 hours and no irritation at 48 hours.

Since the irritation in test group appears comparable to irritation in naive group it is concluded that a sensitization reaction did not occur.

STUDY CLASSIFICATON: Core Guideline Data

TOXICITY CATEGORY: Non-sensitizing

SIMAZINE

Page____ is not included in this copy.

Pages 6 through 8 are not included.

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 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.