4-30-86

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

006194

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 24 1986

MEMORANDUM

SUBJECT: EPA File Symbol 10163-RNT
Gowan Pro Cop R

FROM: Deloris F. Graham DFG 4/30/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

E 4/30/86

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Gowan Company
P.O. Box 5696
Yuma, AZ 85364

Active Ingredient:
Cupric Hydroxide 77%
Inert Ingredients: 23%

Background:

Submitted Acute Oral, Acute Dermal, Eye Irritation, Primary Dermal Irritation, and Dermal Sensitization Studies. Studies conducted by Stillmeadow, Inc. Data under Accession Numbers 259425, 259424, 259423, 259422, and 259421. Method of support not indicated.

Recommendation:

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

2. An Acute Inhalation Study was not submitted and one must be submitted or data to support waiver.

3. Based on data submitted appropriate signal word is DANGER.

1 of 9

Label:

No labeling comments at this time, however, at submission of acute inhalation data label revision may be necessary.

Review:

(1) Acute Oral Toxicity Study: Stillmeadow, Inc.; Project No. 3479-84; January 19, 1985; EPA Accession No. 259425.

Procedure:

Five groups consisting of five male and five female rats each were given one of the following doses of the test material orally: 750, 1000, 1500, 2000, or 5030 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

Results:

At 750 mg/kg, 3/5 F died; at 1000 mg/kg, 1/5 M and 3/5 F died; at 1500 mg/kg, 4/5 M and 4/5 F died; at 2000 mg/kg, 4/5 M and 4/5 F died; at 5030 mg/kg, 5/5 M and 5/5 F died. Toxic signs reported included activity decrease, chromodacryorrhea, constricted pupils, diarrhea, dilated pupils, emaciation, epistaxis, exophthalmos, lacrimation, piloerection, polyuria, ptosis, and salivation. Necropsy report revealed diarrhea, epistaxis, lacrimation, nasal discharge, polyuria and salivation; discoloration of contents of gastrointestinal tract intestinal tract mucosa and kidneys; gastro intestinal tract distended with gas, serosal blood vessels pronounced on small intestine, testes drawn into abdominal cavity, white spot on left kidney, blue paste in stomach, yellow-brown mucoid material in small intestines, green slurry in small intestines, red mucoid material in small intestines, blue-green salivation, dark blue-green material in cecum. LD_{50} for males reported to be 1330.4 mg/kg with 95 percent confidence limits between 1001.1 and 1768 mg/kg. LD_{50} for females reported to be 682.6 mg/kg (332.9 to 1399.6 mg/kg). LD_{50} for males and females combined reported to be 1066.1 mg/kg (788 to 1442.3 mg/kg).

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(2) Acute Dermal Toxicity Study: Stillmeadow, Inc.; Project No. 3480-84; December 28, 1984; EPA Accession No. 259424.

Procedure:

Five male and five female rabbits with intact skin sites each were treated with 2000 mg/kg of the test material under occlusive wrap for 24-hour exposure period. Observations were made for 14 days posttreatment. Necropsy performed on all animals.

Results:

No mortalities or abnormalities at necropsy reported. Toxic signs reported included decreased defecation and diarrhea. LD_{50} reported to be greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(3) Primary Skin Irritation Study: Stillmeadow, Inc.; Project No. 3482-84; December 13, 1984; EPA Accession No. 259421.

Procedure:

Six rabbits with one intact skin site each received 0.5 g of the test material under occlusive wrap for 4-hour exposure period. Observations were made at 1, 24, 48, and 72 hours after exposure period.

Results: No irritation reported.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(4) Eye Irritation Study: Stillmeadow, Inc.; Project No. 348184; December 28, 1984; EPA Accession No. 259422

Procedure:

Nine rabbits received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed with deionized water for 1 minute 30 seconds after treatment. Observations made for 21 days posttreatment.

Results:

At 24 hours, 6/6 animals of the unwashed group and 1/3 of the washed group had corneal opacity (1/6 = 15, 4/6 = 20, 1/6 = 30) (1/3 = 10); 6/6 and 2/3 iris irritation (5/6 = 5, 1/6 = 10) (2/3 = 5); 6/6 and 3/3 conjunctive redness (6/6 = 2) (3/3 = 2),

chemosis (5/6 = 3, 1/6 = 4) (2/3 = 2, 1/3 = 4) and discharge (2/6 = 1, 4/6 = 2) (2/3 = 1, 1/3 = 3).

At day 7, 6/6 and 1/3 corneal opacity (5/6 = 10, 1/6 = 60) (1/3 = 10); 4/6 and 1/3 iris irritation (4/6 = 5), (1/3 = 5), 6/6 and 1/6 redness (3/6 = 1, 3/6 = 2) (1/3 = 3), chemosis (3/6 = 1, 2/6 = 2, 1/6 = 3) (1/3 = 3); 2/6 and 1/3 discharge (2/6 = 2) (1/3 = 2). Invasion of cornea by blood vessels also reported.

At day, 3/6 and 1/3 corneal opacity (1/6 = 5, 1/6 = 10, 1/6 = 40) (1/3 = 20); 1/6 iris irritation (1/6 = 5); 3/6 and 1/3 redness (2/6 = 1, 1/6 = 2) (1/3 = 2) and chemosis (2/6 = 1, 1/6 = 2) (1/3 = 2); 1/3 discharge (1/3 = 1). Invasion of cornea by blood vessels also reported.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER.

(5) Dermal Sensitization Study: Stillmeadow, Inc.; Project No. 3483-84; January 9, 1985; EPA Accession No. 259423.

Procedure:

Two groups consisting of ten male guinea pigs each received applications of one of the following substances: test material or 0.05% w/v solution of 2,4-dinitrochlorobenzene in ethanol (positive control) initially then on alternate days for a total of ten induction phase applications. Five hundred milligram (500 mg) doses of the test material and 0.5 ml doses of the positive control were used. Two weeks after tenth induction phase application a challenge dose was applied. Observations made at 24 and 48 hours after initial induction phase treatment and challenge doses, but only 24 hours after all other applications.

Results:

No irritation produced by test substance at initial treatment, virgin challenge site, or at original challenge site thereby indicating no skin sensitization was induced.

Zero irritation at initial treatment, 1.7 at virgin challenge site and 2.4 at original challenge site produced by positive control, thereby indicating skin sensitization had been induced.

Study Classification: Core Guideline Data.

Toxicity Category: Nonsensitizing.

4

TH Review 006194

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Pages 5 through 8 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

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_____ 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.

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_____ FIFRA registration data.

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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.