4-27-87

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

006212

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File Symbol 359-TEU
Rovral 4 Flowable

FROM: Deloris F. Graham DFG 4/27/87 E 4/27/87
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Lois Rossi, Acting PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Rhone-Poulenc, Inc.
Black Horse Lane
P.O. Box 125
Monmouth Junction, NJ 08852

ACTIVE INGREDIENT:
Iprodione: 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide 41.6%
Inert Ingredients: 58.4%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Skin Irritation, Eye Irritation, Dermal Sensitization, and Acute Inhalation Studies to support conditional registration of this product. Studies conducted by Union Carbide's Bushy Run Research Center. Data under Accession No. 265194. Method of support not indicated.

RECOMMENDATIONS:

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

2. Based on data submitted, the appropriate signal word is CAUTION.

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LABEL: Labeling acceptable as submitted.

REVIEW:

(1) Acute Oral Toxicity Study: Bushy Run Research Center; Project Report 49-505; March 3, 1986.

PROCEDURE:

Four groups consisting of five male and five female rats each were dosed with one of the following doses: 625, 1250, 2500, or 5000 mg/kg. Two groups consisting of five female rats each were dosed with one of the following doses: 884 or 1050 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1250 mg/kg, 1/5 M and 5/5 F died; at 2500 mg/kg, 5/5 M and 5/5 F died; at 5000 mg/kg, 5/5 M and 5/5 F died. Toxicity signs reported include sluggishness, unsteady gait, prostration, lacrimation, kyphosis, piloerection, intermittent tremors, dark red crust on periocular and perinasal fur, emaciation, peri-urogenital wetness, and swollen genitals. Necropsy report revealed lungs dark pink, mottled, light and dark red; intestines contained thick tan material; eyes with red encrustation; kidneys with mild hydronephrosis; bladder severly distended; testes small; penis enlarged; uterine horns dilated, and filled with clear liquid. LD_{50} for males reported to be 1540 mg/kg (with 95% confidence limits between 1140 and 2080) mg/kg. LD_{50} for females reported to be 1160 (1070-1260) mg/kg. LD_{50} for males and females combined reported to be 1170 (919-1480) mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: Bushy Run Research Center; Project Report 49-505; March 3, 1986.

PROCEDURE:

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

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RESULTS:

No mortalities or toxic signs reported. Necropsy report revealed lungs mottled light and dark red in one female rabbit. LD_{50} reported to be greater than 2000 mg/kg for males and females.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Skin Irritation Study: Bushy Run Research Center; Project Report 49-505; March 3, 1986.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 ml dose of the test material under occlusive wrap for 4-hour exposure period. Observations made for 7 days posttreatment.

RESULTS: No irritation reported.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(4) Eye Irritation Study: Bushy Run Research Center; Project Report 49-505; March 3, 1986.

PROCEDURE:

Six rabbits received 0.1 ml of the test material in one eye each. Observations were made for 7 days posttreatment.

RESULTS:

At 1 hour posttreatment, 6/6 rabbits had slight redness (6/6 = 1); 1/6 slight chemosis (1/6 = 1) and 5/6 slight discharge (5/6 = 1). All irritation had cleared at 24 hours posttreatment.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(5) Dermal Sensitization Study: Bushy Run Research Center; Project Report 49-513; April 15, 1986.

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PROCEDURE:

Three groups consisting of ten guinea pigs each received three (one per week) 0.3 ml dose of one of the following substances: undiluted test material, 0.25% w/v aqueous methyl cellulose solution (negative control) or 0.3% w/v dinitrochlorobenzene (DNCB, positive control) during induction phase. Two weeks after final induction phase application, a challenge dose was applied using undiluted test material, 0.25% methyl cellulose solution, or 0.1% DNCB. Observations made at 24 and 48 hours after each application.

RESULTS:

No irritation produced in test material or negative control groups during induction phase, but DNCB group did not dermal reactions.

At challenge, test group animals did not produce any reaction; negative control group did not produce any reaction; positive control did produce a definite allergic reaction.

It is concluded this product did not produce a skin sensitizing reaction.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Non-sensitizing.

(6) Acute Inhalation Toxicity Study: Bushy Run Research Center; Project Report 49-515; June 6, 1986.

PROCEDURE:

Four groups consisting of five male and five female rats each were exposed for 4 hours to one of the following gravimetrical concentrations: 0.58, 1.95, 3.80, or 5.93 mg/L. Mass median diameter for all groups ranged from 1.7 to 8.8 um with geometric standard deviation from 4.6 to 6.9. Mean temperature reported to be 23 $\pm$ 1 and relative humidity 81 to 100%. Observations made for 14 days postexposure. Necropsy performed on all animals.

RESULTS:

At 1.95 mg/L, 1/5 M died; at 3.80 mg/L, 1/5 M and 2/5 F died; at 5.93 mg/L, 4/5 M and 5/5 F died. Clinical signs reported included perinasal, periocular, perioral encrustation and wetness, urogenital wetness; unkempt, discolored fur; respiratory difficulties; decreased motor activity, ataxia,

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tremors, slow surface righting reflect and moribund. Necropsy report revealed discoloration of lung, cloudy eyes, presence of white fluid in the trachea, esophagus, and stomach. LC_{50} for males reported to be 3.33 mg/L (with 95% confidence limits between 1.94 and 5.70) mg/L. LC_{50} for females reported to be 3.59 (2.78-4.63) mg/L. LC_{50} for males and females combined reported to be 3.65 (2.65-5.02) mg/L.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

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Page_____ is not included in this copy.

Pages 6 through 7 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.