7-18-86

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

006115

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

~~JUL 10 1986~~

MEMORANDUM

SUBJECT: EPA File Symbol 9779-ETO
Prozine 40/40

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

MW RHH 7/18/86

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

APPLICANT: Riverside/Terra Corporation
A Subsidiary of Terra International, Inc.
P.O. Box 171376
Memphis, TN 38187

ACTIVE INGREDIENTS:
45601 Pendimethalin (N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine) 40.0%
063 Atrazine (2-chloro-4-ethylamino-6-isopropylamino-s-triazine) 40.0%
INERT INGREDIENTS: 20.0%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, primary skir, and primary eye irritation study. The studies were conducted by American Cyanamid Company, Animal Industry Research Division. The data were not accessioned. The method of support was not indicated.

RECOMMENDATION:

FHB/TSS finds the acute oral, acute dermal, primary skin, and the primary eye irritation studies acceptable to support registration. The signal word is "CAUTION."

The acute inhalation toxicity study is waived based on the registrant's data which indicate that no more than 0.5 percent fines are < 150 microns.

The dermal sensitization study cannot be waived based on the data provided on the technical products. Data must be provided on the formulated product; therefore, the registrant must submit a dermal sensitization study on the product for which registration is sought.

The Product Manager should inform the registrant that when conducting future primary eye irritation studies, individual scores for conjunctivae redness, chemosis, and discharge should be provided.

LABELING:

1. Place the Storage and Disposal instructions in front of the reentry statement or at the end of the Directions for Use.

2. Additional labeling comments may be necessary upon submission of dermal sensitization data.

REVIEW:

(1) Acute Oral Toxicity Study: American Cyanamid Company, Animal Industry Research Division; Report No. A86-10; May 9, 1986.

PROCEDURE:

Three groups each consisting of five male and five female albino rats were administered a single oral dose of either 10,000, 5000, or 2500 mg/kg of an aqueous dispersion of test material. Animals were observed daily for 14 days. All animals were necropsied.

RESULTS:

At 10,000 mg/kg, 4/5 males and 3/5 females died. At 5000 mg/kg, 1/5 males and 1/5 females died. At 2500 mg/kg, 1/5 females died. The LD_{50} for males was reported to be 7071 (5100-9804) mg/kg. The LD_{50} for females was reported to be 7711 (4391-13543) mg/kg.

Toxic symptoms observed were decreased activity, diuresis, decreased respiration, and ataxia. Gross necropsy revealed dark and congested liver, congested kidneys, and dark or hemorrhagic areas in lungs.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.

(2) Acute Dermal Toxicity Study: American Cyanamid Company, Animal Industry Research Division; Report No. A86-10; May 9, 1986.

PROCEDURE:

Five male and five female albino rabbits each received 2000 mg/kg of test material moistened with tap water and applied to a previously shaven test site on each animal. The test sites were kept under occlusive wrap for 24 hours. After exposure, the wrap was removed and the test sites were wiped with gauze pads moistened with tap water to remove residual material. Animals were weighed prior to dosing and at 7 and 14 days. Animals were observed daily for 14 days and necropsied at study conclusion.

RESULTS:

No deaths occurred. The LD_{50} was reported to be > 2000 mg/kg. Toxic symptoms observed were decreased activity which subsided by day 2. At gross necropsy, 1/5 female rabbits exhibited congested lungs and pale liver.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Primary Skin Irritation Study - American Cyanamid Company, Animal Industry Research Division; Report No. A86-10; May 9, 1986.

PROCEDURE:

Six New Zealand White rabbits were shaved 24 hours prior to testing. Each animal received 0.5 gm of test material/site prepared as an aqueous paste and applied to two intact and two abraded test sites/animal. Test sites were kept under occlusive wrap for 24 hours. After exposure, the wrap was removed and residual test material was removed with a moistened gauze pad. Skin irritation was scored at 24, 48, and 72 hours and at 6 days.

RESULTS:

Irritation at intact skin test sites was scored as follows: at 24 hours, 5/6 animals exhibited very slight erythema, 1/6 animals exhibited slight erythema, 2/6 animals exhibited slight

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edema and 4/6 animals exhibited very slight edema; at 48 hours, 1/6 animals exhibited slight erythema, and 4/6 animals exhibited very slight erythema; at 72 hours, 2/6 animals exhibited very slight erythema, dry skin and cracking skin; and at 6 days, all irritation had subsided.

Irritation at abraded skin test sites was scored as follows: at 24 hours, 3/6 animals exhibited slight erythema, 3/6 animals exhibited very slight erythema, 2/6 animals exhibited slight edema and 4/6 animals exhibited very slight edema; at 48 hours, 3/6 animals exhibited slight erythema, 3/6 animals exhibited very slight erythema, and 2/6 animals exhibited very slight edema; at 72 hours, 1/6 animals exhibited very slight erythema and 1/6 animals exhibited dry skim; and at 6 days, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(4) Primary Eye Irritation Study: American Cyanamid Company, Animal Industry Research Division; Report No. A86-10; May 9, 1986.

PROCEDURE:

Six male New Zealand White rabbits each received 100 mg of test material which was instilled into the conjunctival sac of the right eye. The eyelids were held shut for 5 seconds. The left eye served as a control. After 24 hours of exposure, the eyes were rinsed with tap water. Eye irritation was scored at 1, 24, 48, and 72 hours and at 4 and 7 days.

RESULTS:

Eye irritation was scored as follows: at 24 hours, corneal opacity (6/6 = 20) and conjunctivae irritation (1/6 = 16, 5/6 = 8); at 7 days, all irritation had cleared.

STUDY CLASSIFICATION:

Core Minimum Data - See comments under Recommendation.

TOXICITY CATEGORY: Category III - CAUTION.

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Page____ is not included in this copy.

Pages 5 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.