7-17-86

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

006105

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 10 1986

MEMORANDUM

SUBJECT: EPA File Symbol 9779-ETI
Prozine 32/48

FROM: Deloris F. Graham DFG 7/17/86 E 7/17/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Robert J. 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 INGREDIENT:

'354 EB Pendimethalin (N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine) 32.0%

063 Atrazine (2-chloro-4-ethylamino-6-isopropylamino-s-triazine) 48.0%

INERT INGREDIENTS 20.0

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Eye Irritation, and Primary Dermal Irritation Studies. Studies conducted by American Cyanamid Company. Data not accessioned. Method of support not indicated.

RECOMMENDATION:

1. FHB/TSS finds these data acceptable to support conditional registration of this product. However, for future submissions please note, in the Eye

Irritation Study individual scoring for conjunctive irritation (redness, chemosis, and discharge) should be submitted.

2. Based on particle size information stated in a letter to the Agency from American Cyanamid dated May 30, 1986, only .5 percent of fines are 150 microns, therefore, an acute inhalation study is not required.

3. A Dermal Sensitization Study must be submitted on the formulated product.

4. The appropriate signal word is "CAUTION."

LABEL:

1. The statement "Do not apply this product . . . treated must be vacated by unprotected persons" must be deleted from under the heading "Hazards to Humans" and placed under the heading "Directions For Use."

2. The statement "Keep out of lakes, streams and ponds" must be revised to read "Do not apply directly to lakes, streams or ponds."

REVIEW:

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

PROCEDURE:

Three groups consisting of five male and five female rats each were dosed with one of the following doses: 2500, 5000, or 10,000 mg/kg of the test material. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

At 2500 mg/kg, 1/5 F died; at 5000 mg/kg, 1/5 F and 1/5 M died; at 10,000 mg/kg, 3/5 F and 4/5 M died. Toxic signs reported included decreased activity, diuresis, decreased respiration, and ataxia. Necropsy report revealed dark congested liver, congested kidney, hemorrhagic areas in lungs; at 10,000 mg/kg dose three rats were reported to have been accidentally discarded before necropsy and at 2500 mg/kg one female could not be necropsied due to cannibalization. LD_{50} for males reported to be 7071 mg/kg with confidence limits

between 5100 and 9804 mg/kg. LD_{50} for females reported to be 7711 mg/kg with confidence limits between 4391 and 13,543 mg/kg. LD_{50} for males and females combined reported to be 7579 mg/kg with confidence limits between 5648 and 10,169 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

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

PROCEDURE:

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

RESULTS:

No mortalities reported. Decreased active was the toxicity signs reported. Animals reported to be back to normal at day 2 posttreatment. Necropsy report revealed moderate congestion of the lung and a pale liver in one female rabbit. No other abnormalities were reported at necropsy. LD_{50} reported to be greater than 2000 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Primary Dermal Irritation Study: American Cyanamid Company; Report No. A86-10; May 9, 1986.

PROCEDURE:

Six rabbits with abraded and intact skin sites each received 0.5 g of the test material per site under occlusive wrap for 24-hour exposure period. Observations were made for 6 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had slight to well defined erythema and edema (score of 1 and 2 for both). At 72 hours, 2/6 had slight erythema (scores of 1) and dry cracking skin noted at application site. Primary Irritation Score reported to be 1.08. Irritation had cleared by day 6.

3

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

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

PROCEDURE:

Six rabbits received 100 mg of the test material in one eye each. At the end of 24-hour exposure period the treated eyes were rinsed with tap water. Observations made for 7 days posttreatment.

RESULTS:

At 24 hours, 6/6 rabbits had corneal opacity (6/6 = 20); no iris irritation reported; 6/6 conjunctive irritation (5/6 = 8 and 1/6 = 16, cummulative scores). Irritation reported as having cleared by day 7.

STUDY CLASSIFICATION:

Core Minimum Data. Individual score for conjunctive irritation (redness, chemosis, and discharge) should be submitted.

TOXICITY CATEGORY: III - CAUTION.

Pendimethalin Tox review 006105

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.