3-8-88

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

006741

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

FEB 25

MEMORANDUM

SUBJECT: EPA File Symbol 538-EEA
Fertilizer Plus Insecticide/Preemergent
Weed Control

FROM: Deloris F. Graham DFG 3/8/88
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

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

APPLICANT: O.M. Scott and Sons Company
Marysville, Ohio 43041

ACTIVE INGREDIENTS:
Pendimethalin, N-(1-Ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine 2.13%
Chlorpyrifos, O,O-Diethyl-O-(3,5,6-trichloro-2-pyridyl)phosphorothioate 1.42%
INERT INGREDIENTS: 96.45%

ACTIVE INGREDIENTS:
Pendimethalin 0.43%
Chlorpyrifos 0.28%
INERT INGREDIENTS: 99.29%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization studies on high and low active ingredient range formulations. Studies conducted by Hazleton Laboratories America, Inc., Madison, Wisconsin. Data under EPA MRID Nos. 403163-02 thru 10. Method of support not indicated.

RECOMMENDATIONS:

1. FHB/TSS finds these studies acceptable to support the formulation on which tested.

2. The appropriate signal word for both formulations is CAUTION.

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

LABEL:

The statement "Do not contaminate feed or foodstuff or water supplies. Do not graze treated area. Do not feed clippings to livestock." must be deleted from the heading "Hazards to Humans and Domestic Animals" and placed under the heading "Direction For Use."

REVIEW:

(1) Acute Oral Toxicity Study on S-1976: Hazleton Laboratories; Project ID. HLA 70105185; May 12, 1987; EPA MRID No. 403163-02.

PROCEDURE:

Five groups consisting of five female rats each received one of the following doses: 4.0 5.0, 5.0, 6.0 and 6.5 g/kg of the test material. One group consisting of five male rats received a single 5.0 g/kg dose each. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 5.0 g/kg, 2/5 F died; no other deaths reported at 4.0, 5.0, 6.0 and 6.5 g/kg doses. Clinical signs reported included tremors, sensitivity to touch, ataxia, miosis, red stained face, yellow stained genitals, excessive salivation diarrhea, hypoactivity, hypothermic to touch, prostration, dark stained abdomen. Necropsy report revealed yellow area in perineal region; submandibular lymph node enlarge; left side of face and entire head in one cannibalized in 2/5 at 5.0 g/kg dose; perineum stained brown and tan; stomach and small intestine very autolyzed; thymus - red areas; uterus - lumen of both uterine horns filled with clear fluid. LC_{50} for males and females reported to be greater than 5.0 g/kg.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: IV - CAUTION

(2) Acute Dermal Toxicity Study on S-1976: Hazleton Laboratories; Project ID.: HLA 70105187; April 17, 1987; EPA MRID No. 403163-03.

PROCEDURE:

Five male and five female rabbits with intact skin sites each received a single 2.0 g/kg dose of test material. The treated sites were placed under occlusive wrap for 24 hour exposure period. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

No deaths or clinical signs reported. Slight erythema and edema reported. Necropsy report revealed green-firm mass on right median lobe of liver and blood vessels in normal location of spleen enlarged and dilated in 1/5 F, spleen not identified. LD_{50} reported to be greater than 2.0 g/kg for males and females.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(3) Eye Irritation Study on S-1976: Hazleton Laboratories; Project ID.: HLA 70105188; April 9, 1987; EPA MRID No. 403163-04.

PROCEDURE:

Six rabbits received 0.05 g (=0.1 ml) of the test material in the everted lower lid of one eye each. Observations made for 72 hours posttreatment.

Results:

At 24 hours posttreatment, 2/6 rabbits had iris irritation (2/5=6); 5/6 conjunctive redness (3/6=1, 2/6=2). At 72 hours all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(4) Primary Dermal Irritation Study on S-1976: Hazleton Laboratories; Project ID.: HLA 70105186; April 6, 1987; EPA MRID No. 403163-05.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 g of test material moistened with 0.9% saline. Treated sites placed under occlusive wrap for four hour exposure period. Observations made for 72 hours posttreatment.

RESULTS:

At 4 hours posttreatment, 3/6 rabbits had slight erythema (3/6=1) and 2/6 slight edema (2/6=1). At 24 hours, 1/6 had slight erythema (1/6=1) and edema (1/6=1). At 72 hours, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: IV - CAUTION

(5) Dermal Sensitization Study on S-1976: Hazleton Laboratories; Project ID.: HLA 70105189; April 17, 1987; EPA MRID No. 403163-05.

PROCEDURE:

Three group consisting of a test group of 10 guinea pig, naive control group of 10 animals and postive control group of four animals. During induction phase, the test group received 0.2 g of the test material moistened with 0.9% saline applications using the patch method for six hour exposure. The positive control received 0.4 ml of a 0.3% w/v of 2,4-dinitrochlorobenzene (DNCB) in 80% ethanol/ deionized water. Naive control treated in same manner as previous group except no test substance or DNCB was applied. Each of the treated groups received three applications (one per week) during induction phase. Two weeks after final (3rd) induction application challenge dose was applied to all three groups; test material to test group and naive control group; a 0.1% w/v DNCB in acetone for positive control group. Observations made at 24 and 48 hours after each application.

RESULTS:

No irritation produced in test group or naive control group during induction phase or at challenge dose. DNCB produced slight to moderate irritation during induction and slight to well define irritation at challenge with a non-irritating concentration thereby indicating a sensitization reaction. It is concluded that sign the test group produced no irritation that sensitization reaction did not occur.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Non-sensitizing.

(6) Acute Oral Toxicity Study on S-1977: Hazleton Laboratories; Project ID.: HLA 70105190; April 9, 1987; EPA MRID No. 403163-07.

PROCEDURE:

Five male and five female rats each received a single 5.0 g/kg dose of the test material orally. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

No deaths reported. Clinical signs reported included hypoactivity, gasping and diarrhea. Necropsy report revealed spleen - opaque areas or capsule in one male rat. LD_{50} reported to be greater than 5.0 g/kg for males and females.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: IV - CAUTION

(7) Acute Dermal Toxicity Study on S-1977: Hazleton Laboratories; Project ID.: HLA 70105191; April 17, 1987; EPA MRID No. 403163-08.

PROCEDURE:

Five male and five female rabbits with intact skin sites each received a 2.0 g/kg dose of test material moistened with 0.9% saline. The treated sites were placed under occlusive wrap for 24 hour exposure period. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

No deaths. Clinical signs reported to be hypoactivity, slight to moderate erythema, slight edema and desquamation. No abnormalities at necropsy reported. LD_{50} reported to be greater than 2.0 g/kg for males and females.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(8) Eye Irritation Study on S-1977: Hazleton Laboratories; Project ID.: HLA 70105193; April 21, 1987; EPA MRID No. 403163-09.

PROCEDURE:

Six rabbits received 0.03 g (~0.1 ml) in the everted lower lid of one eye each. Observations made for 72 hours posttreatment.

RESULTS:

At one hour posttreatment 6/6 rabbits had iris irritation (6/6=5); 6/6 conjunctive redness (6/6=2), chemosis (2/6=1, 4/6=2) and discharge (4/6=1, 2/6=2). At 24 hours, 2/6 iris irritation (2/6=5); 6/6 redness (6/6=2); 2/6 chemosis (2/6=1). At 72 hours all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(9) Primary Dermal Irritation Study on S-1977: Hazleton Laboratories; Project ID.: HLA 70105192; April 7, 1987; EPA MRID No. 403163-10.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 g of the test material moistened with 0.9% saline. Treated sites placed under occlusive wrap for four hour exposure period. Observations made at 72 hours posttreatment.

RESULTS:

At 4 hours, 5/6 rabbits had slight erythema (5/6=1). At 24 hours, 1/6 had slight erythema (1/6=1). At 72 hours, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

Pendimethalin Tox review 006741

Page_____ is not included in this copy.

Pages 7 through 20 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.

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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.