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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 05 1986

MEMORANDUM

SUBJECT: EPA Registration Number 33660-3
Trifluralin Technical

FROM: Deloris F. Graham DFG 5/13/86 E 5/13/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Industria Prodotti Chimici
Via Fratelli Beltrami 11
20026 Novate Melanis, Italy

Active Ingredient:
Trifluralin (α,α,α-Trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine 96.0%
Inert Ingredients: 4.0%

Background:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization Studies under "400" (miscellaneous data) action code. Studies conducted by Istituto di Recerche Biomediche "Atoine Marxer," RBM S.p.A., Italy and by Research and Consulting Company LTD, Switzerland. Data under Accession Numbers 258817, 258818, 258819, 258820, 258821, and 260338. Method of support not indicated. Label submitted stamped accepted on February 6, 1986.

Recommendation:

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

2. The appropriate signal word is CAUTION.

Label:

1. Precautionary statements must be revised to include "This product may cause allergic skin reaction."

2. The statement of practical treatment section must precede environmental hazard section.

Review:

(1) Acute Dermal Toxicity Study: Istituto di Recerche Biomediche; RBM Exp. No. 2159; July 1, 1985; EPA Accession No. 258817.

Procedure:

Five male and five female rats with intact skin sites were treated with 2000 mg/kg 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, toxic signs or abnormalities at necropsy reported. LD_{50} reported to be greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(2) Eye Irritation Study: Istituto di Recerche Biomediche; RBM Exp. No. 2160; July 1, 1985; EPA Accession No. 258818.

Procedure:

Six rabbits received 0.1 g of the test material in one eye each. Observations made for 4 days posttreatment.

Results:

At 1 hour, 6/6 had conjunctive redness (6/6 = 1) with lachrymation. At 24 hours, 6/6 had conjunctive redness (4/6 = 1, 2/6 = 2). Irritation had cleared by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(3) Dermal Sensitization Study: Istituto di Recerche Biomediche; RBM Exp. No. I 892; June 24, 1985; EPA Registration No. 258819.

Procedure:

One group of ten guinea pigs received three pairs of 0.1 ml intradermal injections of one of the following substances: Freunds Complete Adjuvant (FCA) with equal parts water; test material alone; test material in FCA. A second group of ten guinea pigs received three pairs of 0.1 ml intradermal injections of the following substances: FCA alone; dinitrochlorobenzene (DNCB) positive control, alone; DNCB in FCA. A third group of sixteen guinea pigs received three pairs of 0.1 ml intradermal injections of the following substances: FCA alone (with equal parts water); vehicle (water) alone; vehicle in FCA. Seven days later a second application of three pairs of injections using appropriate material in appropriate groups was applied. This concluded the induction phase. Fourteen days after second set of applications a challenge dose was applied to each group using appropriate material. Ten days after first challenge, a second challenge dose was applied. A 5 percent solution of the test material was used during induction phase and at challenge dose. A 0.4 percent solution of DNCB during induction phase and 0.2 percent solution at challenge. Observations made daily during entire study and at 24 and 48 hours after challenge doses.

Results:

Ulcerations at the site of FCA injection were reported. Four out of ten animals reported to have produced a positive reactive with test material at first challenge and 6/10 at second challenge; average scores reported to be 1 and 1.3, respectively. All animals treated with DNCB reported to have produced a positive reaction, average score at first challenge was 3 and second challenge was 3.4. Vehicle (negative control group) produced no reactions. Therefore, it is concluded that the test material produced a sensitizing reaction.

Study Classification: Core Guideline Data.

Toxicity Category: Sensitizing Agent.

(4) Dermal Irritation Study: Istituto di Recerche Biomediche; RBM Exp. No. 2161; July 1, 1985; EPA Accession No. 258820.

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Procedure:

Six rabbits with intact skin sites were treated with 0.5 g of the test material under occlusive wrap for 4-hour exposure. Observations made for 72 hours posttreatment.

Results: No irritation reported.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(5) Acute Oral Toxicity Study: Istituto di Recerche Biomediche; RBM Exp. No. 2162; July 1, 1985; EPA Accession No. 258821.

Procedure:

Five male and five female rats each were dosed with a single 5000 mg/kg dosage of the test material orally. Observations made for 14 days postdosing. Necropsy performed on all animals.

Results:

No mortalities, toxic signs or abnormalities at necropsy reported. LD_{50} reported to be greater than 5000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(6) Acute Inhalation Toxicity Study: Research and Consulting Company LTD; Project 005477; January 15, 1982; EPA Accession No. 260338.

Procedure:

Three groups consisting of five male and five female rats each were exposed for 4 hours to one of the following: 30 mL/hr, 70 percent test material in acetone; 60 mL/hr, 70 percent test material in acetone; 60 mL/hr, acetone (vehicle control) nominal concentrations. Gravimetric concentrations reported to be 3131 $\pm$ 306 mg/m^3, 4661 $\pm$ 265 mg/m^3, vehicle control, respectively. Twenty-nine to forty-eight percent of particles analyzed reported to be smaller than 7 microns for both test groups. Temperature ranged from 21.7 to 22 °C and relative humidity 60 to 64 percent for both test groups. Observations made for 14 days postexposure. Necropsy performed on all animals.

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Results:

No mortalities reported. Slight sedation, dyspnea and ruffled fur noted during first 24 hours of test, but no other toxic signs were reported in either test group. Necropsy report indicated lung, right and left: distinct red, 2 mm diameter (focal atelectasis?) in some male animals treated with acetone only; lung, left: petecheae, and brown-reddish foci, small in some female animals treated with acetone only. No pathological changes not at necropsy of both test group animals. LC_{50} reported to be greater than 4660 mg/m^3.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

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