BB-137 TM-6306



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

006306

PESTICIDES AND TOXIC SUBSTANCES

MEMORANDU			F incr
SUBJECT:	EPA Registra	ation No. 352-EUP-130 erbicide Dry Flowable	
FROM:	Deloris F. Graham OSA 210/87 Technical Support Section Fungicide-Herbicide Branch Registration Division (TS-767C)		
то:	Richard F. Mountfort, PM 23 Fungicide-Herbicide Branch Registration Division (TS-767C)		
	APPLICANT:	E.I. du Pont de Nemours & Compan Agricultural Chemicals Departmen Walker's Mill Building Barley Mill Plaza Wilmington, DE 19898	y, Inc.
Methyl		methoxy-6-methyl-1, methylamino]carbonyl] enzoate]	. 75% . 25%
BACKGROU			
Skin Iri	ritation, Acu	al Sensitizacion, Acute Oral, Printe Dermal, and Eye Irritation Stude under MRID Numbers: 400498-03,	400 498-04,

RECOMMENDATION

PHB/TSS finds these data acceptable to support an FUP.

400498-05, 400498-06, and 400498-07. Method of support not indicated. Studies conducted by E.I. du Pont de Nemours & Company, Incorporated, Haskell Laboratory for Toxicology and Industrial Medicine.

of a

- An Acute Inhalation Study was not submitted. One must be submitted and/or cited or data to support waiver.
- 3. The appropriate signal word is CAUTION.

LABEL:

- The following subheadings on the label submitted should appear under the heading "Directions For Use": "Storage and Disposal," "Important," "Notice of Warranty," and "General Information" with the appropriate statements under each subheading.
- 2. Additional labeling may be necessary upon submission of acute inhalation data.

REVIEW:

(1) Dermal Sensitization Study: Haskell Laboratory; Report No. 617-86; October 27, 1986; EPA MRID No. 400498-03.

PROCEDURE:

During the primary irritation phase, 10 unexposed guinea pigs each were treated with an approximate 0.05 ml aliquot of the test material by applying and lightly rubbing in 1 drop of a 30% and a 3% suspension of the test material in distilled water on separate shaved, intact shoulder skin. Another group of 10 unexposed guinea pigs were treated in same manner as the previous group except p-phenylenediamine in acetone: dimethyl phthalate (1:9 ratio) was used. The p-phenylenediamine group served as positive control group.

Two days after primary dermal phase, the same 10 guinea pigs were given 4 intradermal injections initially, and once a week for 3 weeks. A 0.1 ml aliquot of a 1.00 (w/v) suspension of the test material in saline was used. Same treatment was applied to positive control using the same concentration of p-phenylenediamine in acetone:dimethyl phthalate (1:9 ratio). Observations made 24 hours after each injection.

Two weeks after final induction phase application, a challenge dose was applied to test and positive control groups using appropriate materials at the same concentrations used during induction phase. At challenge, a group of 10 unexposed guinea pigs were treated with test material at the same concentration used in induction phase. Observations made at 24 and 48 hours after challenge dose.

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RESULTS:

Mild to severe erythema and edema reported in most animals of the test group throughout induction phase. At challenge, 4/10 animals at 30% concentration reported to have had mild crythema at 24 hours postdosing. No other irritation in test or negative control group reported.

Mild to severe erythema and edema in all animals of the positive control group throughout induction phase. Necrosis and blanching also reported during induction phase. At challenge, mild to severe erythema and edema at 30% concentration reported in all animals at 24 and 48 hours postchallenge dose; at 3% concentration no irritation to strong irritation reported.

Based on information submitted in this study, it is concluded that this product did not produce a sensitizing response.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizing.

(2) Acute Oral Toxicity Study: Haskell Laboratory; Report No. 619-86; October 23, 1986; EPA MRID No. 400498-04.

PROCEDURE:

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

RESULTS:

No mortalities or abnormalities at necropsy reported. Clinical signs reported included wet perineum and sporadic slight to moderate weight losses. LD50 reported to be greater than 5000 mg/kg for males and females.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(3) Skin Irritation Study: Haskell Laboratory; Report No. 518-86; September 10, 1986; EPA MRID No. 400498-05.

PROCEDURE:

six rabbits with two abraded and two intact skin sites each were treated with 0.5 g of the test material moistened with distilled water. Treated sites placed under occlusive wrap for 24-hour exposure period. Observations made for 72 hours posttreatment.

RESULTS:

At 24 hours, 6/6 rabbits had slight erythema (6/6 = 1) and no edema. At 72 hours, no irritation reported. Primary Irritation Index reported to be 0.5.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(4) Acute Dermal Toxicity Study: Haskell Laboratory; Report No. 689-86; November 10, 1986; EPA MRID No. 400498-06.

PROCEDURE:

Five male and five female rabbits with abraded skin each received 2000 mg/kg of the test material under occlusive wrap for 24-hour exposure. Observations made for 14 days post-treatment. Necropsy performed on two males and two females at termination of study.

RESULTS:

No mortalities reported. Clinical signs reported included moderate to severe erythema and mild to moderate edema, slight to moderate weight loss, dry and cracked skin. Histopathology revealed mild acute to subacute inflammation in superficial dermis of the treated skin; slight inflammatory exudate in the keratic layer of the epidermis. LD50 reported to be greater than 2000 mg/kg for males and females.

STUDY CLASSIFICATION: Ccre Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(5) Eye Irritation Study: Haskell Laboratory; Report No. 604-86; September 19, 1986; EPA MRID No. 400498-07.

PROCEDURE:

Six rabbits received 0.1 ml of the test material in one eye each. Observations made for 72 hours posttreatment.

RESULTS:

At 1 hour posttreatment, 6/6 rabbits had corneal opacity (6/6 = 20); 5/6 iris irritation (5/6 = 5), and 6/6 conjunctive redness (6/6 = 1), and chemosis (6/6 = 1); 2/6 discharge (2/6 = 3) with hemastix positive for blood. At 24 hours posttreatment, 2/6 had corneal opacity (2/6 = 20) and redness (2/6 = 1); 1/6 chemosis (1/6 = 1). Corneal opacity and other irritation had cleared at 72 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

Express science review			
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