BB-1141
FXR-5140

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

005140

MEMORANDUM

Date: August 24, 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: EPA File Symbol: 476-EEEG
Ordram A 6-E

From: Deloris F. Graham
FHB/TSS
8/29/83

To: Richard Mountfort
Product Manager (23)
Fungicide-Herbicide Branch
Registration Division (TS-767)

Applicant: Stauffer Chemical Company
1200 South 47th Street
Richmond, California 94804

Active Ingredient:
S-ethyl hexahydro-1H-azepine-1
-carbothioate.....69.3%
Inert Ingredients.....30.7%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies. Studies conducted by Stauffer Chemical Company. Data under Accession Number 250520. Method of support not indicated.

Recommendation:

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

(2) An Acute Inhalation Study was not submitted and one must be submitted and/or cited.

(3) The appropriate signal word is II-WARNING

Label:

(1) Labeling adequate as submitted by applicant.

Review:

(1) Acute Oral Toxicity Study: Stauffer Chemical Company; Lab Report #T-10998; March 23, 1983.

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Procedure: Six groups, 5 groups consisting of 10 M rats each and one group consisting of 20 M rats, received one of the following doses: 800, 900, 950, 1000, 1259 and 1585 mg/kg. Observations made daily for 14 days after treatment. Necropsy performed on all animals. A total of 60 male rats were treated with water and served as a vehicle control.

Results: At 800 mg/kg, 2/10 M died; at 900 mg/kg, 2/10 M died; at 950 mg/kg, 4/10M died; at 1000 mg/kg, 19/20 died; at 1259 mg/kg, 9/10 M died; at 1585 mg/kg, 10/10 M died. Toxic signs included severe depression, ptosis, ataxia, piloerection, a hunched posture, slow and shallow respiration, stained rough coats, mild diarrhea, black ano-genital stains, chromodacryorrhea, hypersensitivity to touch and sound, red stained body fur, hindleg weakness, tremors, prostration, diuresis, tail chewing, dyspnea, salivation, inactivity, head tilt, pale eyes and ears, red stains at the muzzle and cannibalistic behavior. Necropsy revealed dark-edged livers and spleens; blackened kidneys, black gelatinous-material in the GI tract; dark greenish-brown areas on the testes; pale areas on liver; enlarged spleens, small purple testes; dark-edged kidneys; GI tracts filled with a dark green or yellow fluid; GI tract filled with gas; reddened lungs; intestines bloated with gas; dark red GI mucosa; darkened spleens; pale, mottled livers; red or black fluid in the bladder; yellow peritonium, epididymides and testes; foamy red fluid in the trachea; a dark reddish-black fluid in the urinary bladder; 18/70 rats found in rigors. LD_{50} was 940 mg/kg, with confidence limits between 872 and 1014 mg/kg. All rats appeared throughout the test period in control group. No abnormalities at necropsy in control group.

Study Classification: Core Guideline Data. When used in conjunction with study number 2.

Toxicity Category: III-CAUTION

(2) Acute Oral Toxicity Study: Stauffer Chemical Company; Lab Report #T-10988; March 23, 1983.

Procedure: 5 groups consisting of 10 F rats each received one of the following doses: 600, 794, 900, 1000 or 1259 mg/kg. Observations made daily for 14 days after treatment. Necropsy performed on all animals. A total of 40 F rats were treated with water and served as a vehicle control.

Results: At 600 mg/kg, 1/10 F died; at 794 mg/kg, 1/10 F died; at 900 mg/kg, 8/10 died; at 1000 mg/kg, 1/10 F died; at 1259 mg/kg, 10/10 F died. Toxic signs included moderate to severe depression, piloerection, red facial stains, ataxia, chromodacryorrhea, prostration, diuresis, slow and shallow respiration, ptosis, vocalization upon touch, lacrimation, diarrhea, red stains at the

muzzle; brown ano-genital stains, cannibalistic behavior and inactivity. Necropsy revealed reddish-black fluid in the GI tract, darkened lungs; dark-edged liver; dark-edged spleen; reddened lungs; reddened GI mucosa; black solid material in the intestine; black spleen and kidneys; dark red and green fluid in the bladder; pale mottled livers with dark edges; reddish-yellow or greenish-yellow fluid in the GI tract; distended stomach and bladder; intestines filled with gas; yellow stained peritoneum; 29/50 rats were found in rigor. LD_{50} was 852 mg/kg, with confidence limits between 765 and 949 mg/kg. No toxic signs or abnormalities noted at necropsy of control of animals.

Study Classification: Core Guideline Data. When used in conjunction with study number 1.

Toxicity Category: III-CAUTION

(3) Acute Dermal Toxicity Study: Stauffer Chemical Company; Lab Report #T-10998; March 23, 1983.

Procedure: Five male and five female rabbits received 2000 mg/kg of the test material under occlusive wrap for 24-hour exposure. The skin was abraded on one-half the animals and intact on the other half of the animals. Observations made daily for 14 days after treatment. Necropsy performed on all animals. Two male and 2 female rabbits were sham-treated and served as controls.

Results: No mortalities. Moderate erythema and edema noted. No other toxic signs noted. No abnormalities at necropsy. LD_{50} greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

(4) Primary Dermal Irritation Study: Stauffer Chemical Company; Lab Report #T-10998; March 23, 1983.

Procedure: Six rabbits received 0.5 ml of the test material at intact and abraded skin sites per animal under occlusive wrap for 4 hours exposure. Observations were made at 4, 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 had erythema (6/6 = 1) and no edema. At 72 hours, 5/6 had slight erythema (5/6 = 1) and 1/6 severe erythema (1/6 = 4): Primary Irritation Score was 1.17.

Study Classification: Core Guideline Data.

Toxicity Category: IV-CAUTION

(5) Eye Irritation Study: Stauffer Chemical Company; Lab Report #T-10998; March 23, 1983.

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with water 20-30 seconds after treatment. Observations made at 1, 24, 48 and 72 hours, and at 4 and 7 days after treatment.

Results: At 24 hours, 6/6 animals of the unwashed group and 1/3 of the washed group had corneal opacity (6/6 = 20)(1/3 = 20); 4/6 + 1/3 iris irritation (4/6 = 5)(1/3 = 5); 6/6 & 3/3 conjunctive redness (5/6 = 2, 1/6 = 3)(3/3 = 2), chemosis (6/6 = 1)(3/3 = 1) and discharge (2/6 = 1, 3/6 = 2, 1/6 = 3)(2/3 = 1), 1/3 = 2).

At 7 days, 1/6 had corneal opacity (1/6 = 20), redness (1/6 = 2), chemosis (1/6 = 1) and discharge (1/6 = 3). At day 14, all irritation had subsided. Neovascularization also noted.

Study Classification: Core Guideline Data

Toxicity Category: II-WARNING

Molinate toxicology review

Page _____ is not included in this copy.

Pages 5 through 14 are not included in this copy.

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 product 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

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