

US EPA ARCHIVE DOCUMENT

100-775
7/12-5137

Date: August 15, 1983
Subject: EPA File Symbol 34704-EGO
Clean Crop Di-Mec Amine

From: Deloris F. Graham
FHB/TSS

005137

To: Richard Mountfort
Product Manager (23)

Applicant: Platte Chemical Co.
150 S. Main St.
Fremont, NE 68025

Active Ingredients:

Dimethylamine Salt of 2,4-Dichloro- phenoxyacetic acid.....	30.56%
Dimethylamine Salt of 2-(2-methyl -4-chlorophenoxy)propionic acid.....	16.34%
Dimethylamine Salt of Dicamba (3,6 -dichloro-o-anisic acid.....	2.77%
Inert Ingredients.....	50.33%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation and Acute Inhalation Studies. Studies conducted by Cannon Laboratories, Inc. Data under accession number 250465. Alternate method of support.

Recommendation:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.
2. The appropriate signal word is DANGER.

Label:

1. The statement "Keep out of reach of children must precede signal word.

Review:

1. Acute Oral Toxicity Study: Cannon Laboratories, Inc.; Project #2F-9035; February 23, 1983.

Procedure: Five groups consisting of 5M and 5F rats each received one of the following doses: 1,500; 2,000; 2,500; 3,000; 5,000 mg/kg. Observations were made at 1, 3 and 6 hours after treatment, then daily thereafter for 14 days. Necropsy performed on all animals.

Results: At 1,500, 2/5 M and 2/5 F died; at 2,000 mg/kg, 4/5 M and 3/5 F died; at 2,500 mg/kg, 5/5 M and 4/5 F died; at 3,000 mg/kg, 5/5 M and 5/5 F died; at 5,000 mg/kg, 5/5 M and 5/5 F died. Toxic signs included

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005137

piloerection, ptosis, sedation, decreased locomotor activity, ataxia, loss of righting reflex, and depressed respiration. Necropsy revealed lungs - congested; stomach - corrosion, irritation and enteritis; small and large intestine - enteritis. LD₅₀ for males was 1,620 mg/kg with confidence limits between 1,286 and 2,041 mg/kg. LD₅₀ for females was 1,720 mg/kg with confidence limits between 1,100 and 2,700 mg/kg. The male and female LD₅₀ combined was 1,650 mg/kg with confidence limits between 1,150 and 2,380 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

2. Acute Dermal Toxicity Study: Cannon Laboratories, Inc.; Project #2F-9038; February 7, 1983.

Procedure: Five male and five female New Zealand rabbits weighing between 2.30 to 2.52 kg received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations were made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Erythema and edema noted. No other toxic signs noted. No abnormalities at necropsy. LD₅₀ greater than 2 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

3. Acute Inhalation Toxicity Study: Cannon Laboratories, Inc.; Project #2F-9039; February 8, 1983.

Procedure: Five male and five female Sprague-Dawley rats weighing between 215 and 298 grams were exposed to an atmospheric concentration of 2.74 mg/l of the test material for 4 hours. Nominal concentration was 93.3 mg/l. Particle size was $3.39 \pm 0.57 \mu$. Chamber temperature was $85.5 \pm 3.0^\circ \text{F}$ and relative humidity was $79.0 \pm 10.9\%$. Observations made daily for 14 days post-exposure.

Results: One out of five males (1/5) died. Toxic signs included ptosis, blinking, roughening of coats, loss of righting reflex and short and rapid respiration. Some reduction in body weight in some animals, but animals had recovered and gained weight on day 14 with the exception of 1 F animal. Necropsy revealed congested lungs in six animals and congested nasal passages in one animal. LC₅₀ is greater than $2.74 \pm 0.55 \text{ mg/l}$.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

4. Eye Irritation Study: Cannon Laboratories, Inc.; Project #2F-9037; February 14, 1983.

2

005137

Procedure: Nine New Zealand rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed for one minute with lukewarm water twenty seconds after treatment. Observations made daily for 21 days.

Results: At 24 hours, 6/6 animals of the unwashed group and 3/3 animals of the washed group had corneal opacity (6/6=40) (1/3=30, 2/3=40); iris irritation (6/6=5) (3/3=5); conjunctive redness (6/6=2) (3/3=2), chemosis (2/6=1, 3/6=2, 1/6=3) (2/3=1, 1/3=2) and discharge (2/6=1, 4/6=2) (3/3=2).

At 7 days, 6/6 and 3/3 corneal opacity (2/6=5, 3/6=20, 1/6=30) (1/3=5, 1/3=10, 1/3=20); 4/6 and 1/3 iris irritation (4/6=5) (1/3=5); 6/6 and 3/3 redness (6/6=2) (2/3=2, 1/3=3); 5/6 and 1/3 chemosis (2/6=1, 3/6=2) (1/3=1); 5/6 and 1/3 discharge (2/6=1, 2/6=2, 1/6=3) (1/3=1).

At 14 days, 6/6 and 1/3 corneal opacity (3/6=5, 3/6=80) (1/3=10); 3/6 iris irritation (3/6=10); 6/6 redness (2/6=1, 4/6=2); 4/6 chemosis (2/6=1, 2/6=2); 5/6 discharge (1/6=1, 4/6=3).

At 21 days, 6/6 and 1/3 corneal opacity (3/6=5, 3/6=80) (1/3=10); 3/6 iris irritation (3/6=10); 6/6 redness (2/6=1, 4/6=2); 3/6 chemosis (3/6=1); 5/6 discharge (2/6=1, 3/6=2).

Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER

5. Primary Dermal Irritation Study: Cannon Laboratories, Inc.; Project #2F-9036; January 27, 1983.

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

Results: At 24 hours, 6/6 animals had slight erythema (6/6=1) and no edema. At 72 hours all irritation had cleared. Primary Irritation Index = 0.25.

Study Classification: Core Guideline Data.

Toxicity Category: IV-CAUTION

3

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Pages _____ through _____ are not included in this copy.

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