

Memorandum

Date: 5 August 1982

Subject: EPA File Symbol: 34704-ENT CLEAN CROP DIMETHOATE 400  
Caswell #358

From: B. T. Backus  
IRB/TSS

To: Mr. William Miller  
Product Manager 16

Applicant: Platte Chemical Co.  
P.O. Box 667  
Greeley, CO 80632

Active Ingredient:  
Dimethoate.....43.5%  
Inert Ingredients:.....56.5%

Background:

Product is proposed for a number of agricultural uses.

Comments and Recommendations:

1. The acute oral LD50, dermal LD50, primary eye and dermal irritation studies received 6-7-82 are acceptable and adequate in defining the short-term hazards of this product by these exposure routes.
2. The inhalation LC50 study will be acceptable, provided the particle size distribution data (used to calculate "particle size") are submitted. Also, is the term "particle size" as used in this report the same as "geometric mean (median) diameter?"
3. The following are recommended revisions in precautionary and statement of practical treatment labeling for this proposed product.

Labeling:

1. This product should be labeled "For Agricultural Use Only" if there is no intention of using child-resistant packaging.
2. "Keep Out of Reach of Children" should appear above the signal word WARNING on the front panel.
3. The IF SWALLOWED statement of practical treatment should be revised to something like the following:

IF SWALLOWED: Call a physician or Poison Control Center immediately.  
Gastric lavage is indicated if material was taken

internally. DO NOT INDUCE VOMITING EXCEPT UNDER MEDICAL SUPERVISION. Vomiting may cause aspiration pneumonia. If it is necessary to induce vomiting give victim one or two glasses of water and touch finger to back of throat. Do not induce vomiting or give anything by mouth to an unconscious or convulsing person.

4. The first two sentences of the NOTE TO PHYSICIAN should be revised to something like:

Atropine is antidotal only if symptoms of cholinesterase inhibition are present.

5. "Keep out of lakes, streams and ponds." should be revised to "Do not apply directly to water." The sentence: "Do not apply where these are important resources." is inappropriate, and should be deleted.

Review:

The following studies were conducted on the product as proposed for registration. Studies were conducted at Cannon Laboratories, Inc. P.O. Box 3627, Reading PA, 19605 and were received at EPA 6-7-82.

1. Acute Oral LD50 - Rat. Project No. 1F-8317; dated 11-30-81. In Acc. 247669.

Procedure: Following a range-finding study, groups of 5M, 5F SD rats received oral dosages of 300, 400, 500 and 600 mg/kg, administered as a 10% w/v suspension in corn oil, with subsequent 14-day observation.

Results:

Dosage Level (mg/kg)

300

400

500

600

Mortalities/Rats Dosed

M

F

0/5

0/5

2/5

2/5

4/5

5/5

5/5

5/5

Deaths occurred days 1-2.

Oral LD50 (M) = 428 (366-501) mg/kg

Oral LD50 (F) = 415 (346-498) mg/kg

combined = 420 (386-458) mg/kg.

Symptoms: tremors, sedation, exophthalmia, lacrimation, piloerection, salivation. All symptoms were gone in survivors after day 6. Some rats which died showed such effects as lung congestion and/or enteritis and/or distended stomachs. Post-sacrifice necropsies of survivors showed nothing remarkable.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. II

2. Acute Inhalation LC50 - Rat. Project No. 1F-8319; dated 12-4-81. In Acc. 247668.

Procedure: Groups of 5M, 5F SD rats were exposed for 4 hours to measured concentrations of 0.54, 1.10 and 1.98 mg/L, with subsequent 14-day observation. An initial group of 5M, 5F all died following exposure to a concentration of 2.18 mg/L.

Results:

Measured Concentration mg/L	Nominal Concentration mg/L	"Particle Size" u	Mortalities/Rats Exposed	
			M	F
0.54±0.07	6.7	1.18±0.33	0/5	0/5
1.10±0.28	17.3	1.06±0.23	4/5	5/5
1.98±0.09	46.7	1.48±0.01	5/5	5/5

Inhalation LC50 (M) = 0.91(0.59-1.41) mg/L

Inhalation LC50 (F) = 0.60(0.20-1.80) mg/L

Combined LC50 = 0.69(0.25-1.93) mg/L

Symptoms: ptosis, short and rapid respiration, exophthalmia, tremors, piloerection.  
Necropsies of mortalities: hemorrhagic and congested lungs; post-sacrifice necropsies of survivors: hemorrhagic spots in lungs.

Study Classification: Core Minimum Data, provided particle size distribution data are received.

Product Classification: (Tox. Cat. III)

3. Acute Dermal LD50 - Rabbit. Project No. 1F-8318; dated 11-30-81. In Acc. 247667.

Procedure: 5M, 5F NZ rabbits received a 24-hr occluded dermal exposure to a dosage level of 2 g/kg.

Results: No mortalities. Some erythema and/or edema at all skin sites, reported as clearing by day 3. However, stated that histopathology of skin application sites showed subchronic to chronic focal inflammation in 3 rabbits on day 14. No other symptoms noted.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

4. Primary Dermal Irritation - Rabbit. Project No. 1F-8320; dated 11-19-81. In Acc. 247666.

Procedure: 0.5 ml was applied to each of 4 sites, 2 intact, 2 abraded, on each of 6 rabbits, with 24-hr occluded dermal exposure.

Results: PDIS = -0.29, with all sites clear at 72 hrs.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. IV

5. Primary Eye Irritation - Rabbit. Project No. 1F-8321; dated 12-16-81. In Acc. 247665.

Procedure: 0.1 ml was applied to the conjunctival sac of one eye of each of 9 NZ rabbits. Three eyes were flushed with water for one minute starting 20 seconds after instillation.

Results: Corneal involvement in 6/6 unwashed, 3/3 washed eyes at 24 hrs. Still present in 2/6 unwashed eyes (but none of the washed eyes) at 7 days. Minimal opacity (area = 1, opacity = 1) still present in one eye on day 21.

Study Classification: Core Guidelines Data

Product Classification: Tox. Cat. II

*Byron T Backus*

08/05/82

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