435

009099

10/10/91

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 10182-GEG Eradicane25-G

From: Mark Perry, Biologist MJP 10-8-91
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head E 10/10/91
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: ICI Americas Inc.
Agricultural Products
Concord Pike & New Murphy Rd.
Wilmington, DE 19897

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): S-ethyl dipropylthiocarbamate	25.0
Inert Ingredient(s):	75.0
Total:	100%

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BACKGROUND

ICI Americas submitted an acute inhalation toxicity study for review. The product is Eradicane 25-G, a selective herbicide, and the active ingredient is S-ethyl dipropyl-thiocarbamate (EPTC) 25.0%. The study was performed by ICI Central Toxicology Laboratories and the MRID number is 419920-01.

RECOMMENDATION

The acute inhalation study, MRID number 419920-01, is unacceptable and has been graded supplementary. The study is unacceptable because the active ingredient comprised 12.1% of the total particulate atmosphere concentration during testing, yet the subject product contains 25% active ingredient. According to the study authors, this discrepancy may have been caused by the milling of the product which "resulted in unequal distribution of of active ingredient across the range of resultant particle sizes". Therefore, the larger particles, which were removed in the elutriation system, contained more active ingredient than the smaller particles.

Although this explanation may be correct, the material tested in this study does not represent the subject product, hence, additional acute inhalation data is required. Since the subject product inerts (EPTC technical impurities and [redacted]) have been sufficiently tested, toxicity data is needed for the active ingredient only. The Agency has acute inhalation data for EPTC technical on file which would satisfy this data gap (EPA Acc. No. 261729, see attachment). EPA Acc. No. 261729 resulted in an LC50 of 1.39 mg/L which places EPTC technical in inhalation toxicity category three. Therefore, the registrant may repeat the study with an acceptable percentage of active ingredient in the test atmosphere (i.e. 25%) or make the proper arrangements to cite EPA Acc. No. 261729, in which case Eradicane 25-G will be placed in inhalation toxicity category three.

LABELING

If the registrant properly cites EPA Acc. No. 261729 to support registration of the subject product, the following labeling will be appropriate:

[1] The precautionary statements should read as follows:

> Harmful if inhaled or absorbed through skin. Causes eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

[2] The statements of practical treatment should include the following:

If Inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably by mouth to mouth. Get medical attention.

ACUTE TOXICITY PROFILE

Acute Oral*	Category 4/Guideline
Acute Dermal*	Category 3/Minimum
Acute Inhalation	Category -/Supplementary
Eye Irritation*	Category 3/Guideline
Dermal Irritation*	Category 4/Guideline
Dermal Sensitization*	Negative /Guideline

* See M. Perry review, 6-25-91

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES/HED/SACB
TOX ONELINERS

TOXCHEM NO. 435- S-Ethyl dipropylthiocarbamate FILE LAST PRINTED: 08/19/91

CITATION	MATERIAL	ACCESSION/ MRID NO.	RESULTS	TOX CAT	COREGRADE/ DOCUMENT#
81-2 Acute Dermal LD50 Species: rabbit	R-1608 (Eptam 100% a.i.)		LD50 > 2.15 ml/kg (Mild irritation and mild erythema, which subsided in 4-6 days; no mortalities). Doses tested: 1.00 & 2.15 ml/kg.	3	000945
81-2 Acute Dermal LD50 Species: rabbit Raltech Sci. Services Lab 8/9/79	Eptam 87,8% a.i.		LD50 > 2 gm/kg (ODT). (No mortalities). NZW rabbits - 24 hr. exposure.	3	Guideline 000948
81-2 Acute Dermal LD50 Species: rabbit	Eptam 6E (77.1% a.i.)		LD50 > 4.64 gm/kg (HDT). (Severe erythema and edema, desquamation; no mortalities). Doses tested: 1000 & 4640 mg/kg.	3	000946
81-2 Acute Dermal LD50 Species: rabbit Interntl. Res. and Develop. Co 5/11/78	Banvel + Eradicane 6.7 EC		LD50 > 20 gm/kg (ODT). (Erythema & edema - no mortalities) NZW atr.		Minimum 000947
81-2 Acute Dermal LD50 Species: rabbit Stauffer Chemical T-10911; 5/12/82	Eptam 73.4%	248776	LD50 > 2000 mg/kg.	3	Guideline 004672
81-2 Acute Dermal LD50 Species: rabbit Wil Research Lab 13036; 12/18/84	EPTC Tech	261729	LD50 > 2000 mg/kg.	3	Guideline 005170
81-3 Acute Inhalation LC50 Species: rat	Eptam 6E (77.1% a.i.)		LC50 > 31.5 mg/L/1 hr. (HDT) (distress, lacrimation & ataxia, reddening and consolidation of the lungs; no mortalities). Doses: 7.1 & 31.5 mg/L.	4	000946
81-3 Acute Inhalation LC50 S...: rat 1... ics Inc. 420-1v53; 4/10/85	EPTC Tech.	261729	LC50 (combined) = 1.39 (0.97-2.00) mg/L/4 hr. (analytical).	3	Guideline 005170 005652

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CBI

009059

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: 25
MRID No.: 419920-01
Testing Laboratory: ICI Central Tox. Lab.
Author(s): A. P. Mould, K. O. Gibson
Species: Rat
Weight: 197-236 g
Source: Charles River
Test Material: EPTC 250g/kg formulation
Quality Assurance (40 CFR §100.12): Present

Reviewer: M. Perry
Report Date: 8-16-91
Report #: CTL/P/3419

Summary:

1. LC_{50} (mg/kg): Males = --
   Females = --
   Combined = --

2. The estimated LC_{50} is > 0.62 mg/L

3. Mean Concentration: ---

4. Tox. Category: -- Classification: Supplementary

Procedure (Deviation From §81-3): See recommendations

Results:

mg/l							
Nom Conc	Grav Conc	Analyt Conc	MMAD	GSD	Temp[C]	Hum%	Air Flow [l/m]
---	0.62	---	1.38	1.77	21-22	49-53	20

Reported Mortality

Exposure Concentration mg/L	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.62	0/5	0/5	0/10

Symptoms and Gross Necropsy Findings: All animals gained weight during the study. Clinical signs of toxicity include salivation, lachrymation, piloerection, and hunched posture. No significant treatment-related finding were observed during necropsy.

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INHALATION TOXICITY DATA SHEET

EPA REG.# 10182-GEG MRID# 419920-01

ANIMAL [RAT]	✓	
5/SEX/DOSE LEVEL	✓	
LIMIT TEST	✓	0.62 mg/ℓ
TYPE OF EXPOSURE	✓	4 hr, Nose-only
TEST MATERIAL DESCRIPTION	✓	Milled solid (Dust)
EXPOSURE TIME	✓	4hrs
EXPOSURE CHAMBER DESCRIPTION	✓	27.6 ℓ, Circular Nose-only chamber (2 tiered)
ATMOSPHERE GENERATION	✓	Wright's Dust feed
TEMP, HUMIDITY, & OXYGEN LEVELS	✓	
AIR CHANGES & FLOW	✓	25-30 changes / hr
CHAMBER CONC [METHOD, FREQ, ZONE]	✓	Grav
PARTICLE SIZES [DESCRIPTION & METHOD]	✓	Marple Cascade Impactor
MMAD & GSD	✓	
OBSERVATION PERIOD & FREQUENCY	✓	
BODY WEIGHT FREQUENCY & RESULTS	✓	All gained
MORTALITY CHART & LD-50	✓	No mortality
CLINICAL EXAM RESULTS	✓	
NECROPSY RESULTS	✓	