

5-19-92

09998

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 3125-96 / DEF Technical

From: Ian Blackwell, Biologist *CDZ 5/14/92*
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 5/19/92*
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: Mobay Corporation
Agricultural Chemicals Division
Box 4913
Kansas City, MO 64120

FORMULATION FROM LABEL:

<u>Active Ingredient(s)::</u>	<u>% by wt.</u>
S,S,S- Tributyl phosphorotrithioate	97
<u>Inert Ingredient(s):</u>	
	<u>3</u>
Total:	100%

BACKGROUND: Mobay Corporation has submitted an acute inhalation toxicity study in support of DEF Technical. The registrant had the study reconducted in order to change the inhalation toxicity category from II to III. The study was conducted by Mobay Corporation's Toxicology Department. The MRID number is 417823-01. The active ingredient content has been revised (letter September, 1990) from 92% to 97%.

The registrant has also proposed updated labeling for this product to conform with the 1984 proposed regulations and has provided MRID numbers for the acute toxicity battery supporting this product.

RECOMMENDATIONS: RSB/PRS findings are:

1. The acute inhalation toxicity study is graded guideline data and is acceptable to support the product.
2. RSB/PRS will not allow the registrant to cite acute toxicity data on a 92% formulation to support the 97% formulation. The registrant must submit an acute toxicity battery on the 97% formulation so that appropriate labeling can be determined.

LABELING

Note: The current precautionary labeling, including the signal word, may be inadequate. With the exceptions noted below, the labeling cannot be evaluated until data on the current formula is submitted.

1. Revise the precautionary statements as follows:

Add: "Harmful if inhaled." (Correct spelling of "inahled".)

2. The statements of practical treatment should be revised to:

"If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting in or give anything by mouth to an unconscious person."

"If on skin: Wash skin with plenty of soap and water. Get medical attention."

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

"If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention if irritation persists."

With the exception of the statements for inhalation exposure, these statements of practical treatment are based on revising the existing label statements to current equivalent EPA statements. Due to a lack of data on the current formulation (97% active ingredient), these labeling recommendations may be subject to further revision upon submission of the outstanding data.

3. The repeated administration of syrup of ipecac after only 10 minutes is contrary to the labeling on at least some ^{IPECAC} containers. Delete the statement concerning the 10-minute repeated administration on your label. Pesticide labeling should not contradict other products' labeling instructions.

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

Product Manager: 25
MRID No.: 417823-01

Reviewer: I. Blackwell
Report Date: 12/26/90
Report No.: 90-042-HQ (100593)

Testing Laboratory: Mobay Corporation, Corporate Tox. Dept.
Author(s): D. Warren

Quality Assurance (40 CFR §160.12): Included

Test Material: Technical Grade Def "clear, pale yellow liquid"
Concentration: 1.590, 2.920, 3.190, 5.690 and 6.030 mg/L
(analytical)

Species: Sprague-Dawley rats

Weight: 181-299 g

Age: 7 to 9 weeks

Sex: 18 males + 18 females

Source: Sasco, Inc.

Summary:

- LC₅₀ (mg/kg): Males = 4.650 mg/L (1410-6180)
Females = 2.460 mg/L (not determined)
Combined =
- Tox. Category: III Classification: guideline

Procedure (Deviation From §81-3):

Results:

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
Conc. = 1.6 MMAD = 1.40 um	---	1/6	1/6
Conc. = 2.9 MMAD = 1.51 um	1/6	3/6	4/12
Conc. = 3.2 MMAD = 1.55 um	---	6/6	6/6
Conc. = 5.7 MMAD = 1.45 um	4/6	---	4/6
Conc. = 6.0 MMAD = 1.46 um	5/6	---	5/6

Clinical observations: abnormal body position, abnormal lack of thirst, anorexia, apparent paralysis, ataxia, bloody urine, dyspnea, excitability, hypoactivity, increased vocalization, lacrimation, muscle tremors, nasal discharge; red ocular, oral and vaginal discharges; tremors, unthriftiness, urine stains and yellow eye discharge.

Gross necropsy observations: evidence of salivation and lacrimation; wet stained ventrum; reddened lungs, firm consistency of lungs, nasal staining, mottled red thymus, alopecia, reddened nasal bones, and self-disintegrating tissues.

PC Code 864

File Last Updated

Current date

11/22/91

Study/Study #/Animal/Lab Date	Material	MRID No.	Results	Tox. Cat.	Core Grade
acute inhalation toxicity/ 90-042-HQ / rat / Mobay Corporation Corporate Toxicology Department / 12-26-90	S,S,S- Tributyl phosphorotrithioate ...97%	417823- 01	males = 4.65 mg/L (1410-6180) females = 2.46 mg/L (not determined) analytical concs.	III	guide