6-27-91

862AA

008709

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: Bayleton 50% WP Fungicide [3125-320] and Bayleton 50% WP Fungicide in Water Soluble Packets [3125-340].

MJP 6.27.91

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

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

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Applicant: Mobay Corporation
P.O. Box 4913
Kansas City, Missouri 64120

FORMULATION FROM LABEL: [3125-320]

862AA

	% by wt.
Active Ingredient(s):	
1-[4-Chlorophenoxy]-3,3-dimethyl-1-[1H-1,2,4-triazol-1-yl]-2-butanone	50.0
Inert Ingredient(s):	50.0
Total:	100%

FORMULATION FROM LABEL: [3125-340]

	% by wt.
Active Ingredient(s):	
1-[4-Chlorophenoxy]-3,3-dimethyl-1-[1H-1,2,4-triazol-1-yl]-2-butanone	50.0
Inert Ingredient(s):	50.0
Total:	100%

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BACKGROUND The Mobay Corporation has submitted a primary eye irritation and a dermal sensitization [technical material] study for review. The products are Bayleton 50% WP Fungicide [3125-320] and Bayleton 50% WP Fungicide in Water Soluble Packets [3125-340], and the active ingredient, in both products, is 1-[4-Chlorophenoxy]-3,3-dimethyl-1-[1H-1,2,4-triazol-1-yl]-2-butanone [50%]. The product [3125-340] is identical to [3125-320] except it is contained in water soluble packets. The study was performed by Mobay and the MRID numbers are 417825-01 and 415540-01.

RECOMMENDATION The primary eye irritation and dermal sensitization studies have been found acceptable and graded core guideline.

[1] The test material was only slightly irritating to the eyes of the test animals, therefore, this product belongs in toxicity category four (4) for the eye.

LABELING

[1] The appropriate signal word is CAUTION.

[2] The precautionary statements should be revised as follows:

-Remove the "Causes eye irritation" statement

[3] The statements of practical treatment should read as follows:

IF SWALLOWED: Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash 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.

[4] The directions for use of syrup of ipecac included in the statements of practical treatment [If vomiting does not occur within 10 to 20 minutes, administer a second dose] must comply with the directions which appear on the ipecac label. The agency will not approve instructions for the use of syrup of ipecac which conflict with those instructions on the ipecac label.

ACUTE TOXICITY PROFILE

Acute Oral	Category 3
Acute Dermal	Category 3
Acute Inhalation	Category 3
Eye Irritation	Category 4/Guideline
Dermal Irritation	Category 4
Dermal Sensitization	Positive /Guideline

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 21
MRID No.: 417825-01
Testing Laboratory: Mobay Corp.
Author(s): L.P. Sheets
Species: Rabbit
Sex: 6 males
Weight: --
Source: Small Stock, Industries
Dosage: 0.1 ml [28 mg]
Test Material: Bayleton 50% WP
Quality Assurance (40 CFR §160.12): Present

Reviewer: M. Perry
Report Date: 5-27-91
Report No.: 90-335-GY

Summary:

1. **Toxicity Category:** 4

2. **Classification:** Guideline

Procedure (Deviations From §81-4):

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	0/6	0/6	0/6				
Iris	0/6	0/6	0/6	0/6				
Conjunctivae								
Redness	0/6	0/6	0/6	0/6				
Chemosis	1/6	0/6	0/6	0/6				
Discharge								

Comments: The test material was slightly irritating to the rabbit eye.

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EYE IRRITATION DATA SHEET

EPA REG.# 3125-320/340

MRID# 417825-01

ANIMAL [RABBIT]	✓	6 young adult males
DOSE VOLUME [0.1ml]	✓	28 mg
TEST MATERIAL DESCRIPTION	✓	undiluted, [redacted] w.p.
METHOD OF ADMINISTRATION	✓	conjunctival sac
DOSE CONC	✓	28mg (0.1ml) undiluted
OBSERVATION PERIOD & FREQUENCY	✓	1, 24, 48, 72 hrs post dose + 7 days
OBSERVATION METHOD	✓	Pre examined, light
EVALUATION RESULTS	✓	No corneal or iridal lesions, NO positive scores at 24 hrs

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: 21
MRID No.: 415540-01
Testing Laboratory: Mobay Corp.
Author(s): L.P. Sheets
Species: Guinea Pig
Weight: 248-314g
Source: Sasco, Inc.
Test Material: Technical Grade Triadimefon (Bayleton)
Positive Control Material: DNCB
Quality Assurance (40 CFR §160.12): Present

Reviewer: M. Perry
Report Date: 5-27-91
Report No.: 90-324EL

Method: Buehler

Summary:

1. **This Product is a dermal sensitizer.**

2. **Classification:** Guideline

Procedure (Deviation From §81-6): This study used a 24 hour challenge exposure.

Results: Dermal irritation scores ranging from grade zero to grade two were observed in the induced group 24 and 48 hours after challenge. No irritation was observed in the naive control group after challenge. The positive control study verified the test method employed.

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DERMAL SENSITIZATION DATA SHEET

EPA REG.# 3125-320/340

MRID# 415540-01

ANIMAL [GUINEA PIG]	✓	
POSITIVE CONTROL DESCRIPTION	✓	DNCB, Positive
TEST METHOD	✓	Buehler
PRE-SCREEN RESULTS	✓	1, 10, 50, 100% > No irritation
INDUCTION DESCRIPTION	✓	One 6hr exp/wk for 3 wks
EXPOSURE TIME	✓	Induc 6hrs Chall 24hrs
EXPOSURE SITES & PREP	✓	Induction: left shoulder Challenge: left hip
OCCLUSION	✓	
CHALLENGE DESCRIPTION	✓	24hrs
NAIVE CONTROLS	✓	5
INDUCTION RESULTS	✓	no irritation
CHALLENGE RESULTS	✓	test animals: 0-2 erythema naive control: no irritation