2-26-90

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES
February 26, 1990

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 3125-604 ; 3125-606 ; 3125-609
Folicur 3.6F ; Raxil 0.26F ; Raxil 2.6F

FROM: Olga Odiott OO E 3/6/90
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: Susan Lewis (PM 21)
Fungicide-Herbicide Branch
Registration Division (H75-05C)

APPLICANT: Mobay Corporation
Agricultural Chemicals Division
P.O. Box 4913
Kansas City, Missouri 64120

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.		
	3.6 %	0.26 %	2.6 %
α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol	38.7	3.0	28.3 %
Inert Ingredient(s):	61.3	97.0	71.7 %
Total	100.0%		

238(1)

BACKGROUND

Acute oral, acute dermal, primary eye irritation, skin irritation, skin sensitization and acute inhalation studies were submitted to support registration No. 3125-GOU, 3125-GOE and 3125-GOG (Folicur 3.6 F, Raxil 0.26 F and Raxil 2.6 F, respectively). The studies were conducted on Folicur 3.6 F. MRID No 412633-04 through 412633-09.

RECOMMENDATION

RSB/PRS finds the acute oral, acute dermal, primary eye irritation, skin irritation and skin sensitization studies acceptable to support registration of the three aforementioned formulations.

The acute inhalation study is considered supplementary data, therefore a new study must be submitted. The mass median aerodynamic diameter is higher than the 1.0 u required by the Agency. A Memo by Dr. Stanley Gross on inhalation toxicity testing is included for registrant reference.

LABELING

Precautionary statements:

Delete the statement "Causes eye injury."

Statements of practical treatment

Revise the "If swallowed" and "If on skin" statements as follows:

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or, if available, by administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconcious person.

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

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

Product Manager: (21)
MRID No.: 412633-04
Testing Laboratory: Mobay Corp.
Author(s): L. P. Sheets
Species: New Zealand white Rabbits
Sex: 2 mals, 4 females Weight:
Source:
Dosage: 0.1 ml
Test Material: Folicur, 3.6 Flowable
Quality Assurance (40 CFR §160.12): attached.

Reviewer: O. Odiott
Report Date: April 21, 1989
Report No. 98591

Summary:

Tox. Category: IV Classification: Guideline

Procedure (Deviation 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	0/6	0/6	0/6	0/6	—	—	—	
Discharge	1/6	0/6	0/6	0/6	—	—	—	

Comments:

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

Product Manager: (21)
MRID No.: 412633-05
Testing Laboratory: Mobay
Author(s): R.D. Shotsuka
Species: Sprague-Dawley Rats
Sex: 18 males, 18 females. Weight: 187 - 269 gm
Source: Sasco, Inc. Omaha, Nebraska.
Test Material: Folicur 3.6 Flowable
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: May 11, 1987
Report No. 99160

Summary:

1. LC_{50} (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LC_{50} is _____
3. Mean Concentration: _____
4. Tox. Category: _____. Classification: Supplementary

Procedure (Deviations From §81-2): MMAD greater than 1.0 μ;

Results:

Exposure Concentration (mg/L)	Reported Mortality (NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
3.909 (± .746 SD) mg/l	0/6	0/6	0/12
MMAD: 6.8 ± .4			
7.138 (± 1.370) mg/l	0/6	0/6	0/12
MMAD = 5.6 ± .4			

Symptomology & Gross Necropsy Findings:

Nasal discharge, ataxia and rough corneal zone were observed in females only. The signs cleared by day 2 post-exposure. Abnormalities were not observed at necropsy.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (21)
MRID No.: 412633-06
Testing Facility: Mobay Corp.
Author(s): L.P. Sheets.
Species: Sprague-Dawley rats
Age: 7-10 weeks of age
Weight: 203-359 gm
Source: SASCO, Inc. Omaha, Nebraska.
Test Material: Folicur 3.6 Flowable
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: May 16, 1989
Report No. 99161

Observation Days (Post Exposure): (14); other ( )

Conclusion:

1. LD_{50} (mg/kg): Males = 4154 mg/kg.; Females = 3162 mg/kg; Combined =
2. The estimated LD_{50} is
3. Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-1):

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
1000 mg/kg	—	0/5	0/5
2000 mg/kg	0/5	2/5	2/10
3500 mg/kg	1/5	—	1/5
5000 mg/kg.	4/5	3/5	8/10

Symptomology & Gross Necropsy Findings:

Lacrimation, urine stain, weight loss, decreased motor activity, salivation, and ataxia were observed. Hyperactivity, alopecia and tail bite were observed for some animals.

At gross necropsy, Ventrum / inguinal / perineal stain were observed. Nasal and oral stain were also observed. Red glandular stomach mucosa, discolored fluid in the stomach mucosa in non-glandular mucosa.

5

242

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (21)
MRID No.: 412433-07
Testing Laboratory: Mobay Corp
Author(s): L. P. Sheets
Species: New Zealand white rabbits.
Age: 33 weeks
Sex: one female, five males
Weight:
Dosage: 0.5 ml
Test Material: Folicur 3.6 flowable
Quality Assurance (40 CFR §160.12): attached.

Reviewer: O. Odiott
Report Date: May 4, 1989
Report No. 99162

Summary:

The Primary Irritation Index = 0.21

Toxicity Category: IV

Classification: Guideline.

Procedure (Deviations From §81-5):

Results:

Edema was not observed. Very slight erythema noted in 3/6 animals 1 hour after the exposure period and in 2/6 animals 24 hours after exposure. All symptoms cleared by 40 hours.

Special Comments:

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: (21)
MRID No.: 412633-08
Testing Laboratory: Mobay Corp.
Author(s): L. P. Sheets
Species: New Zealand white Rabbit
Sex: 6 males, 6 females Wt.: 2.17 - 2.42 kg.
Test Material: Folicur 3.6 Flowable
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: May 19, 1989
Report No. 99174

Summary:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____;
2. The estimated LD_{50} is >2,000 mg/kg.
3. Tox. Category: III. Classification: Guideline.

Procedure (Deviations From §81-2): _____

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
2000 mg/kg.	0/6	0/6	0/12

Symptomology & Gross Necropsy Findings:

Erythema was observed at the dose site for 10/12 animals white nasal discharge in 1/12 animals. No other symptoms observed. At necropsy, gross lesions were not found.

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

Product Manager: (21)
MRID No.: 412433-09
Testing Laboratory: Mobay Corp.
Author(s): L.P. Shultz
Species: Hartley albino guinea pig
Sex :
Source: Sasco, Inc. Madison, WI
Test Material: Folicur 3.6 flowable
Positive Control Material: DCNB - 0.1% w/v in 50% ethanol
Quality Assurance (40 CFR §160.12): attached.

Reviewer: O. Odiott
Report Date: Aug. 8, 1989
Report No. 99665

Weight: 308-383 gm

Method: Buehler's Closed-Patch Technique.

Summary:
1. This product is / is not a dermal sensitizer.
2. Classification: Guideline.

Procedure (Deviation From §81-6):

Results: Test substance was applied undiluted for a total of 3 induction periods. There were no signs of irritation in the animals. The positive control group was treated with DCNB and after the third induction period signs of irritation were absent. Upon challenge, no irritation was observed in the test group. Signs of sensitization were observed in the positive control group

8

295