31/MAR/1998

MEMORANDUM

Subject: EPA Reg. No: 4-389
DP Barcode: D241181, D241182, D241183*
Case No: 061466 061547 061468

From: Masih Hashim, Toxicologist/**s/masih hashim and jcr**
Technical Review Branch
Registration Division (7505C)

To: Linda Deluise, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Bonide Products, Inc.
2 Wurz Avenue
Yorkville, NY 13495

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
109701 Permethrin	4.0
067501 Piperonyl butoxide	4.0
Inert Ingredient(s):	92.0
Total:	100%

*Note: This memo only approves formulations up to 10% of each of the above active ingredients, consistent with the in-vivo studies (registrants letter 11-19-97).

BACKGROUND: Bonide Products has submitted a complete set of acute toxicity studies in support of Mosquito Beater 2-2. The MRID numbers are 444304-01 through 06. These studies were summarized by an Agency contractor, then revised and evaluated by TRB. All six studies were conducted at Product Safety Laboratories.

RECOMMENDATION:

Each of the six studies is acceptable in accordance with the Sub-Division F guidelines. The

acute toxicology profile for the File Symbol # 4-389 is as follows:

acute oral toxicity	IV	acceptable
acute dermal toxicity	IV	acceptable
acute inhalation toxicity	IV	acceptable
primary eye irritation	III	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	Not a sensitizer	acceptable

LABELING:

ID #: 000004-00389 MOSQUITO BEATER 2-2

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes or clothing.
Wear long-sleeved shirt and long pants, socks and shoes. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

NOTE TO PHYSICIAN:

The proposed label should contain a Note to Physicians. Some suggested types of information include the following:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological

effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

The proposed label should contain the following guidance:

May pose an aspiration pneumonia hazard

DATA EVALUATION REPORT

MOSQUITO BEATER 10-10

STUDY TYPES: ACUTE ORAL TOXICITY - RAT (81-1)
ACUTE DERMAL TOXICITY - RABBIT (81-2)
ACUTE INHALATION TOXICITY - RAT (81-3)
PRIMARY EYE IRRITATION - RABBIT (81-4)
PRIMARY DERMAL IRRITATION - RABBIT (81-5)
DERMAL SENSITIZATION - GUINEA PIG (81-6)

SUMMARY: ACUTE TOXICITY ONE-LINERS (81-1 through 81-6)

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831

Primary Reviewer:		
Susan Chang, M.S.	Signature:	/s/RH Ross for S Chang
	Date:	3/11/98
Secondary Reviewers:		
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.	Signature:	/s/H T Borges
	Date:	3/11/98
Robert H. Ross, M.S., Group Leader	Signature:	R H Ross
	Date:	3/11/98
Quality Assurance:		
LeeAnn Wilson, M.A.	Signature:	/s/Lee Ann Wilson
	Date:	3/11/98

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1, 870.1100)

Product Manager: 03
MRID No.: 44430401

Reviewer: Masih Hashim
Study Completion Date: October 31, 1997
Study No.: 5555

Testing Facility: Product Safety Labs
Author : Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Lot MB-10-10; amber liquid
Species: Rats; Sprague-Dawley
Age: Young adult
Weight: Males: 210-213 g; Females: 184-213 g

Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. LD_{50} (mg/kg):
   Males: >5000 mg/kg
   Females: >5000 mg/kg
   Combined: >5000 mg/kg
2. The estimated LD_{50} is >5000 mg/kg
3. Tox. Category: IV

Classification: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: Anogenital staining was noted in all rats between days 1and 2. All rats had normal body weight gains.

Gross Necropsy: Gross Necropsy findings were generally unremarkable.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 03
MRID No.: 44430402

Reviewer: Masih Hashim
Study Completion Date: November 7, 1997
Study No.: 5556

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Lot MB-10-10; amber liquid
Species: Rabbits; Albino, New Zealand White
Age: Young adult
Weight: Males: 2.5-2.6 kg; Females: 2.4-2.7 kg

Source: Davidson's Mill Farm, South Brunswick, NJ

Dermal LD_{50} Testing:

Conclusion:

1. LD_{50} (mg/kg):
   Males: >5000 mg/kg
   Females: >5000 mg/kg
   Combined: >5000 mg/kg
2. The estimated LD_{50} is >5000 mg/kg
3. Tox. Category: IV

Classification: Acceptable

Procedure (Deviations from §81-2): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: No animals died during the study. All rabbits were active and healthy throughout the study. Dermal irritation (erythema/edema) was noted at the site of test material application on days 1 through 6, 8, 9, 12, or 13. One female had decreased body weight during the first week of the study but recovered her initial weight by the termination of the study. All other animals had normal body weight gains.

Gross Necropsy: All tissues and organs appeared normal.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: 03
MRID No.: 44430403

Reviewer: Masih Hashim
Study Completion Date: November 7, 1997
Study No.: 5557

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Batch 10-FLA 10; amber liquid
Species: Rats; Albino, Sprague-Dawley
Age: Young adult
Weight: Males: 237-257 g; Females: 204-236 g

Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. LC_{50} (mg/L):
   Males: >2.05 mg/L
   Females: >2.05 mg/L
   Combined: >2.05 mg/L
2. The estimated LC_{50} is >2.05 mg/L
3. Tox. Category: IV

Classification: Acceptable

Procedure (Deviations from §81-3): None

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.05	0/5	0/5	0/10

Clinical Observations: No rats died during the study. Test material on the fur was noted upon removal of the rats from the exposure chamber and up to day 2 post exposure. All rats appeared active and healthy through out the study. All rats had normal body weight gains.

Gross Necropsy Findings: The gross necropsy findings were generally unremarkable.

Chamber Atmosphere		
Grav. Conc.	MMAD	GSD
2.05 mg/L	2.4 μm	1.73-1.82

Chamber Environment [a]	
Chamber Volume	150 L
Airflow	45.6 LPM
Temperature	69-70°F
Relative Humidity	50-57%

[a] Whole body

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 03
MRID No.: 44430404

Reviewer: Masih Hashim
Study Completion Date: 11-7-97
Study No.: 5558

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Lot MB-10-10; amber liquid
Dosage: 0.1 mL
Species: Rabbits; Albino, New Zealand White
Age: Adult
Weight: Not reported

Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:
1. Toxicity Category: III (Moderate irritant)
2. Classification: Acceptable

Procedure (Deviations from §81-4): None

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
	Unwashed eyes			
Corneal Opacity	0/6	0/6	0/6	0/6
Iritis	0/6	0/6	0/6	0/6
Conjunctivae:				
Redness	6/6	5/6	0/6	0/6
Chemosis	0/6	0/6	0/6	0/6
Discharge	0/6	0/6	0/6	0/6

Summary: All rabbits exhibited conjunctivitis one and 24 hours after test material instillation. Moderate to severe conjunctival redness on 6/6 rabbits at 1 hour; moderate conjunctival redness on 5/6 rabbits at 24 hours; and slight conjunctival redness on 3/6 rabbits at 48 hours was observed. Conjunctival chemosis in 3/6 rabbits and discharge in 5/6 rabbits was observed at 1 hour. The incidence and severity of irritation decreased thereafter. By 72 hours, all animals were free of any irritation.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 03
MRID No.: 44430405

Reviewer: Masih Hashim
Study Completion Date: November 7, 1997
Study No.: 5559

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Lot MB-10-10; amber liquid
Dosage: 0.5 mL
Species: Rabbits; Albino, New Zealand White
Age: Adult
Weight: Not reported

Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. Toxicity Category: IV (slight irritant)
2. Classification: Acceptable

Procedure (Deviations from §81-5): None

Results: PDIS = 1.0 (slight irritant). One hour after the patch removal, very slight erythema with slight edema on 5/6 rabbits and well defined erythema with slight edema on 1/6 rabbits were present. By 24 hours, 3/6 rabbits had very slight erythema with slight edema, and one rabbit had slight erythema with very slight edema. Two rabbits had very slight erythema at 48 hours. All rabbits cleared of any irritation by 72 hours.

Special Comments: None

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 03
MRID No.: 44430406

Reviewer: Masih Hashim
Study Completion Date: November 7, 1997
Study No.: 5560

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included

Test Material: Mosquito Beater 10-10; Lot MB-10-10; amber liquid
Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)
Species: Guinea pigs; Albino, Hartley
Age: Young adult
Weight: Males: 294-398 g
Source: Davidson's Mill Farm, South Brunswick, NJ
Method: Buehler

Conclusion:

1. There is no indication that this product is a dermal sensitizer.
2. Classification: Acceptable

Procedure (Deviations from §81-6): None

Procedure: For the induction phase, 0.4 mL of the test material (50% w/w in mineral oil) was applied under occlusion for six hours once each week for three weeks. Guinea pigs were left untreated for thirteen days before challenge. The animals were challenged with 0.4 mL of the test material (50% w/w in mineral oil) under occlusion at naive sites for 6 hours.

A naive control group was treated with the test material (50% w/w in mineral oil) at challenge only.

The positive control animals were induced with 0.4 mL of 0.08% DNCB in 80% ethanol and challenged with 0.4 mL of 0.04% DNCB in acetone using the same procedures as for the test animals.

Reactions were scored at 24 and 48 hours post exposure.

Results: Very faint erythema was present on 4/10 rabbits after the first induction. After the second induction, 6/10 and 2/10 rabbits had very faint and faint erythema, respectively. Following the third induction, all rabbits exhibited very faint to moderate erythema and desquamation was noted on 3/10 rabbits. Very faint erythema was present on 5/10 rabbits 24 and 48 hours following challenge. Very faint erythema was noted on 4/5 and 2/5 naive control rabbits at 24 and 48 hours following test material application.

The positive control rabbits had very faint to severe erythema with eschar following each induction. Twenty-four hours after challenge, very faint and faint erythema were present on 2/10 and 8/10 positive control rabbits. By 48 hours, 3/10 and 7/10 positive control rabbits had very faint and faint erythema. Very faint erythema was seen on 2/5 positive naive control rabbits at

48 hours.

The test substance is not considered as a dermal sensitizer.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D241181
2. PC CODE: 109701, 067501
3. CURRENT DATE: March 3, 1998
4. TEST MATERIAL: Mosquito Beater 10-10

109701 Permethrin 10%
067501 Piperonyl butoxide 10%
[redacted] solvent 80%

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity rat/Product Safety Labs, 5555/10-31-97	444304-01	LD_{50} >5000 mg/kg (males, females, combined)	IV	A
Acute dermal toxicity rabbit/Product Safety Labs, 5556/11-7-97	444304-02	LD_{50} > 5000 mg/kg (males, females, combined)	IV	A
Acute inhalation toxicity rat/Product Safety Labs, 5557/11-7-97	444304-03	LC_{50} > 2.05 mg/L (males, females, combined)	IV	A
Primary eye irritation rabbit/Product Safety Labs, 5558/11-7-97	444304-04	Moderate irritant; conjunctival redness in 3/6 rabbits through 48 hours.	III	A
Primary dermal irritation rabbit/Product Safety Labs, 5559/11-7-97	444304-05	Slight irritant; very slight erythema on 2/6 rabbits at 48 hours, cleared by 72 hours.	IV	A
Dermal sensitization guinea pig/Product Safety Labs, 5560/11-7-97	444304-06	Not a sensitizer	--	A

Core Grade Key: A =Acceptable