

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

FEB 2 1990

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 62673-R  
BMP 144 (2X)

FROM: Mary L. Waller *Mary Waller* *E 2/2/90*  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H75-05C)

TO: Phil Hutton (PM 17)  
Insecticide-Rodenticide Branch  
Registration Division (H75-05C)

APPLICANT: Becker Microbial Products  
9464 NW 11<sup>th</sup> Street  
Plantation, FL 33322

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
<u>Bacillus thuringiensis var. israelensis</u>	<u>1.27%</u>
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Inert Ingredient(s):	<u>98.87%</u>
Total	100.0%

PC 24-82-

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BACKGROUND: The applicant has submitted an acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation, and dermal sensitization studies. The studies were conducted by Cosmopolitan Safety Evaluation, Inc. The MPID numbers are 412220-02 through -07.

RECOMMENDATION: RSB/PRS finds the data acceptable if the product tested is the same as that for which registration is sought. The registrant should verify in writing that BMP 144(2X) (62673-R) is the same as BMP 144 (product tested). PRS wants to make certain that the product as formulated was tested and not a dilution.

The dermal sensitization study was classified as core minimum data. In future studies, the laboratory should include the data on the positive control which should be conducted approximately every six months

LABELING: Revise the label as follows:

1. The label should include a referral statement if the precautionary statements and the statements of practical treatment do not appear on the front panel. The following is an example of such a statement: "See additional precautionary statements and statements of practical treatment on side/back panel."

2. The heading "Directions for Use" currently appears at the end of the actual directions. Delete the heading "Application Directions" and move the heading "Directions for Use" and the misuse statement into that space.

3. Revise the precautionary statements as follows:

"CAUTION. Harmful if inhaled or absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

4. Add the heading "Statements of Practical Treatment" and information as follows:

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

BMP 144 (2X)  
High Potency Biological Larvicide  
Aqueous Suspension

ACTIVE INGREDIENT: Bacillus thuringiensis var. israelensis,  
1200 International Units (ITU) per milligram (Equivalent to  
4.84 billion ITU/gallon; 1.28 billion ITU/liter).....1.2%  
INERT INGREDIENTS.....98.8%

KEEP OUT OF REACH OF CHILDREN

CAUTION

BMP 144 (2X) is a highly selective microbial insecticide effective against mosquitoes and blackflies in a variety of habitats.

APPLICATION DIRECTIONS

MOSQUITOES

<u>habitat</u>	<u>Rate Required for Control</u>
Flood water, roadside ditches, irrigation ditches, rice fields, pastures, woodland pools, snow melt pools.....	0.25-0.5 pts./A
Tidal water, salt marshes, catch basins, storm water retention areas.....	0.50-1.0 pts/A
Polluted water (sewage lagoons etc.), water with moderate organic matter, and water with a high concentration of suspended solids.....	1.0-2.0 pts/A

.....  
Specific Application Instructions: BMP 144 (2X) may be applied in conventional aerial and ground application equipment with sufficient water to provide thorough coverage of the target area. The amount of water needed will be dependent on weather, type of spray equipment and mosquito habitat.

Ground applications should be made in 5-100 gallons per acre in conventional equipment. As low as one gallon per surface area can be used when the target area is open with a light vegetative cover.

Aerial applications may be done diluted or undiluted. For undiluted applications, apply 0.2 to 2.0 pts/A of BMP 144 (2X) through fixed wing aircraft or helicopters equipped with conventional boom and nozzles or rotary mist atomizers. For diluted applications, fill the mix tank or aircraft hopper with the appropriate volume of water and agitate before adding BMP 144 (2X). Maintain agitation during loading and spraying.

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BLACKFLIES

SUGGESTED CONCENTRATION RANGE.....0.5-0.75 PPM  
(0.5-0.75 mg/liter  
of stream water)

The concentration should be maintained in the stream for 15 minutes. If shorter dosage times are required use a higher rate of BMP 144 (2X) to maintain effective concentration.

Specific Application Instructions: Apply with conventional ground and aerial application equipment or metered release systems from infested sites to achieve larvicidal concentrations. Insecticidal activity should occur within 24 hours. Reapply as needed. BMP 144 (2X) may be applied undiluted through appropriate ULV application equipment.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS:

Avoid inhalation or contact with the eyes or open wounds. As a precautionary measure in case of contact, flush eyes or open wound with water. In case of irritation, contact a physician.

DIRECTIONS FOR USE: General Classification. It is a violation of federal law to apply this product in a manner inconsistent with its labeling. BMP 144 (2X) may be applied to any water sites except treated, finished drinking water reservoirs or drinking water receptacles. Since the active ingredient in BMP 144 (2X) is exempt from the requirement of a tolerance on all raw agricultural commodities, applications to irrigation water are permissible.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a cool dry place.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent), then puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke. Do not reuse container.

**NOTICE TO USER**

Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with label instructions.

ECKER MICROBIAL PRODUCTS, INC.  
9464 N.W. 11th Street  
Plantation, Florida 33322

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

Product Manager: (17) Reviewer: M. Waller  
 MRID No.: 412220-02 Report Date: 12/20/88  
 Testing Facility: Cosmopolitan Safety Evaluation, Inc. Report No. A1917  
 Author(s): Geoffrey Robbins  
 Species: Albino rats (Sprague-Dawley derived)  
 Age: Young Adult Observation Days (Post  
 Weight: ♂ = 240-340 g, ♀ = 200-300g Exposure): (14); other ( )  
 Source: Laboratory colony  
 Test Material: Bacillus thuringiensis var. israelensis (BMP 144)  
 Quality Assurance (40 CFR §160.12): attached

Conclusion:

1. LD50 (mg/kg): Males = \_\_\_\_\_; Females = \_\_\_\_\_; Combined = \_\_\_\_\_
2. The estimated LD50 is > 5.0 g/kg
3. Tox. Category: IV. Classification: Guideline

Procedure (Deviations From §81-1): None

Results:

Reported Mortality

DOSAGE ( /kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
<u>5.0 g/kg</u>	<u>0/5</u>	<u>0/5</u>	<u>0/10</u>

Symptomology & Gross Necropsy Findings:

No toxic symptoms or abnormalities upon necropsy  
were noted.

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

Product Manager: ( 17 ) Reviewer: M. Waller  
 MRID No.: 412220-03 Report Date: 12-22-88  
 Testing Laboratory: Cosmopolitan Safety, Evaluation, Inc. Report No. B1917  
 Author(s): Geoffrey Robbins  
 Species: albino rabbit  
 Sex: 5 ♂ and 5 ♀ Wt.: 2.5-3.5 Kg  
 Test Material: Bacillus thuringiensis var israelensis (BMP 144)  
 Quality Assurance (40 CFR §160.12): attached

Summary:

1. LD50 (mg/kg): Males = \_\_\_\_\_; Females = \_\_\_\_\_; Combined = \_\_\_\_\_;
2. The estimated LD50 is > 2.0 g/kg
3. Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

DOSAGE ( /kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0 g/kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

Animals exhibited very slight erythema and edema at test site. No other toxic symptoms were exhibited. No abnormalities were noted at necropsy.

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

Product Manager: ( 17 )  
 MRID No.: 412120-04  
 Testing Laboratory: Cosmopolitan Safety Evaluation, Inc.  
 Author(s): Geoffrey Robbins  
 Species: rats (Sprague-Dawley derived)  
 Sex: 5 ♂ and 5 ♀  
 Source: laboratory colony  
 Test Material: Bacillus thuringiensis var. israelensis (BMP-144)  
 Quality Assurance (40 CFR §160.12): attached

Reviewer: M. Waller  
 Report Date: 1-27-89  
 Report No. C1917

Summary:

1. LC50 (mg/kg): Males = \_\_\_\_\_; Females = \_\_\_\_\_; Combined = \_\_\_\_\_
2. The estimated LC50 is > 2.1 mg/L
3. Mean Concentration: 2.1 mg/L
4. Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-2): none

Results:

Exposure Concentration (mg/L)	Reported Mortality (NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.1 mg/L	0/5	0/5	0/10
MMAD 0.72 μ at 1 hr. 11 min			
MMAD 1.3 μ at 2 hrs. 40 min.			

Symptomology & Gross Necropsy Findings:

At end of exposure, animals exhibited slight brown stain on dorsal surface and at nostril area. Animals appeared normal one hour later. No ~~toxic~~ toxic symptoms were observed.

No abnormalities were noted at necropsy.

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

Product Manager: ( 17 )  
 MRID No.: 412220-05  
 Testing Laboratory: Cosmopolitan Safety Evaluation, Inc.  
 Author(s): Geoffrey Robbins  
 Species: albino rabbits  
 Sex: 2 ♂ and 4 ♀ Weight: 2.0-3.5 Kg  
 Source: laboratory colony  
 Dosage: 0.1 ml  
 Test Material: Bacillus thuringiensis VAR. israelensis (BMP-144)  
 Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller  
 Report Date: 12-8-88  
 Report No. D1917

Summary:

Tox. Category: IV Classification: Guideline

Procedure (Deviation From §81-4): none

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	/	/	/	/				

Comments:

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

Product Manager: ( 17 )  
MRID No.: 412220 - 06  
Testing Laboratory: Cosmopolitan Safety Evaluation, Inc.  
Author(s): Geoffrey Robbins  
Species: Adult Albino Rabbits  
Age: Young Adult  
Sex: 2 ♂ and 4 ♀  
Weight: 2.0 - 3.5 Kg  
Dosage: 0.5 ml  
Test Material: Bacillus thuringiensis var. israelensis (BMP-144)  
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller  
Report Date: 12-8-88  
Report No. E1917

Summary:

The Primary Irritation Index = 0.0

Toxicity Category: IV

Classification: Guideline

Procedure (Deviations From §81-5): None

Results:

No irritation was observed.

Special Comments:

