US EPA ARCHIVE DOCUMENT

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

7/19/1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 11540-1 / ULD BP-300 Insecticide

From: Ian Blackwell, Biologist IDB 7/18/94
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

To: Richard Mountfort, PM 10
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head Thomas C. Ellwanger for 7-19-94
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

Applicant: Micro-Gen Equipment Corporation
10700 Sentinel Drive
San Antonio, Texas 78217

FORMULATION FROM LABEL:

Active Ingredient(s)::	% by wt.
Pyrethrins	3.00
Piperonyl butoxide, Technical	6.00
N-Octyl bicycloheptene dicarboximide	10.00
Inert Ingredient(s):	81.00
Total:	100.00%

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

BACKGROUND: Micro-Gen Corporation has submitted a dermal sensitization in support of "ULD BP-300". This study was submitted as 6(a)2 data. It was conducted by Hazleton Wisconsin. The MRID number is 430940-1. PRS was not able to locate any previous acute toxicity reviews for this product.

RECOMMENDATIONS:

1. The dermal sensitization study is classified core-guideline data and is acceptable to support the registration of the product.

2. PRS requests that the registrant cite or submit acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation and primary skin irritation studies in support of reg. no. 11540-1.

The acute toxicity profile for reg. no. 11540-1 is currently:

acute oral toxicity	REQUESTED	
acute dermal toxicity	REQUESTED	
acute inhalation toxicity	REQUESTED	
primary eye irritation	REQUESTED	
primary skin irritation	REQUESTED	
dermal sensitization	Sensitizer	guideline

LABELING:

The following should be added to the precautionary statements:

"Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

Due to a lack of data, PRS is unable to comment on other precautionary statements or on statements of practical treatment. Judging from the data submitted in this dermal sensitization study, it appears that (under the conditions of this study) Isopar M and/or 7731W24-2 have the potential to evoke an allergic dermal reaction when used as a challenge agent. While this may imply that an individual that is sensitized to ULD BP-300 may then also be sensitized to Isopar M or 7731W24-2, PRS feels that it is not in good judgement to include a precautionary statement warning users of potential sensitization to either of these two inert ingredients. Such a statement would probably be too broad and may not apply to other products containing either of these two inert ingredients.

Statements on the submitted label found under the precautionary statements pertaining to pesticide application and exposure of food and animals should be moved to the directions

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

Product Manager: 10
MRID No.: 430940-01

Reviewer: I. Blackwell
Study Completion Date: 6/18/93
Lab Project No.: HWI 30202518

Testing Laboratory: Hazleton Wisconsin, Inc.
Author: Steven M. Glaza

Quality Assurance (40 CFR §160.12): Included

Test Material: ULD BP-300; Lot no. ETA 352, clear, "dark-yellow liquid"
Positive Control Material: DNCB

Species: young adult guinea pigs, Crl:(HA)BR strain
Weight: 444-548 grams
Sex: all males
Source: Charles River Laboratories, Inc.
Age: young adult

Method:

Summary:

1. **This Product is a dermal sensitizer.**
   ☞Animals treated with the test material also displayed sensitization to Isopar M and 7731W24-2.

2. **Classification:** core-guideline

Procedure (Deviation From §81-6):

Procedures: The test material concentrations were applied in volumes of 0.4 mL in Hill Top Chambers. The test material was screened at 25%, 50%, 75% and undiluted in mineral oil. The test material was administered undiluted for induction and at 75% in mineral oil for challenge. The test animals received one application per week over three weeksfor a total of three induction treatments. A second challenge dose was conducted 10 days following the initial challenge application to determine the sensitizing potential of two additional test materials (Isopar M and 7731W24-2).

Results:

Induction Applications						
Animal No.	1		2		3	
	24 hr.	48 hr.	24 hr.	48 hr.	24 hr.	48 hr.
6649	0	0	1	1	2	2
6650	0	0.5	0.5	1	2	1
6651	0	0	1	1	2	2
6652	0	0.5	1	2	2	2
6653	0.5	0.5	1	1	3	1
6654	0	0	2	2	2	2
6655	0	0.5	2	2	3A	2
6656	1	1	2	2	3	2
6657	0	0	1	1	3	2
6658	1	1	2	2	2	2

A-subcutaneous hemorrhage

Challenge						
	Test material		7731W24-2		Isopar M	
Animal Number	24 hours	48 hours	24 hours	48 hours	24 hours	48 hours
6649	2	2	1	1	0	1
6650	2	1	1	1	0	0.5
6651	2	2	0	0.5	0	0.5
6652	2	2	2	2	0	1
6653	3	1	1	2	0	2
6654	2	2	0.5	0	0	0
6655	3A	2	0.5	1	0	1
6656	3	2	1	2	0	1
6657	3	2	2	2	0	1
6658	2	2	0	1	0	1

Naive Challenge						
	Test material		7731W24-2		Isopar M	
Animal Number	24 hr.	48 hr.	24 hr.	48 hr.	24 hr.	48 hr.
6659	0	0	0	1	0	0.5
6660	0	0	0	0.5	0	0
6661	0	0	0	0	0	0.5
6662	0	0	0	0.5	0	0.5
6663	0.5	0	0	0	0	0.5
6664	0.5	0	0	0.5	0	0.5
6665	0	0	0	0	0	0.5
6666	0.5	0.5	0	0	0	0.5
6667	0	0	0.5	0.5	0	0.5
6668	0	0	0.5	0.5	0.5	0.5

0 no reaction
0.5 very faint erythema, usually nonconfluent
1 faint erythema, usually confluent
2 moderate erythema
3 strong erythema, with or without edema

Twenty-four hours after induction treatment #1, 1/4 positive control animals displayed moderate erythema and 3/4 very faint, usually nonconfluent erythema. Twnety-four hours after challenge with the positive control, 2/4 positive control animals displayed strong erythema and 2/4 displayed moderate erythema.

ACUTE TOX ONE-LINER

1. PC CODE: 063503, 057001, 067501, 069001

2. CURRENT DATE: July 18, 1994

3. TEST MATERIAL:

Pyrethrins	3.00%
Piperonyl butoxide, Technical	6.00%
N-Octyl bicycloheptene dicarboximide	10.00%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
dermal sensitization / guinea pig / Hazleton Wisconsin / HWI 30202518 / 6-18-93	430940-01	This product is a dermal sensitizer. The product also sensitized the test animals to Isopar M and 7731W24-2.	—	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary