



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  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H7505W)

QDB 7/18/94

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

Thru: Thomas C. Ellwanger, Section Head  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H7505W)

Thomas C. Ellwanger /  
Wms /  
for 7-19-94

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

FORMULATION FROM LABEL:

Active Ingredient(s)::

Pyrethrins  
Piperonyl butoxide, Technical  
N-Octyl bicycloheptene dicarboximide

Inert Ingredient(s):

% by wt.

3.00

6.00

10.00

81.00

Total:

100.00%



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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

**Age:** young adult

**Sex:** all males

**Source:** Charles River Laboratories, Inc.

**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 weeks for 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     |               |          |           |          |          |          |
|---------------|---------------|----------|-----------|----------|----------|----------|
| Animal Number | Test material |          | 7731W24-2 |          | Isopar M |          |
|               | 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. Twenty-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/<br>Study#/Date                                                        | MRID No.  | Results                                                                                                               | Tox.<br>Cat. | Core<br>Grade |
|------------------------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------|--------------|---------------|
| dermal sensitization /<br>guinea pig / Hazleton<br>Wisconsin / HWI 30202518 /<br>6-18-93 | 430940-01 | This product is a dermal sensitizer.<br>The product also sensitized the test<br>animals to Isopar M and<br>7731W24-2. | —            | G             |

Core Grade Key:

G = Guideline

M = Minimum

S = Supplementary