DATA EVALUATION RECORD
HONEY BEE - ACUTE CONTACT LC₅₀ TEST
§141-1

1. CHEMICAL: Penoxsulam
   PC Code No.: 199031

2. TEST MATERIAL: GF-443
   Purity: 21.9%

3. CITATION:

   Author: R. Hahne and J. Aufderheide
   Title: GF-443: Acute Contact Toxicity Test with the Honeybee
   (Apis mellifera)
   Study Completion Date: July 10, 2002
   Laboratory: ABC Laboratories
   7200 E. ABC Lane
   Columbia, Missouri 65202
   Sponsor: The Dow Chemical Company
   Midland, MI for
   Dow AgroSciences LLC
   Indianapolis, IN 46268
   Laboratory Report ID: ABC Study No. 47288/Dow Study No. 021046
   DP Barcode: D288160
   MRID No.: 45831126

4. REVIEWED BY: Rebecca Bryan, Staff Scientist, Dynamac Corporation
   Signature: 
   Date: 12/29/03

   APPROVED BY: Dana Worcester, Staff Scientist, Dynamac Corporation
   Signature: 
   Date: 12/29/03

5. APPROVED BY: Bill Erickson
   Signature: 
   Date: 12/29/03

   James J. Goodyear, Ph.D.
   Ecological Effects Biologist
   Office of Pesticide Programs
   703-305-7726

   Date: 12/29/03
6. STUDY PARAMETERS:

   **Scientific Name of Test Organism:** *Apis mellifera*

   **Age or Size of Test Organism at Test Initiation:** Not reported

   **Type of Concentrations:** Nominal

   **Definitive Study Duration:** 48 hours

7. CONCLUSIONS:

   **[Penoxsulam end-use product] GF-443: Acute Contact Toxicity Test with the Honeybee (Apis mellifera)**

   The honey bee, *Apis mellifera*, was exposed to GF-443 for 48 hours, at nominal concentrations of 0.1, 1.0, 10, and 100 μg a.i./bee. Since GF-443 is only 21.9% a.i., penoxsulam, the test concentrations were 0.02, 0.22, 2.19, and 21.9 μg a.i./bee. The LD₅₀ was >22 μg a.i./bee. Since there were deaths at lower dose levels, the NOAEC could not be determined. This study is scientifically sound but does not fully satisfy the EFED guideline requirements for a contact toxicity test with honey bees (§141-1 or 850.3020).

   Since the analytical measurements were not reported for the test concentrations, the solvent was not properly identified and the NOAEC could not be determined. The highest dose was 21.9 μg a.i./bee, not >100 μg a.i./bee as reported.

   **Reviewer’s Statistical Results:**
   
   LD₅₀: >21.9 μg a.i./bee 95% C.I.: N/A
   NOAEC: cannot be calculated Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

   **A. Classification:** This acute contact study is classified as **Supplemental but need not be repeated**.

   **B. Rationale:** The nominal study levels were made from a 21.9% standard. The analytical measurements were not reported for the test concentrations, the solvent was not properly identified and the NOAEC could not be determined. The highest dose was 21.9 μg a.i./bee, not >100 μg a.i./bee as reported.

   **C. Repairability:** None
9. GUIDELINE DEVIATIONS:

The age of honey bees at study initiation was not reported.
The test chemical was not technical grade Penoxsulam.
The highest dose was 21.9 µg a.i./bee, not >100 µg a.i./bee.
The LD$_{50}$ could not be calculated.
The solvent was not identified by chemical.

10. SUBMISSION PURPOSE: This study was submitted to provide data on the acute contact
toxicity of GF-443 to honeybees for the purpose of chemical registration.

11. MATERIALS AND METHODS:

A. Test Organisms

<table>
<thead>
<tr>
<th>Guideline Criteria</th>
<th>Reported Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species:</td>
<td>Apis mellifera</td>
</tr>
<tr>
<td>Age at beginning of test:</td>
<td>Not reported</td>
</tr>
<tr>
<td>Supplier:</td>
<td>Gibbons Honey Farm, Rocheport, Missouri</td>
</tr>
<tr>
<td>All bees from the same source?</td>
<td>Yes, from a single, disease-free colony.</td>
</tr>
</tbody>
</table>

B. Test System

<table>
<thead>
<tr>
<th>Guideline Criteria</th>
<th>Reported Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cage size adequate?</td>
<td>The cages were plastic and screened. Cages are 14-cm wide x 20-cm long x 10-cm high.</td>
</tr>
<tr>
<td>Lighting:</td>
<td>Continuous darkness except at observation periods.</td>
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<tr>
<td>Temperature:</td>
<td>24-26°C</td>
</tr>
<tr>
<td>Relative humidity:</td>
<td>50-62%</td>
</tr>
</tbody>
</table>
C. Test Design

<table>
<thead>
<tr>
<th>Guideline Criteria</th>
<th>Reported Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range finding test?</td>
<td>No range-finding test was reported.</td>
</tr>
<tr>
<td>Reference toxicant test?</td>
<td>A reference toxicant test was conducted with dimethoate at concentrations of 0.020, 0.20, and 0.40 ( \mu \text{g a.i./bee} ). The 24-hour ( \text{LD}_{50} ) was 0.072 ( \mu \text{g a.i./bee} ) with 95% confidence limits of 0.062 to 0.084 ( \mu \text{g a.i./bee} ).</td>
</tr>
<tr>
<td>Method of administration:</td>
<td>The test substance was diluted with Tween 80. 1 ( \mu \text{L} ) of the test substance suspension was applied to the dorsal thorax of each bee.</td>
</tr>
<tr>
<td>Nominal doses:</td>
<td>0.10, 1.0, 10, and 100 ( \mu \text{g a.i./bee} )</td>
</tr>
<tr>
<td>Calculated doses</td>
<td>0.02, 0.22, 2.19, 21.9 ( \mu \text{g a.i./bee} )</td>
</tr>
<tr>
<td>Controls:</td>
<td>Negative and Vehicle (15% Tween 80) controls</td>
</tr>
<tr>
<td>Number of colonies per group:</td>
<td>3 replicates (control and 22 ( \mu \text{g a.i./bee} ) treatment group) and 1 replicate (0.02, 0.22, and 2.19 ( \mu \text{g a.i./bee} ) treatment groups); 10 bees/replicate</td>
</tr>
<tr>
<td>Solvent:</td>
<td>15% Tween 80 (vehicle control) not identified</td>
</tr>
<tr>
<td>Feeding:</td>
<td>500 g/L (w/v) sucrose solution was provided \textit{ad libitum}.</td>
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<tr>
<td>Observations period:</td>
<td>48 hours</td>
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</tbody>
</table>

12. REPORTED RESULTS:

<table>
<thead>
<tr>
<th>Guideline Criteria</th>
<th>Reported Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assurance and GLP compliance statements were included in the report?</td>
<td>Yes</td>
</tr>
<tr>
<td>Control performance:</td>
<td>By 48 hours, negative control mortality was</td>
</tr>
</tbody>
</table>
### Guideline Criteria | Reported Information
---|---
| 0% and vehicle control mortality was 7%.
| Raw data included: | Replicate data were provided.
| Signs of toxicity (if any) were described? | No signs of toxicity were observed.

### Reported Mortality

<table>
<thead>
<tr>
<th>Dosage (µg a.i./bee)</th>
<th>No. of bees</th>
<th>Percent Mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>4 Hours</td>
</tr>
<tr>
<td>Test Substance (GF-443):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative control</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>Solvent control</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>0.10 (0.02)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>1.0 (0.22)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>10 (2.19)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>100 (21.9)</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

Observations: There were 2 deaths in the 0.02% levels, 0% negative control mortality and 2 deaths in the vehicle control. No sublethal effects were observed during the study.

Statistical method: The registrant estimated the LD₅₀ to be greater than the highest dose level. The dimethoate LD₅₀ value was calculated using the probit method (SAS).

**Reported Statistical Results:**

- LD₅₀: >100 µg a.i./bee  95% C.I.: N/A
- NOAEC: Not reported  Probit Slope: N/A
13. VERIFICATION OF STATISTICAL RESULTS:

**Statistical method:** The registrant did not do statistical analyses, because they said that the highest dose was >100 μg a.i./bee. However, since the chemical used was 21.9% a.i. rather than the technical grade, the highest dose was only 21.9 μg a.i./bee. Since there was mortality in the lowest dose, it is not accurate to say that the LD₅₀ was greater than the highest dose. The LD₅₀ was 21.9 μg a.i./bee. Since there were deaths at lower dose levels, the NOAEC could not be calculated.

LD₅₀ = 21.9 μg a.i./bee

14. REVIEWER’S COMMENTS:

Analytical measurements were not reported for the test concentrations.
The solvent was not properly identified.
The NOAEC could not be determined.
The observation that the LD₅₀ > 22 μg a.i./bee can accepted

The study is **Supplemental, but it need not be repeated**

The LD₅₀ for dimethoate was outside the published range of toxicity to honeybees (0.10-0.35 μg a.i./bee). However, the LD₅₀ was consistent with the historical laboratory values (0.023-0.133 μg a.i./bee).

15. REFERENCES:


