DATA EVALUATION RECORD
HONEY BEE - ACUTE CONTACT LC_{50} TEST
§141-1

1. **CHEMICAL:** Penoxsulam — PC Code No.: ~~199031~~ 119031

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: Rebecca Bryan **Date:** 12/29/03

APPROVED BY: Dana Worcester, Staff Scientist, Dynamac Corporation

Signature: Dana Worcester **Date:** 12/29/03

5. **APPROVED BY:** ~~Bill Erickson~~ James J. Goodyear, Ph.D.
Ecological Effects Biologist
Office of Pesticide Programs
703-305-7726

Signature: JGoodyear **Date:**

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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 LD_{50} 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 study is classified as Supplemental. It can be used for a risk assessment and need not be repeated. It cannot be repaired.

Reviewer's Statistical Results:

LD_{50}: >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

Guideline Criteria	Reported Information
Species:	*Apis mellifera*
Age at beginning of test:	Not reported
Supplier:	Gibbons Honey Farm, Rocheport, Missouri
All bees from the same source?	Yes, from a single, disease-free colony.

B. Test System

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

C. Test Design

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

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control performance:	By 48 hours, negative control mortality was

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

Dosage (µg a.i./bee)	No. of bees	Percent Mortality (%)		
		4 Hours	24 Hours	48 Hours
Test Substance (GF-443):				
Negative control	30	0	0	0
Solvent control	30	0	0	7
0.10 (0.02)	10	0	20	20
1.0 (0.22)	10	0	0	0
10 (2.19)	10	0	0	0
100 (21.9)	30	0	0	0

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 LD_{50} to be greater than the highest dose level. The dimethoate LD_{50} value was calculated using the probit method (SAS).

Reported Statistical Results:

LD_{50}: >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 LD_{50} was greater than the highest dose. The LD_{50} was 21.9 µg a.i./bee. Since there were deaths at lower dose levels, the NOAEC could not e calculated.

LD_{50} = 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 LD_{50}> 22 µg a.i./bee can accepted

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

The LD_{50} for dimethoate was outside the published range of toxicity to honeybees (0.10-0.35 µg a.i./bee). However, the LD_{50} was consistent with the historical laboratory values (0.023-0.133 µg a.i./bee).

15. REFERENCES:

U.S. Environmental Protection Agency (U.S. EPA). 1989. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). *Federal Register*.

Organization for Economic Cooperation and Development. 1997. Decision of the Council, Revised Principles of GLP [C{97} 186/Final].

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Gough, H.J., McIndoe, E.C., Lewis, G.B. (1994). The use of dimethoate as a reference compound

in laboratory acute toxicity tests on honey bees (*Apis mellifera* L.). 1981-1992. Journal of Apicultural Research 22, 119-125.