DATA EVALUATION RECORD
HONEY BEE - ACUTE ORAL LC_{50} TEST
Non-Guideline (OECD 213)

119031

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 Oral Toxicity Test with the Honeybee (*Apis mellifera*)

Study Completion Date: July 10, 2000

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. 47289/Dow Study No. 021047

DP Barcode: D288160

MRID No.: 45831127

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~~

Signature: James J. Goodyear, Ph.D.
Ecological Effects Biologist
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703-305-7726

Date:

Goodyear

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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 and actual intake

Definitive Study Duration: 48 hours

7. CONCLUSIONS:

Honey bees were exposed to GF-443 for 48 hours, at test concentrations of 0.10, 1.0, 10, and 100 µg GF-44 / bee. Actual ingested doses were 0.095, 1.1, 3.8, and 96.7 µg GF-443 / bee or 0.02, 0.24, 0.83, and 21.2 µg a.i./bee for 48 hours. There was no mortality and no sublethal effect observed in the treatment groups or in the negative control.

The LD_{50} value was >21.2 µg a.i./bee.

This acute contact study is classified as Supplemental. This acute oral study is scientifically sound, but it is not a guideline study and, therefore, does not fulfill an OPP guideline requirement.

Reported Statistical Results:

LD_{50}: >21.2 µg a.i./bee	95% C.I.: N/A
NOAEL: 21.2 µg a.i./bee	Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: The acute oral study is scientifically sound and is classified as Supplemental.

B. Rationale: This acute oral study is scientifically sound and is classified as Supplemental because the study is a non-guideline study and does not fulfill an OPP guideline requirement.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

The age of honey bees at study initiation was not reported.

10. SUBMISSION PURPOSE: This study was submitted to provide data on the acute oral toxicity of an end use product (GF-443) to honeybees for the purpose of chemical registration.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera*)	*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:	48-64%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No range finding test was reported.
Reference toxicant test?	The reference toxicant, dimethoate, was tested for 24 hours. The test concentrations were 0.020, 0.20, and 0.40 µg/bee (assuming 100% consumption).
Method of administration:	The test substance was mixed with a 500 g/L (w/v) sucrose solution.
Nominal doses:	0.10, 1.0, 10, and 100 µg GF-443 / bee (Actual ingested doses were 0.095, 1.1, 3.8, and 94-99 µg GF-443 / bee; 0.02, 0.24, 0.83, and 21.2 µg a.i./bee).
Controls: Negative control and/or diluent/solvent control	Negative control
Number of colonies per group:	Negative Control and 100 µg GF-443 / bee treatment group: 3 replicates; 10 bees/replicate 0.10, 1.0, and 10 µg GF-443 / bee treatment groups: 1 replicate; 10

Guideline Criteria	Reported Information
	bees/replicate
Solvent:	N/A
Feeding:	The test solutions were provided for 5.58 hours. Then, the bees were supplied with untreated 500 g/L sucrose solution, *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:	0% negative control mortality by 48 hours.
Raw data included:	Replicate data were provided.
Signs of toxicity (if any) were described?	No signs of toxicity were observed.

Mortality

Dosage (actual intake) µg a.i./bee	No. of bees	Percent Mortality (%)		
		4 Hours	24 Hours	48 Hours
Test Substance (XR-225)				
Control Group	30	0	0	0
0.02	10	0	0	0
0.24	10	0	0	0
0.83	10	0	0	0
21.2	10	0	0	0
21.7	10	0	0	0
20.6	10	0	0	0
Toxic Standard (dimethoate, µg/bee):				
Control	30	Not reported	0	N/A
0.020 (0.021)	30	Not reported	0	N/A
0.20 (0.21)	30	Not reported	77	N/A

Dosage (actual intake) µg a.i./bee	No. of bees	Percent Mortality (%)		
		4 Hours	24 Hours	48 Hours
0.40 (0.31)	30	Not reported	100	N/A

Observations: By 48 hours, there was 0% mortality observed in the treatment groups and the negative control.

Statistical method: The LD_{50} values were estimated due to less than 50% mortality. The LD_{50} was based on the actual intake concentrations.

Reported Statistical Results:
LD_{50}: >99 µg a.i./bee 95% C.I.: N/A
NOAEL: 99 µg a.i./bee Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical analyses were not required, as there was no mortality and no sublethal effect. The results should be expressed in concentrations of penoxsulam not GF-443 (a 21.9 % end-use product).

Results:
LD_{50}: >21.2 µg a.i./bee 95% C.I.: N/A
NOAEL: 21.2 µg a.i./bee Probit Slope: N/A

14. REVIEWER'S COMMENTS:

The reviewer concluded that the study authors reported their results as "µg a.i./bee," whereas it should have been "µg GF-443/bee." GF-443 is an end use product that is only 21.9% a.i. Since this is not a guideline study, it cannot be categorized.

The bees were starved for approximately two hours prior to introduction of the definitive test solution feeders.

The 24-hour LD_{50} of the toxic standard, dimethoate, was 0.092 µg/bee. This value was determined by the SAS Spearman-Karber method. 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 (0.043-0.134 µg a.i./bee).

The mean actual consumed dosages were reviewer-calculated from replicate calculated dosages.

The consumption of the treatment groups ranged from 34.6 to100% and negative control diets were 100% consumed. The consumption of the reference substance diets ranged from 67.6 to 100%.

15. REFERENCES:

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

Finney, D.J. 1971. Probit Analysis. Cambridge University Press.

The SAS System for Windows, Release 6.12. Copyright 1989-96 by SAS Institute, Cary, North Carolina, 27513 USA.

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.