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

1. CHEMICAL: Penoxsulam PC Code No.: 119031

2. TEST MATERIAL: XDE-638 Purity: 97.5%

3. CITATION:

Author: J. A. Kranzfelder

Title: XDE-638: Acute Contact Toxicity Test with the Honeybee, *Apis mellifera*

Study Completion Date: January 3, 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. 45473/Dow Study No. 990122

DP Barcode: D288160

MRID No.: 45831124

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: James Goodyear, Ph.D., Biologist, EFED/ERB3

Signature:  **Date:**

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:

The honey bee, *Apis mellifera*, was exposed to XDE-638 for 48 hours, at a single nominal concentration of 100 µg a.i./bee. By 48 hours, mortality was 13% in the 100 µg a.i./bee treatment group. There was 3% negative control mortality and 0% solvent control mortality. No sublethal effects were observed during the study. **The LD_{50} value was >100 µg a.i./bee. As a result, XDE-638 is categorized as practically nontoxic to honeybees on an acute contact basis.**

This acute contact study is classified as Core. This study is scientifically sound and it satisfies the EFED concerning the guideline requirements for a contact toxicity test with honey bees (Subdivision L, §141-1 or 850.3020).

Reported Statistical Results:
LD_{50}: >100 µg a.i./bee 95% C.I.: N/A
NOAEC: 100 µg a.i./bee Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: This acute contact study is classified as Core. This study is scientifically sound and it satisfies the EFED concerning the guideline requirements for a contact toxicity test with honey bees (Subdivision L, §141-1 or 850.3020).

B. Rationale: N/A

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 contact toxicity of XDE-638 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:	SPR Farms, Inc., Columbia, 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:	25-26°C
Relative humidity:	40-52%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Two range finding studies were conducted at concentrations of 1, 10, and 100 µg a.i./bee with negative and solvent (acetone) controls. After 48 hours in the second test, there was 0% mortality in the treatment groups, compared to 60% negative control and 0% solvent control mortality.
Reference toxicant test?	No reference toxicant test was conducted.
Method of administration:	The test substance was diluted with acetone, and 1 µL of the test substance suspension was applied to the dorsal thorax of each bee.
Nominal doses:	100 µg a.i./bee
Controls:	Negative and Solvent (acetone) controls
Number of colonies per group:	3 replicates; 10 bees/replicate
Solvent:	Acetone
Feeding:	500 g/L (w/v) sucrose solution was provided *ad libitum.*

Guideline Criteria	Reported Information
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 3% and solvent control mortality was 0%.
Raw data included:	Replicate data were provided.
Signs of toxicity (if any) were described?	No signs of toxicity were observed.

Mortality

Dosage (µg a.i./bee)	No. of bees	Percent Mortality (%)		
		4 Hours	24 Hours	48 hours
Test Substance (XDE-638):				
Negative control	30	3	3	3
Solvent control	30	0	0	0
100	30	7	10	13

Observations: By 48 hours, mortality was 13% in the 100 µg a.i./bee treatment group. There was 3% negative control mortality and 0% solvent control mortality. No sublethal effects were observed during the study.

Statistical method: The controls were compared using a t-test and were not statistically different. The LD_{50} value was estimated based on mortality data.

Reported Statistical Results:

LD_{50}: >100 µg a.i./bee 95% C.I.: N/A
NOAEC: <100 µg a.i./bee Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical method: The LC_{50} could be determined visually, as mortality did not exceed

50%; the NOAEC was determined using a t-test.

Results:

LD_{50}: >100 µg a.i./bee 95% C.I.: N/A

NOAEC: 100 µg a.i./bee Probit Slope: N/A

14. REVIEWER'S COMMENTS:

The reviewer's conclusions regarding the LD_{50} were identical to those of the study author; **The LD_{50} value was >100 µg a.i./bee. As a result, XDE-638 is categorized as practically nontoxic to honeybees on an acute contact basis.** However, the reviewer's analysis did not detect significant mortality, as the study author's did, for the group treated with XDE-638. Because the study author's NOAEC is more conservative, it is reported in the Conclusions section.

Analytical measurements were not conducted for the test concentrations

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].

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

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

t-Test: Two-Sample Assuming Unequal Variances

	Control	*100*
Mean	10	8.666667
Variance	0	2.333333
Observations	3	3
Hypothesized Mean Difference	0	
df	2	
t Stat	1.511858	
P(T<=t) one-tail	0.134852	
t Critical one-tail	2.919987	
P(T<=t) two-tail	0.269703	
t Critical two-tail	4.302656	