DATA EVALUATION RECORD
HONEY BEE - ACUTE ORAL LC_{50} TEST
Non-guideline

1. **CHEMICAL:** Thidiazuron formulation — PC Code No.: 120301

2. **TEST MATERIAL:** AE B049537 00 SC42 A204 — Purity: 41.9%

3. **CITATION:**

Author: Waltersdorfer, A.

Title: Oral toxicity (LD50) to the honey bees (*Apis mellifera* L.), Thidiazuron, Water miscible suspension concentrate 500 g/L

Study Completion Date: October 29, 2002

Laboratory: Bayer CropScience GmbH, Ecotoxicology
Industriepark Hochst
D-65926 Frankfurt am Main
Federal Republic of Germany

Sponsor: Bayer CropScience GmbH, Ecotoxicology
D-65926 Frankfurt am Main
Federal Republic of Germany

Laboratory Report ID: CW02/053

DP Barcode: D294536

MRID No.: 46203519

4. **REVIEWED BY:** Rebecca Bryan, Staff Scientist, Dynamac Corporation

Signature: **Date:** 4/28/04

APPROVED BY: Teri Myers, Ph.D., Staff Scientist, Dynamac Corporation

Signature: **Date:** 4/28/04

5. **APPROVED BY:** William Evans, Biologist, ERB-1

Signature: William Evans, EFED/ERB-1 **Date:** 11/16/04

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5. **APPROVED BY:**

Signature: **Date:**

6. STUDY PARAMETERS:

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

Age or Size of Test Organism at Test Initiation: Worker honey bee

Type of Concentrations: Nominal and actual ingested doses

Definitive Study Duration: 72 hours

7. CONCLUSIONS:

The honey bee, *Apis mellifera*, was exposed to a Thidiazuron formulation for 72 hours in an oral test. The nominal concentrations were 0.0239, 0.239, and 2.39% product in diet and the actual ingested doses were 6.03, 57.25, and 472.07 µg product/bee. By 48 hours, percent mortality was 2, 2, and 0% in the 6.03, 57.25, and 472.07 µg product/bee groups, respectively. There was 0% mortality in the negative control. **The LD_{50} value was estimated as >472.07 µg product/bee (>197.8 µg a.i./bee), the highest test concentration. As a result, Thidiazuron is categorized as practically nontoxic to honeybees on an acute oral basis.** The NOEL was 472.07 µg product/bee (197.8 µg a.i./bee).

This study is scientifically sound, however, the study is a non-guideline study and does not fulfill an OPP guideline requirement. **The study is classified as Supplemental.**

Reported Statistical Results:

LD_{50}: >472.07 µg product/bee (>197.8 µg a.i./bee) 95% C.I.: N/A
NOEL: 472.07 µg product/bee (197.8 µg a.i./bee) Probit Slope: N/A
LOEL: >472.07 µg product/bee (>197.8 µg a.i./bee)

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:

No deviations noted.

10. SUBMISSION PURPOSE: This study was submitted to provide data on the acute oral toxicity of a Thidiazuron formulation to honeybees for the purpose of chemical reregistration.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera, Megachile rotundata,* or *Nomia melanderi*)	*Apis mellifera* L.
Age at beginning of test:	Worker honey bee
Supplier:	Laboratory colonies
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	The cylindrical cages were made of wire mesh screening and closed on each end with a cork plug. Cage dimensions were 12-13 cm high and 5 cm diameter.
Lighting:	Continuous darkness
Temperature:	24-25.9°C
Relative humidity:	58-65%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No range finding study was conducted.

Guideline Criteria	Reported Information
Reference toxicant test?	The reference toxicant was Triazophos, 40.9% w/w. The applied concentrations were 0.0006, 0.0012, and 0.0047% product in diet (actual ingested dose 0.096, 0.17, and 0.82 µg product/bee).
Method of administration:	The test chemical was mixed with 50% sucrose solution. Then 0.4 mL of the mixture was provided in the feeding tubes. The food was offered in cages for 5 hours of uptake.
Nominal doses:	0.0239, 0.239, and 2.39% product in diet (actual ingested dose 6.03, 57.25, and 472.07 µg product/bee).
Controls: Negative control and/or diluent/solvent control	Negative control
Number of colonies per group:	5 replicates; 10 bees/replicate
Solvent: The following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	N/A
Feeding:	Prior to test initiation, bees were starved for 2 hours. A 50% sucrose solution was provided *ad libitum.*
Observations period:	24, 48, and 72 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 72 hours.
Raw data included:	Replicate data were provided.
Signs of toxicity (if any) were described?	No signs of toxicity were described.

Mortality

Dosage % product in diet (actual intake, µg product/bee)	No. of bees	Percent Mortality (%) Hour of Study 24	48	72
Test Substance (Thidiazuron):				
Negative Control	50	0	0	0
0.0239 (6.03)	50	0	0	2
0.239 (57.25)	50	2	2	2
2.39 (472.07)	50	0	0	0
Toxic Standard (Triazophos):				
0.00060 (0.096)	50	18	18	18
0.00120 (0.17)	50	26	34	34
0.00470 (0.82)	50	100	100	100

Observations: By 48 hours, percent mortality was 2, 2, and 0% in the 6.03, 57.25, and 472.07 µg product/bee groups, respectively. There was 0% mortality in the negative control.

Statistical method: The LD_{50} value was not calculated due to less than 50% mortality in all treatment groups. The NOEL and LOEL were determined based on mortalities.

Reported Statistical Results:

LD_{50}: >472.07 µg product/bee
NOEL: 472.07 µg product/bee
LOEL: >472.07 µg product/bee

95% C.I.: N/A
Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

The LD_{50} and NOEC estimates could be determined visually.

Results:

LD_{50}: >472.07 µg product/bee (>197.8 µg a.i./bee) 95% C.I.: N/A
NOEL: 472.07 µg product/bee (197.8 µg a.i./bee) Probit Slope: N/A
LOEL: >472.07 µg product/bee (>197.8 µg a.i./bee)

14. REVIEWER'S COMMENTS:

The reviewer's conclusions were similar to the study author's. **The LD_{50} value was estimated as >472.07 µg product/bee (>197.8 µg a.i./bee), the highest test concentration. As a result, Thidiazuron is categorized as practically nontoxic to honeybees on an acute oral basis.**

The test was conducted in compliance with the OECD Principles of Good Laboratory Practice, adopted November 26, 1997 [(C97) 186/Final] (p. 3).

The reference LD_{50} was calculated using SAS probit-analysis. In the oral test, the Triazophos LD_{50} was 0.196 µg product/bee.

15. REFERENCES:

Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. EPPO Bulletin 22, 203-215 (1992) No. 170.

OECD Guidelines for the Testing of Chemicals; Honeybees, Acute Oral Toxicity Test; 213; Adopted 21st September 1998

The SAS System for Windows, Release 6.12 TS Level 0060, 1989-1996.