DP Barcode: D328639 MRID No.: 468017-35

DATA EVALUATION RECORD
ACUTE CONTACT TOXICITY TEST WITH THE HONEY BEE
• 141-1 (OPPTS 850.3020)

1. **CHEMICAL:** Pyrasulfotole PC Code No.: 000692

2. **TEST MATERIAL:** AE 0317309 Purity: 98.1%.

3. **CITATION**

Authors: Waltersdorfer, A.

Title: Contact toxicity (LD50) to honey bees (*Apis mellifera* L.), Substance technical

Study Completion Date: September 26, 2002

Laboratory: Bayer CropScience GmbH, Ecotoxicology
Frankfurt, Germany

Sponsor: Bayer CropScience GmbH, Ecotoxicology
Frankfurt, Germany

Laboratory Report ID: CW02/048

MRID No.: 468017-35

DP Barcode: D328639

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

Signature: Rebecca L. Bryan **Date:** 5/15/06

APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental Inc.

Signature: Teri S Myers **Date:** 5/24/06

5. **REVIEWED BY:** Melissa Panger, Biologist, EPA

Signature: **Date:** 11/29/06

REVIEWED BY: Martin LeMay, Biologist, Officer No. 1629, PMRA

Signature:  **Date:** 11/03/06

REVIEWED BY: David McAdam, Australian Government Department of the Environment and Heritage (DEH)

Signature:  **Date:** 11/07/06

6. DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to honey bees following contact exposure. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

7. STUDY PARAMETERS:

Test Species: *Apis mellifera* L.
Age of Test Organism at Test Initiation: Not reported
Exposure Duration: 72 hours

8. CONCLUSIONS:

In this 72-hour acute contact LD_{50} test, the honey bee, *Apis mellifera*, was exposed to Pyrasulfotole at nominal concentrations of 10, 25, 50, and 75 µg a.i./bee; a solvent (acetone) control was the only control group tested in this study. By 72 hours, there was 16, 8, 4, and 10% mortality in the 10, 25, 50, and 75 µg a.i./bee dosage levels, respectively, compared to 12% control mortality. The LD_{50} and NOAEL values were >75 and 75 µg ai/bee, respectively.

LD_{50}: >75 µg ai/bee
Toxicity category: Practically non-toxic
Slope of Response: Not reported
NOAEL: 75 µg ai/bee

9. ADEQUACY OF THE STUDY:

A. Classification: The **US EPA** and **DEH** classify this study as **Supplemental** (see below)

The **PMRA** classifies this study as **Acceptable**

B. Rationale: Guidelines require the use of two concurrent controls (a negative and a solvent control). In this study only a solvent control and no negative control was tested, therefore, the US EPA and DEH classify the study as supplemental. Based on the assumption that the solvent control group would have been more sensitive than the negative control group, the PMRA classifies this study as acceptable.

C. Repairability: N/A

10. GUIDELINE DEVIATIONS:

A solvent (acetone) control was tested without a concurrent negative control.

11. SUBMISSION PURPOSE: This study was submitted to provide data on the acute contact toxicity of Pyrasulfotole to honeybees for the purpose of chemical registration.

12. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera, Megachile rotundata,* or *Nomia melanderi*)	*Apis mellifera*
Age at beginning of test Worker bees of uniform age.	Worker bees of similar age; age not reported
Source	Laboratory colonies
Were bees from disease-free colonies?	Yes
Were bees kept in conditions conforming to proper cultural practices?	Yes

B. Test System

Guideline Criteria	Reported Information
Test Chambers	Cylindrical cages of wire mesh screening (12-13 cm high and 5 cm diameter) with cork plugs at each end.
Temperature during exposure	Mean: Not calculable Range: 22.5 to 26EC
Relative humidity during exposure	Mean: Not calculable Range: 57 to 80%
Lighting	Continuous darkness, except at observations.
Feeding	A 50% w/v sucrose solution was provided *ad libitum.*

C. Test Design

Guideline Criteria	Reported Information
Nominal dosage levels tested	10, 25, 50, and 75 µg a.i./bee
Number of bees exposed per dosage level	50 bees
Other experimental design information	5 replicates; 10 bees/replicate
Bees randomly or impartially assigned to test groups	Yes
Control	N/A
Solvent control	Acetone control
Total observation period and frequency of interim observations	72 hours; observations at 24, 48, and 72 hours

13. <u>REPORTED RESULTS</u>:

Guideline Criteria	Reported Information

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Observed adverse effects on bees at respective dosages	No adverse effects were observed.
Control and Solvent Control Mortality	12% acetone control mortality.
Were raw data included?	Yes.

Mortality and Observations

Experimental Group (µg ai/bee)	Number Exposed	Number (Percent) Dead	Observations
Acetone Control	50	6 (12%)	None
10	50	8 (16%)	None
25	50	4 (8%)	None
50	50	2 (4%)	None
75	50	5 (10%)	None

Observations: By 72 hours, there was 16, 8, 4, and 10% mortality in the 10, 25, 50, and 75 µg a.i./bee dosage levels, respectively, compared to 12% control mortality.

Reported Statistical Results: The LD_{50} value was estimated since there was no treatment group with mortality greater than 50%. The NOAEL was determined based on mortalities.

Statistical Method:

LD_{50}: >75 µg ai/bee 95% C.I.: Not calculable

Probit Slope: N/A

NOAEL: 75 µg ai/bee

14. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: The LD_{50} and NOAEL were visually estimated based on the lack of a dose-dependent response and absence of replicate data in the report.

LD_{50}: >75 µg ai/bee 95% C.I.: Not calculable

Probit Slope: N/A

NOAEL: 75 µg ai/bee

15. REVIEWERS' COMMENTS:

The reviewers' conclusions agreed with the study author's.

The test was conducted in compliance with the OECD Principles of Good Laboratory Practice. The quality assurance and no data confidentiality statements were included.

The reference toxicant, Triazophos (40.9% w/w) was tested at 0.2, 0.3, and 0.4 µg a.i./bee. After 72 hours, there was 20, 60, and 94% mortality in the 0.2, 0.3, and 0.4 µg a.i./bee dosage levels, respectively. The Triazophos LD_{50} was 0.256 µg a.i./bee calculated using SAS probit-analysis.

The test substance was diluted with acetone, and 1 µL droplet of the test solution was applied to the ventral thorax of each bee using a microapplicator.

Guidelines require the use of two concurrent controls (a negative and a solvent control). In this study only a solvent control and no negative control was tested. Due to the lack of negative control the study is rated as supplemental by the US EPA and DEH. Based on the assumption that the solvent control group would have been more sensitive than the negative control group, the PMRA classifies this study as acceptable.

The experimental start date was June 14, 2002 and the experimental termination date was June 21, 2002.

16. 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 Contact Toxicity Test; Adopted 21st September 1998.

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