DP Barcode: D328639 MRID No.: 468017-34

DATA EVALUATION RECORD
HONEY BEE – DIETARY (ORAL) LD_{50} TEST
NON-GUIDELINE STUDY

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

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

3. **CITATION**

Authors: Waltersdorfer, A.

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

Study Completion Date: October 29, 2002

Laboratory: Bayer CropScience GmbH, Ecotoxicology
Frankfurt, Germany

Sponsor: Bayer CropScience GmbH, Ecotoxicology
Frankfurt, Germany

Laboratory Report ID: CW02/051

MRID No.: 468017-34

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, OPP/EFED/ERB-4

Signature: **Date:** 12-06-06

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PEER REVIEWED BY: Martin LeMay, Biologist, PMRA

Signature:  **Date:** 11/26/06

REVIEWED BY: David McAdam **Date:** 6 Nov 2006
Australian Government Department of the Environment and Heritage (DEH)

D. McAd

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 oral (dietary) toxicity of a pesticide to honey bees. 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:

Scientific Name of Test Organism:	*Apis mellifera* L.
Age of Test Organism at Test Initiation:	Not reported
Type of Concentrations:	Nominal and calculated
Definitive Test Duration:	72 hours

8. CONCLUSIONS:

In this 72-hour acute oral LD_{50} test, the honey bee, *Apis mellifera*, was exposed to Pyrasulfotole at nominal concentrations of 1.78, 19.6, and 120 µg a.i./bee (concentrations of 0.01, 0.1, and 1% w/w in diet, respectively). By 72 hours, there were no mortalities in the control, 1.78, 19.6, and 120 µg a.i./bee dosage levels. The LD_{50} and NOAEL values were >120 and 120 µg ai/bee, respectively.

Reported Statistical Results:
LD_{50}: >120 µg ai/bee 95% C.I.: Not calculable
NOAEL: 120 µg ai/bee

This study is classified as **SUPPLEMENTAL** by the **US EPA** and **ACCEPTABLE** by the **PMRA** and **DEH.** Although the dilution steps for pyrasulfotole are not provided, this study appears scientifically sound and provides useful information. It is a non-guideline study for the **US EPA** and cannot be used to satisfy their guideline data requirements.

9. ADEQUACY OF THE STUDY:

A. Classification: Supplemental (**US EPA**)
Acceptable, as a range finding study (**PMRA** and **DEH**)

B. Rationale: This study is scientifically sound and provides useful information. It is a non-guideline study for the **US EPA** and cannot be used to satisfy their guideline data requirements.

C. Repairability: N/A

10. GUIDELINE DEVIATIONS: N/A

11. SUBMISSION PURPOSE: This study was submitted to provide data on the acute oral 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 similar age; age not reported
Supplier:	Laboratory colonies
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information

Guideline Criteria	Reported Information
Cage size adequate?	Cylindrical cages of wire mesh screening (12-13 cm high and 5 cm diameter) with cork plugs at each end.
Lighting:	Continuous darkness, except at observations.
Temperature:	24.0-25.8°C
Relative humidity:	55-75%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No range-finding test was conducted.
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 doses of 0.097, 0.170, and 0.564 µg a.i./bee, respectively). After 72 hours, there was 14, 32, and 76% mortality in the 0.09703, 0.17014, and 0.56391 µg a.i./bee dosage levels, respectively, compared to 0% control mortality.
Method of administration:	The test chemical was mixed with bee food (consisting of powdered sugar, honey, and deionized water). The test diet pastes (200 mg) were provided in the feeding tubes. The food was offered in cages for 5 hours of uptake.
Nominal doses:	0.01, 0.1, and 1.0% product in diet (actual ingested doses of 1.78, 19.6, and 120 µg a.i./bee). (The dilution steps for the concentration of pyrasulfotole in the diet were not provided)
Controls: Negative control and/or diluent/solvent control	Negative control
Number of colonies per group:	5 replicates; 10 bees/replicate
Solvent: Distilled water or the following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	N/A

Guideline Criteria	Reported Information
Feeding:	A 50% sucrose solution was provided *ad libitum.*
Observations period:	At 24, 48, and 72 hours.

13. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control performance:	0% control mortality.
Raw data included:	Yes
Signs of toxicity (if any) were described?	No signs of toxicity were observed.

Mortality - Oral Test

Test Level (Φg ai/bee)	No. of bees	Rep.	Cumulative Number of Dead		
			Hour of Study		
			24	48	72
Control Group	50	A	0	0	0
		B	0	0	0
		C	0	0	0
		D	0	0	0
		E	0	0	0
Test substance					
1.78	50	A	0	0	0
		B	0	0	0
		C	0	0	0
		D	0	0	0
		E	0	0	0
19.6	50	A	0	0	0
		B	0	0	0
		C	0	0	0
		D	0	0	0
		E	0	0	0
120	50	A	0	0	0
		B	0	0	0
		C	0	0	0
		D	0	0	0
		E	0	0	0

Observations: By 72 hours, there were no mortalities in the control, 1.78, 19.6, and 120 µg a.i./bee dosage levels.

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}: >120 µg ai/bee 95% C.I.: Not calculable

Probit Slope: N/A

NOAEL: 120 µg ai/bee

14. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: The LD_{50} and NOAEL were estimated based on mortality data.

LD_{50}: >120 µg ai/bee 95% C.I.: Not calculable

Probit Slope: N/A

NOAEL: 120 µg ai/bee

15. REVIEWERS' COMMENTS:

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

The dilution steps for the concentration of pyrasulfotole in the diet were not provided.

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 LD_{50} was calculated using SAS probit-analysis. The Triazophos LD_{50} was 0.277 µg a.i./bee.

The experimental start date was July 16, 2002 and the experimental termination date was July 19, 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.

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

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