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6-12-00

MRID No. 443735-28

DATA EVALUATION RECORD
§ 141-1 - HONEY BEE ACUTE CONTACT AND ORAL LD_{50} TEST

1. **CHEMICAL:** Mesotrione — PC Code No.: 122990

2. **TEST MATERIAL:** ZA1296 — Purity: 96.8%

3. **CITATION:**

Authors:	D. Jackson and H.J. Gough
Title:	ZA1296: Acute Contact and Oral Toxicity to Honey Bees (*Apis mellifera*) of Technical Material
Study Completion Date:	October 24, 1995
Laboratory:	Jealott's Hill Research Station, Bracknell, Berkshire, UK
Laboratory Report ID:	RJ1959B
Sponsor:	ZENECA Ag Products, Wilmington, DE
DP Barcode:	D245475
MRID No.:	443735-28

4. **REVIEWED BY:** Max Feken, M.S., Environmental Toxicologist, Golder Associates Inc.

Signature: [signature] **Date:** 8/25/98

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist, Golder Associates Inc.

Signature: P. Kosalwat **Date:** 8/25/98

5. **APPROVED BY:** [signature]

Signature: **Date:** 6/12/00

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: *Apis mellifera*
Definitive Study Duration: 48 hours

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements. Based on the nominal concentrations, the 24-hour acute contact and oral LD_{50} were greater than 100 and 11 µg ai/bee, respectively, which classifies ZA1296 as ~~relatively~~ PRACTICALLY non-toxic to the honey bee. The NOELs were determined to be 100 and 11 µg ai/bee, respectively.

Results Synopsis (acute contact)

LD_{50}: >100 µg ai/bee 95% C.I.: N/A

NOEL: 100 µg ai/bee Probit Slope: N/A

Results Synopsis (acute oral)

LD_{50}: >11 µg ai/bee 95% C.I.: N/A

NOEL: 11 µg ai/bee Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**

A. Classification: Core

B. Rationale: Fulfills guidelines

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS:**

1. The number of bees (10) per replicate (cage) was less than recommended (25 bees per replicate).

2. The age of the test bees prior to testing was either not reported or undetermined.

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS:**

A. Test Organisms

Guideline Criteria	Reported Information
Species: Honey bee (*Apis mellifera*).	*Apis mellifera*
Age at beginning of test: Worker bees of uniform age.	Worker bees, age not reported
Supplier	In-house hive
All bees from the same source?	Yes, hive 1991/16

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Yes
Lighting: Bees should be maintained in the dark.	Held in the dark during testing
Temperature: 27°C (80°F).	22.5 - 23.5°C
Relative humidity: Approx. 65%	42-72% relative humidity

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, no effects were observed at dosages up to 100 and 11 µg/bee for the contact and oral exposures, respectively.
Reference toxicant tested?	Yes; dimethoate
Method of administration: Whole body exposure in a nontoxic dust diluent; or topical exposure via microapplicator.	Oral and contact (thorax).
Definitive Test **Nominal dosages:** Sufficient number of dosage levels to yield statistically sound data unless it can be determined that the LD_{50} will be greater than 25 µg/bee.	Contact 2, 5, 10, 20, 50, and 100 µg ai/bee Oral 0.5, 1, 2, 5, and 11 µg ai/bee
Controls: Negative control and/or diluent/solvent control	Solvent control for both tests
Number of bees per cage: 25 bees per cage (recommended)	10 bees per cage
Number of cages per group: 3 replicate cages per group is recommended.	3 cages per treatment group

Guideline Criteria	Reported Information
Carrier: Non-toxic dust (e.g., Pyrolite)	N/A
Solvent: Distilled water or the following solvents: dimethyl-formamide, triethylene glycol, methanol, acetone, ethanol.	Acetone
Volume of test solution: ≤2 µl/bee (for contact toxicity tests).	1 µl/bee
Observations period: At least 48 hours.	48 hours

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Controls: Mortality not more than 15%	0% for both (oral and contact) tests.
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of toxicity were observed.

Mortality - Contact Test

Dosage (µg ai/bee)	No. of Bees	Cumulative Number of Dead	
		Hour of Study	
		24	48
Control	30	0	0
2	30	0	0
5	30	0	0
10	30	0	0
20	30	1	1
50	30	0	0
100	30	0	0

Mortality - Oral Test

Dosage (µg ai/bee)	No. of Bees	Cumulative Number of Dead	
		Hour of Study	
		24	48
Control	30	0	0
0.5	30	0	0
1	30	1	10*
2	30	0	0
5	30	0	0
11	30	1	1

*All of the bees from one replicate starved; therefore, this replicate was excluded from the analysis.

Other Significant Results: The 48 h LC_{50} for dimethoate was 0.20 µg ai/bee for the contact test and 0.11 µg ai/bee for the oral test. Both values were within the normal expected limits.

The author states that "preliminary work showed that ZA1296 would not form a stable, homogenous dispersion in 50% w/v aqueous sucrose solution unless it was first dissolved in acetone. Even so, the maximum dose which could be tested was 11 µg ai bee^{-1}."

Reported Statistical Results - Acute Contact

Statistical Method: By visual inspection

LD_{50}: >100 µg ai/bee 95% C.I.: N/A

NOEL: 100 µg ai/bee Probit Slope: N/A

Reported Statistical Results - Acute Oral

Statistical Method: By visual inspection

LD_{50}: >11 µg ai/bee 95% C.I.: N/A

NOEL: 11 µg ai/bee Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method (Contact): By visual inspection

LD_{50}: >100 µg ai/bee 95% C.I.: N/A

NOEL: 100 µg ai/bee Probit Slope: N/A

Statistical Method (Oral): By visual inspection

LD_{50}: >11 µg ai/bee 95% C.I.: N/A

NOEL: 11 µg ai/bee Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study is scientifically sound and meets the guideline requirements for a honey bee acute contact and oral toxicity test. Based on nominal concentrations of the dosing solution, the acute contact and oral LD_{50} were greater than 100 and 11 µg ai/bee, respectively, which classifies ZA1296 as ~~relatively~~ non-toxic to *Apis mellifera*. The NOELs were 100 and 11 µg ai/bee, respectively. This study is classified as **Core**.

PRACTICALLY