

DATA EVALUATION RECORD
§ 141-1 - HONEY BEE ACUTE CONTACT AND ORAL LD₅₀ TEST

1. **CHEMICAL:** Azoxystrobin PC Code No.: 128810

2. **TEST MATERIAL:** ICIA5504 technical Purity: 96.2%

3. **CITATION**
Authors: Gough, H.J., D. Jackson, and G.B. Lewis
Title: ICIA5504: Acute Contact and Oral Toxicity to Honey Bees (*Apis mellifera*) of Technical Material
Study Completion Date: November 22, 1993
Laboratory: Jealott's Hill Research Station, Bracknell, Berkshire, UK
Laboratory Report ID: RJ1517B
Sponsor: Zeneca Inc., Wilmington, DE
MRID No.: 436781-66

4. **REVIEWED BY:**

William Erickson
Biologist
EEB/EFED/EPA

Signature:
Date:

W. Erickson
4/01/96

5. **APPROVED BY:**

Harry Craven
Section Head 4
EEB/EFED/EPA

Signature:
Date:

H. F. Craven
6/21/96

6. **STUDY PARAMETERS:**

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

7. **CONCLUSIONS:** This study is scientifically sound and meets guideline requirement. Based on nominal concentrations, the acute contact LD₅₀ was greater than 200 µg ai/bee, which classifies ICIA5504 technical as practically nontoxic to the honey bee.

Results Synopsis - Contact Test

LD₅₀: >200 µg/bee
NOEL: 200 µg/bee

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

8. **ADEQUACY OF THE STUDY**

- A. Classification: Core
- B. Rationale: N/A
- C. Repairability: N/A

9. **GUIDELINE DEVIATIONS:**

- 1. Age of the test bees was not reported.
- 2. The number of bees (10) per replicate (cage) was less than recommended (25 bees per replicate).

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species: Honey bee (<i>Apis mellifera</i>).	<i>Apis mellifera</i>
Age at beginning of test: Worker bees of uniform age.	Not reported
Supplier	Jealott's Hill Research Station, Bracknell, Berkshire, UK
All bees from the same source?	Yes, bees from hive 1990/2.

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Yes
Lighting: Bees should be maintained in the dark.	Bees maintained in the dark except during observations.
Temperature: 27°C (80°F).	25°C

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Sulfentrazone 128810
PC Code No.: 129081

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DP Barcode: ~~D217072, D217078~~

MRID No.: 436781-66

4. **REVIEWED BY:** Max A. Feken, M.S., Environmental Toxicologist, KBN Engineering and Applied Sciences, Inc.

Signature:  Date: 1/23/96

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist, KBN Engineering and Applied Sciences, Inc.

Signature: P. Kosalwat Date: 1/23/96

5. **APPROVED BY:**

Signature: Date:

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Definitive Study Duration: 48 hours

7. **CONCLUSIONS:** This study is scientifically sound and meets guideline requirements. Based on nominal concentrations, the acute contact LD₅₀ was greater than 200 µg ai/bee, which classifies ICIA5504 technical as practically non-toxic to the honey bee. The NOEL was determined to be 200 µg ai/bee.

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LD₅₀: >200 µg/bee

NOEL: 200 µg/bee

95% C.I.: N/A

Probit Slope: N/A

Guideline Criteria	Reported Information
Relative humidity: Approx. 65%	70-78% relative humidity

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Range finding test concentrations: control, 0.1, 1, 10, and 100 $\mu\text{g}/\text{bee}$ for acute contact and 0.1, 1, 10, and 25 $\mu\text{g}/\text{bee}$ for acute oral toxicity tests. No treatment related mortalities or sublethal effects were observed in the contact test. Only one bee died at the highest concentration level in the oral test.
Reference toxicant tested?	Yes, dimethoate.
Method of administration: Whole body exposure in a nontoxic dust diluent; or topical exposure via microapplicator.	Contact test: Topical exposure via micro-syringe (Burkard micro-applicator). Oral test: Dose administered via feeding tube.
<u>Definitive Test</u> 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 $\mu\text{g}/\text{bee}$.	Contact test: Nominal concentrations of 5, 10, 20, 50, 100, and 200 $\mu\text{g ai}/\text{bee}$. Oral test: Nominal concentrations of 0.5, 1, 2, 5, 10, 25 $\mu\text{g ai}/\text{bee}$.
Controls: Negative control and/or diluent/solvent control	Solvent control used in both acute contact and oral toxicity tests.
Number of bees per cage: 25 (recommended)	10 bees per cage (both tests).

Guideline Criteria	Reported Information
Number of cages per group: 3 replicate cages per group is recommended.	3 cages per treatment group (both tests).
Carrier: Non-toxic dust (e.g., Pyrolite)	N/A.
Solvent: Distilled water or the following solvents: dimethylformamide, triethylene glycol, methanol, acetone, ethanol.	Acetone used in both tests.
Volume of test solution: ≤2 µl/bee (for contact toxicity tests).	Contact test: 1 µl drop. Oral test: 0.2 ml (total volume) per cage or 0.02 ml per bee. Test solution consisted of solvent dissolved technical material diluted in 50% sucrose solution. Concentration of solvent no greater than 5% v.v.
Observations period: At least 48 hours.	48 hours (both tests).

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 acute contact and 3% for oral toxicity test.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality - Contact Test

Dosage ($\mu\text{g ai/bee}$)	No. of Bees	Rep	Cumulative Number of Dead			
			Hour of Study			
			1	4	24	48
Solvent Control	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
5	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
10	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
20	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
50	10	a	0	0	0	0
		b	0	0	0	0
		c	1	1	1	1
100	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
200	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0

Other Significant Results: Only one mortality occurred at the 50 $\mu\text{g ai/bee}$ level, although it did not appear to be treatment related. There were no sublethal effects observed at any of the dosage levels during the 48-hour test.

Mortality - Oral Test

Dosage ($\mu\text{g/ai bee}$)	No. of Bees	Rep	Cumulative Number of Dead			
			Hour of Study			
			1	4	24	48
Solvent Control	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	1

Dosage ($\mu\text{g}/\text{ai bee}$)	No. of Bees	Rep	Cumulative Number of Dead			
			Hour of Study			
			1	4	24	48
0.5	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
1	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
2	10	a	0	0	1	1
		b	0	0	0	0
		c	0	0	0	0
5	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	0
10	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	1
25	10	a	0	0	0	0
		b	0	0	0	0
		c	0	0	0	1

Other Significant Results: No dose-related response was evident in this test.

Reported Statistical Results - Contact Test

Statistical Method: By visual inspection

LD₅₀: >200 $\mu\text{g ai/bee}$

95% C.I.: N/A

NOEL: 200 $\mu\text{g ai/bee}$

Probit Slope: N/A

Reported Statistical Results - Oral Test

Statistical Method: By visual inspection

LD₅₀: >25 $\mu\text{g ai/bee}$

95% C.I.: N/A

NOEL: 25 $\mu\text{g ai/bee}$

Probit Slope: N/A

13. Verification of Statistical Results - Contact Test

Statistical Method: By visual inspection

LD₅₀: >200 µg ai/bee 95% C.I.: N/A

NOEL: 200 µg ai/bee Probit Slope: N/A

Verification of Statistical Results - Oral Test

Statistical Method: By visual inspection

LD₅₀: >25 µg ai/bee 95% C.I.: N/A

NOEL: 25 µg ai/bee Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study is scientifically sound, meets the guideline requirements for honey bee acute contact and oral toxicity tests, and can be classified as Core. Based on nominal concentrations, the acute contact LD₅₀ was greater than 200 µg ai/bee, which classifies ICIA5504 technical as practically non-toxic to *Apis mellifera*. The NOEL was determined to be 200 µg ai/bee.