

DATA EVALUATION RECORD
HONEY BEE - ACUTE CONTACT LC₅₀ TEST
§141-1

1. **CHEMICAL**: Glyphosate

PC Code No.: 103601

2. **TEST MATERIAL**: MON 77360

Purity: 30.0% w/w glyphosate acid
equivalents

3. **CITATION**:

Author: Palmer, S. and Krueger, H.

Title: MON 77360: An Acute Contact Toxicity Study with the
Honey Bee

Study Completion Date: February 16, 2001

Laboratory: Wildlife International Ltd.
8598 Commerce Drive
Easton, MD 21601

Sponsor: Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

Laboratory Report ID: 139-433

DP Barcode: D294119

MRID No.: 45370301

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

Signature: 

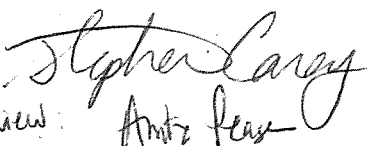
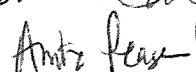
Date: 3/6/04

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

Signature: 

Date: 3/6/04

5. **APPROVED BY**: Stephanie Syslo, Environmental Scientist, OPP/EFED/ERB III

Signature: 
Secondary Review: 

Date: 6/28/04
9/23/04



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6. STUDY PARAMETERS:

Scientific Name of Test Organism: *Apis mellifera*

Age or Size of Test Organism at Test Initiation: 1 to 5 days old

Type of Concentrations: Nominal

Definitive Study Duration: 48 hours

7. CONCLUSIONS:

The honey bee, *Apis mellifera*, was exposed to MON 77360 for 48 hours in a contact toxicity test, at nominal concentrations of 6.25, 12.5, 25.0, 50.0, and 100 µg MON 77360/bee. By 48 hours, there was 0% mortality in the negative and solvent controls. The 6.25, 12.5, 25.0, 50.0, and 100 µg MON 77360/bee treatment groups had 0, 2, 0, 0, and 3% mortality, respectively. Incidental sublethal effects included immobility, lethargy, and loss of equilibrium in the 50.0 and 100 µg MON 77360/bee treatment groups; with the exception of one bee that exhibited loss of equilibrium, no sublethal effects persisted to 48 hours. **The LD₅₀ value was >100 µg MON 77360/bee. As a result, MON 77360 is categorized as practically nontoxic to honeybees on an acute contact basis.** The NOAEC was the highest concentration tested, 100 µg MON 77360/bee.

This study is scientifically sound and it satisfies the guideline requirements for a contact toxicity test with honeybees (Subdivision L, §141-1). **This study is classified as Core.**

Reported Statistical Results:

LD₅₀: >100 µg MON 77360/bee 95% C.I.: N/A
NOAEC: 100 µg MON 77360/bee Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: Core

B. Rationale: This study satisfies the U.S. EPA guideline requirements for an acute contact toxicity test with honey bees.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

None

10. SUBMISSION PURPOSE: This study was submitted to provide data on the acute contact toxicity of MON 77360 to honeybees for the purpose of chemical registration.

11. MATERIALS AND METHODS:**A. Test Organisms**

Guideline Criteria	Reported Information
Species: Species of concern (<i>Apis mellifera</i> , <i>Megachile rotundata</i> , or <i>Nomia melanderi</i>)	<i>Apis mellifera</i>
Age at beginning of test:	1-5 days old
Supplier:	Apiary at Wildlife International, Ltd., Easton, Maryland.
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Stainless steel cylinders (9 cm diameter and 9 cm high) with plastic petri dish (10 cm diameter) covering each end.

Guideline Criteria	Reported Information
Lighting:	Continuous darkness except at observation periods.
Temperature:	26.7-27.5°C
Relative humidity:	63-94%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Not reported.
Reference toxicant test?	The reference toxicant, dimethoate, was tested concurrently with the definitive test under the same test conditions. The nominal dimethoate concentrations were 0.05, 0.10, and 0.20 µg a.i./bee.
Method of administration:	The test substance was mixed with methanol, and 2 µL of the test substance solution was applied to the abdomen and/or thorax of each bee using a micropipette.
Nominal doses:	6.25, 12.5, 25.0, 50.0, and 100 µg a.i./bee.
Controls: Negative control and/or diluent/solvent control	Negative and Solvent controls
Number of colonies per group:	3 replicates; 20 bees/replicate
Solvent: The following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	Methanol
Feeding:	A 50% aqueous sucrose solution was provided <i>ad libitum</i> .
Observations period:	1 ¼, 2, 24, and 48 hours

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control performance:	Negative and solvent controls had 0% mortality by 48 hours.
Raw data included:	Replicate data were provided.
Signs of toxicity (if any) were described?	Signs of toxicity included immobility, lethargic, and loss of equilibrium.

Mortality

Dosage (µg*/bee)	No. of bees	Rep.	Cumulative Number of Dead			
			Hour of Study			
			1 ¼	2	24	48
Test Substance (MON 77360):						
Negative Control	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	0	0
Solvent Control	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	0	0
6.25	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	0	0
12.5	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	1	1
25.0	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	0	0

Dosage ($\mu\text{g}^*/\text{bee}$)	No. of bees	Rep.	Cumulative Number of Dead			
			Hour of Study			
			1 ¼	2	24	48
50.0	20	1	0	0	0	0
	20	2	0	0	0	0
	20	3	0	0	0	0
100	20	1	0	0	1	1
	20	2	0	0	0	0
	20	3	0	0	1	1
Toxic Standard (Dimethoate):						
0.05	20	1	0	0	4	6
	20	2	0	0	2	3
	20	3	0	0	1	1
0.10	20	1	0	0	2	2
	20	2	0	0	6	6
	20	3	0	0	6	7
0.20	20	1	0	0	17	17
	20	2	0	0	16	17
	20	3	0	0	19	19

* Test substance concentrations are expressed as μg MON 77360/bee, while toxic standard concentrations are expressed as μg a.i./bee.

Observations: By 48 hours, there was 0% mortality in the negative and solvent controls. The 6.25, 12.5, 25.0, 50.0, and 100 μg a.i./bee treatment groups had 0, 2, 0, 0, and 3% mortality, respectively. The sublethal effects included one lethargic bee in the 50.0 μg a.i./bee treatment group and three 100 μg a.i./bee treatment group bees were either immobile, lethargic or had loss of equilibrium during the test. The mortalities and sublethal effects were not treatment-related.

Statistical method: The exact LD_{50} value was not calculated due to less than 50% mortality in all treatment groups. The LD_{50} was based on the nominal concentrations. The NOAEC was based on a visual assessment of the mortality and sublethal effects data.

Reported Statistical Results:

LD_{50} : >100 μg MON 77360/bee 95% C.I.: N/A

NOEL: 100 µg MON 77360/bee Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical analyses were not necessary, as there was no significant mortality. LD₅₀ and NOAEC estimates could be determined visually.

Results:

LD₅₀: >100 µg MON 77360/bee 95% C.I.: N/A
NOAEC: 100 µg MON 77360/bee Probit Slope: N/A

14. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to the study authors. **The LD₅₀ value was >100 µg MON 77360/bee, the highest concentration. As a result, MON 77360 is categorized as practically nontoxic to honeybees on an acute contact basis.**

The LD₅₀ of the toxic standard, dimethoate, was 0.11 µg a.i./bee with 95% confidence interval of 0.09 to 0.12 µg a.i./bee. This value was determined by the binomial method. The LD₅₀ was consistent with the published data.

The registrant provided the following information in an email to EFED (attn: Vickie Walters) dated 10/29/03: MON 77360 is 41% isopropylamine glyphosate by weight, corresponding to 360 g glyphosate acid per liter. It contains a surfactant blend as specified on the CSF for 524-475, and is a complete product for application without the need of added surfactant.

15. REFERENCES:

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- European and Mediterranean Plant Protection Organization. 1992. *Guideline on Test Methods for Evaluating the Side Effects of Plant Protection Products on Honey Bees*. EPPO Bulletin. 22, 203-215.
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Personal Communication.
- Finney, D.J. 1971. *Statistical Methods in Biological Assay*. 2nd Ed. Griffin Press, London.
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