File
11-25-96

DP Barcode : D228313
PC Code No : 129081
EEB Out : NOV 25 1996

To: Joanne Miller
Product Manager 23
Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 000279-GRUO
Chemical Name : Sulfentrazone Technical
Type Product : Herbicide
Product Name : Authority
Company Name : FMC Corporation
Purpose : Submission of honey bee acute contact toxicity study in support of registration.

Action Code : 101 Date Due : 11/12/96
Scientist : A. Vaughan Date In : 08/08/96

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1	440549-02	Y
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D228313

CASE: 044863 DATA PACKAGE RECORD DATE: 07/25/96
SUBMISSION: S508577 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 101 RESB NC-FOOD/FEED USE
RANKING : 0 POINTS ()
CHEMICALS: 129081 Sulfentrazone 91.0000%

ID#: 000279-GRUO SULFENTRAZONE TECHNICAL
COMPANY: 000279 FMC CORP AGRICULTURAL PRODUCTS GROUP
PRODUCT MANAGER: 23 JOANNE MILLER 703-305-6224 ROOM: CM2 237
PM TEAM REVIEWER: DIANNE MORGAN 703-305-6217 ROOM: CM2 235
RECEIVED DATE: 07/11/96 DUE OUT DATE: 01/17/97

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 228313 EXPEDITE: N DATE SENT: 07/25/96 DATE RET.: / /
CHEMICAL: 129081 Sulfentrazone
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	7/29/96	/ /
BRAN: EEB	7/29/96	/ /
SECT: RS2	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 11/12/96
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review Honey Bee acute contact (#440549-02) Att. Al Vaughan

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
228154	EEB/RS4	07/22/96	11/19/96	Y	N	N

2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 25 1996

MEMORANDUM

SUBJECT: EEB Review of Honey Bee Acute Study with Sulfentrazone (PC Code# 129081; DP Barcode 228313; ID# 000279-GRUO; Case# 044863; Sponsor: FMC Corp.)

FROM: Norman J. Cook, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

TO: Joanne Miller, PMT-23
Fungicide/Herbicide Branch
Registration Division (7505C)

EEB has reviewed the honey bee acute contact study submitted to support the registration of sulfentrazone. The study (MRID # 440549-02) was determined to be Core for the technical pesticide, and showed that technical sulfentrazone was relatively nontoxic to honey bees. This study fulfills the requirement for acute testing with honey bees and will support the registration of sulfentrazone.

Any questions or comments on this memo should be referred to Allen Vaughan at 305-6464.

Attachment

3

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

1. **CHEMICAL:** Sulfentrazone PC Code No.: 129081

2. **TEST MATERIAL:** Sulfentrazone Technical Purity: 94.2%

3. **CITATION:**

Authors: John A. Aufderheide and James A. Kranzfelder
Title: Sulfentrazone Technical: Honey Bee Acute Contact LD_{50}
Study Completion Date: February 1, 1996
Laboratory: Toxikon Environmental Sciences, Jupiter, FL
Laboratory Report ID: J9507010
Sponsor: FMC Corporation, Princeton, NJ
DP Barcode: D228313
MRID No.: 440549-02

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

Signature: [signature] **Date:** 9/25/96

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

Signature: P. Kosalwat **Date:** 9/25/96

5. **APPROVED BY:** Allen W Vaughan 11.19.96

Signature: [signature] **Date:** 11-19-96

6. **STUDY PARAMETERS:**

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

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements. Based on the mean measured concentration of the dosing solution, the acute contact LD_{50} was greater than 25.1 µg ai/bee, which classifies Sulfentrazone Technical as practically non-toxic to the honey bee. The NOEL was determined to be 25.1 µg ai/bee.

Results Synopsis

LD_{50}: >25.1 µg ai/bee 95% C.I.: N/A

NOEL: 25.1 µg ai/bee Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**

A. Classification: Core

B. Rationale: Although the mortality in the control was greater than 15 percent, both the solvent control and the treatment groups had ≤10% mortality.

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. Bees were not maintained in the dark.
3. The test temperature (22.8-26.4°C) was lower than recommended (27°C).
4. The mortality in the control (20%) was higher than recommended (less than 15%). However, only 7% mortality occurred in the solvent control group.

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.	The age of the test bees was unknown. The test protocol attached to the report indicated worker bees of uniform age would be used.

5

Guideline Criteria	Reported Information
Supplier	Van Husen Honey Farms, Boynton Beach, FL
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Yes
Lighting: Bees should be maintained in the dark.	Bees were maintained in 12 hours of light and 12 hours of darkness.
Temperature: 27°C (80°F).	22.8-26.4°C
Relative humidity: Approx. 65%	63-65% relative humidity

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Two preliminary tests were conducted consisting of a control, a solvent control, and nominal concentrations of 1.6, 3.1, 6.3, 12.5, and 25.0 µg ai/bee. Mortality for the control was 40%. The highest concentration had only 10% mortality. The highest mortality (50%) was observed in the 1.6 µg ai/bee concentration. The second test had 5 and 10% mortality in the control and solvent control, respectively. No mortality at the highest treatment level.
Reference toxicant tested?	No.

6

Guideline Criteria	Reported Information
Method of administration: Whole body exposure in a nontoxic dust diluent; or topical exposure via microapplicator.	Topical exposure on the ventral thoracic region via a Finnpipette.
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.	25 µg ai/bee
Controls: Negative control and/or diluent/solvent control	Negative and solvent control
Number of bees per cage: 25 (recommended)	10 bees per cage
Number of cages per group: 3 replicate cages per group is recommended.	3 cages per treatment group
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 drop
Observations period: At least 48 hours.	48 hours

7

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%	20% and 7% in the negative and solvent control, respectively.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality - Contact Test

Dosage (µg ai/bee)	No. of Bees/ Rep	Rep	Cumulative Number of Dead			
			Hour of Study			
			3	8	24	48
Control	10	a	0	1	1	1
		b	0	1	1	4
		c	0	0	0	1
Solvent Control	10	a	0	0	0	1
		b	0	0	0	0
		c	0	0	0	1
25.1	10	a	0	0	0	0
		b	0	0	0	3
		c	0	0	0	0

Other Significant Results: The mean measured concentration was 25.1 µg/µL or 100 percent of nominal. There were no sublethal effects observed in any groups during the 48-hour test.

Reported Statistical Results

Statistical Method: By visual inspection

LD_{50}: >25.1 µg ai/bee 95% C.I.: N/A

NOEL: 25.1 µg ai/bee Probit Slope: N/A

8

13. **VERIFICATION OF STATISTICAL RESULTS:**

Statistical Method: By visual inspection

LD_{50}: >25.1 µg ai/bee 95% C.I.: N/A

NOEL: 25.1 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 toxicity test. Mortality in the control was greater than 15 percent. However, the solvent control and treated groups had ≤10% mortality. Based on the mean measured concentration of the dosing solution, the acute contact LD_{50} was greater than 25.1 µg ai/bee, which classifies Sulfentrazone Technical as practically non-toxic to *Apis mellifera*. The NOEL was determined to be 25.1 µg ai/bee. This study is classified as **Core.**