Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Freshwater Invertebrates - *Daphnia magna*
PMRA Submission Number{.....} EPA MRID Number 45386233

Data Requirement:

PMRA DATA CODE	
EPA DP Barcode	D284719
OECD Data Point	
EPA MRID	45386233
EPA Guideline	§72-2

1/9/04

Test material: AE F 130060 Technical **Purity:** 94.6%
Common name: Mesosulfuron-methyl
Chemical name: IUPAC: Methyl 2-[3-(4,6-dimethoxyprimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethylbenzoate
CAS name: Not reported
CAS No.: Not reported
Synonyms: Code: AE F130060 00 1C95 0001

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Staff Scientist, Dynamac Corporation

Signature: Rebecca Bryan
Date: 8/22/03

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Secondary Reviewer(s):
{EPA/OECD/PMRA}

Date:

Reference/Submission No.:

Company Code:
Active Code:
EPA PC Code: 122009

Date Evaluation Completed:

CITATION: Sowig, P., *et al.* 1999. Acute Toxicity to Waterflea (*Daphnia magna*), AE F130060; substance, technical. Unpublished study performed by Hoechst Schering AgrEvo GmbH, Frankfort, Germany. Laboratory Study Identification CE97/027. Study submitted by Aventis CropScience, Research Triangle Park, NC. Study initiated May 20, 1997 and completed October 5, 1999.

EXECUTIVE SUMMARY: This is a 48 hour Limit Test. - 2 control groups & treatment groups

The 48-hour acute toxicity of AE F130060 Technical (Mesosulfuron-methyl) to the water flea, *Daphnia magna*, was studied under static conditions. Daphnids were exposed to the test material at nominal concentrations of 0 (negative control) and 100 ppm (limit concentration). Mean-measured concentrations were 0 (negative control) and 90.2 ppm a.i.

No mortality/immobilization or sub-lethal signs of toxicity were observed during the 48-hour study. The 48-hour EC_{50} was >90.2 ppm a.i., which categorizes AE F130060 Technical (Mesosulfuron-methyl) as slightly toxic to the water flea (*Daphnia magna*) on an acute toxicity basis. The 48-hour NOEC and LOEC levels were 90.2 and >90.2 ppm a.i., respectively.

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with freshwater invertebrates (§72-2). This study is classified as CORE.

Results Synopsis

Test Organism Age (eg. 1st instar): Neonates, <24 hours old
Test Type (Flow-through, Static, Static Renewal): Static

48-Hour
EC_{50}: >90.2 ppm a.i.
NOEC: 90.2 ppm a.i.
LOEC: >90.2 ppm a.i.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the OECD Guideline No. 202, the U.S. EPA Pesticide Assessment Guidelines, Series §72-2 (1982), and the EU Directive 92/69/EWG Annex Part C:C.2. Deviations from U.S. EPA FIFRA Guideline §72-2 include:

1. The storage conditions of the test material were not reported.
2. Pre-test health (including mortality) of the laboratory culture and/or brood was not described.
3. Water hardness was not reported as mg $CaCO_3$/L.
4. Dissolved oxygen in terms of percent saturation was not reported.
5. The total organic carbon and particulate matter contents, and levels of metals, pesticides, and chlorine in the dilution water were not reported.
6. The biomass loading rate was not specified.

These deviations did not affect the validity or acceptability of the study.

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements

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were provided. This study was conducted in accordance with OECD principles of GLP (p. 3).

A. MATERIALS:

1. Test Material AE F 130060 Technical (Mesosulfuron-methyl)

Description: Light beige powder

Lot No./Batch No. : Code: AE F130060 00 1C95 0001

Purity: 94.6%

Stability of Compound Under Test Conditions: The stability of the test substance in the dilution water during the course of the study was demonstrated by analytical determination at 0 and 48 hours. Mean recoveries ranged from 93.2 to 98.3% of nominal values (Table 6.2, p. 23).

Storage conditions of test chemicals: Not reported.

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. OECD requirements were not reported.

2. Test organism:

Species: *Daphnia magna*

Age at test initiation: Neonates, <24 hours old

Source: In-house laboratory cultures (original supplier: University of Goettingen, Goettingen, Germany)

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: No range-finding test was reported.

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	Continuous laboratory cultures were maintained. Same as test *Daphnia* cultures were fed twice a week with unicellular green algae, *Scenedesmus subspicatus*. Not specified	*EPA requires 7 day minimum acclimation period.*
Duration of the test	48 hours	*EPA requires 48 hours*
Test condition - static/flow through Type of dilution system (for flow through method) Renewal rate (for static renewal)	Static N/A N/A	*EPA requires consistent flow rate of 5 - 10 volumes/24 hours, meter systems calibrated before study and checked twice daily during test period*
Aeration, if any	No aeration was used during the study.	
Test vessel Material: *(glass/stainless steel)* Size: Fill volume:	Glass jars with glass lids 300 mL 200 mL	*EPA requires: size 20 ml or 3.9 L fill 200 ml*
Source of dilution water	Deionized water and artificial mineral medium M4 (Elendt 1990) were used to prepare eight different stock solutions, each containing different chemical components (pp. 12-14). Varying volumes of each of the prepared solutions were combined to make 1 L of the dilution water.	*EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water.*

Parameter	Details	Remarks *Criteria*
Water parameters: Hardness pH Dissolved oxygen Temperature Total Organic Carbon Particulate matter Metals Pesticides Chlorine	1.73 mmol/L (Ca^{2+} + Mg^{2+}) 7.4-7.7 8.9-9.0 mg/L 19.7-20.0°C Not reported Not reported Not reported Not reported Not reported	The water hardness in terms of mg/L as $CaCO_3$ was not provided. Dissolved oxygen in terms of percent saturation was not reported. *EPA requires:* *hardness: 40 - 48 mg/L as $CaCO_3$* *pH: 7.2 - 7.6* *-Temperature: 20°C (measured continuously or if water baths are used, every 6 hr, may not vary > 1°C* *Dissolved oxygen:* *Static: ≥ 60% during 1st 48 hr and ≥ 40% during 2nd 48 hr* *Flow-through: ≥60%*
Number of replicates Solvent control: Negative control: Treatments:	N/A 2 6	
Number of organisms per replicate Solvent control: Negative control: Treatments:	N/A 10 10	The biomass loading rate was not specified. *EPA requires 5 treatment levels plus control with a minimum of 20 daphnid per treatment. Biomass loading rate for static ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day.*

Parameter	Details	Remarks *Criteria*
Treatment concentrations nominal: measured:	0 (negative control) and 100 ppm 0 (negative control) and 90.2 ppm a.i.	This study was designed as a limit test. The mean-measured test concentration was reviewer-calculated from adjusted (for purity) recoveries in second table on p. 23. *EPA requires a geometric series with each concentration being at least 60% of the next higher one.*
Solvent (type, percentage, if used)	N/A	*EPA requires solvents not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-though tests.*
Lighting	16 hours light/8 hours dark	*EPA requires 16 hours light, 8 hours dark.*
Feeding	Animals were not fed during testing.	*EPA/OECD requires: No feeding during the study*
Stability of chemical in the test system	Verified. Although declines were observed, the test material was still present at concentrations exceeding 86% after 48 hours.	Corrected concentrations were 97.4-102.7% of nominal concentrations at 0 hours and 86.2-93.9% after 48 hours (second table on p. 23).
Recovery of chemical Level of Quantitation Level of Detection	99.3-100.5% of nominal 4.08 mg/L 2.45 mg/L	Based on matrix spikes analyzed concurrently with the samples on Days 0 and 2 (second table on p. 23).
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	N/A	

2. Observations:

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Table 2: Observations

Criteria	Details	Remarks *Criteria*
Parameters measured including the sublethal effects	Mortality/immobility Other sub-lethal effects	
Observation intervals	After 24 and 48 hours	
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION

A. SUB-LETHAL TOXICITY ENDPOINTS:

No mortality/immobilization or sub-lethal signs of toxicity were observed during the 48-hour study (Table 6.3, p. 24).

Table 3: Sublethal Effects of AE F130060 Technical on *Daphnia magna*.

Treatment, ppm measured and (nominal conc.)	Observation period			
	24 hours		48 hours	
	endpoint	% affected	endpoint	% affected
Dilution water Control	Immobile	0	Immobile	0
90.2 (100)	Immobile	0	Immobile	0
NOEC, ppm	100		100	
LOEC, ppm	>100		>100	
EC_{50} (with 95% C.I.), ppm	>100		>100	

B. REPORTED STATISTICS:

The 48-hour EC_{50} value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. The nominal concentration was reported.

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C. VERIFICATION OF STATISTICAL RESULTS:

The 48-hour EC_{50} value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. The mean-measured concentration was reported.

48-Hour
EC_{50}: >90.2 ppm a.i.
NOEC: 90.2 ppm a.i.
LOEC: >90.2 ppm a.i.

D. STUDY DEFICIENCIES:

There were no significant deviations from U.S. EPA guideline §72-2 that affected the acceptability of this study.

E. REVIEWER'S COMMENTS:

The reviewer's conclusions are identical to those reported by the study authors.

Since the mean-measured concentration was below the required limit level of 100 ppm, a more conservative Toxicity Category was assigned.

G. CONCLUSIONS:

This study is scientifically sound, fulfills U.S. EPA guideline §72-2, and is classified as CORE. Based on the results of this study, AE F130060 Technical (Mesosulfuron-methyl) is categorized as slightly toxic to the water flea, *Daphnia magna*, on an acute toxicity basis.

48-Hour
EC_{50}: >90.2 ppm a.i.
NOEC: 90.2 ppm a.i.
LOEC: >90.2 ppm a.i.

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III. REFERENCES:

Organization for Economic Co-Operation and Development. 1984. OECD Guideline for Testing of Chemicals; Guideline No. 202: Daphnia sp., Acute Immobilization Test and Reproduction Test. April 4, 1984.

Pesticide Assessment Guidelines. Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, §72-2, Acute Toxicity Test for Freshwater Aquatic Invertebrates.

U.S. Environmental Protection Agency (EPA). 1975. Committee on Methods for Toxicity Tests with Aquatic Organisms, Method for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. EPA-660/3-75-009.

EU Directive 92/69/EWG Annex Part C: Methods for the Determination of Ecotoxicity; C.2. Acute Toxicity to Daphnia.

Bradley, M.C. 1988. Report of the Results and Conclusions of the EEC Daphnia Magna Genetic Typing Exercise. University of Sheffield. Department of Zoology. February 3, 1988.

Deutsches Institut fur Normung (DIN). 1989. German Standard Methods for the Examination of Water, Waste Water, and Sludge. Normenausschuß Wasserwesen (NAW) im DIN Deutsches Institut fur Normung e.V. Berlin.

Elendt, B.P. 1990. Selenium Deficiency in Crustacea, An Ultrastructural Approach to Antennal Damage in Daphnia Magna STRAUS. Protoplasma 154:25-33.

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