

US EPA ARCHIVE DOCUMENT

See page 9

**Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)**

PMRA Submission Number

EPA MRID Number 45386301

<b>Data Requirement:</b>	PMRA DATA CODE	
	EPA DP Barcode	D284719
	OECD Data Point	
	EPA MRID	45386301
	EPA Guideline	§72-3a

1/9/04

**Test material:** AE F 130060 Technical **Purity:** 95.7% (w:w)  
**Common name:** Mesosulfuron-methyl  
**Chemical name:** IUPAC: Methyl 2-[3-(4,6-dimethoxyprimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethylbenzoate  
 CA name: Methyl 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl-4-[[methylsulfonyl]amino]methyl]benzoate  
 CAS No.: 208465-21-8  
 Synonyms: Code: AE F130060 00 1C95 0001

**Primary Reviewer:** Rebecca Bryan  
Staff Scientist, Dynamac Corporation

**Signature:** *Rebecca Bryan*  
**Date:** 8/22/03

**QC Reviewer:** Christie E. Padova, B.S.  
Staff Scientist, Dynamac Corporation

**Signature:** *C. E. Padova*  
**Date:** 8/22/03

**Primary Reviewer:** *LeLaSohn* Tim Bargar, Biologist  
OPP/EFED/ERB - III

**Date:** *01/09/04* *Le LaSohn*

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

**Date:**

**Reference/Submission No.:**

**Company Code:**  
**Active Code:**  
**EPA PC Code:** 122009

**Date Evaluation Completed:**

**CITATION:** Abedi, J., *et al.* 2001. 96 Hour Acute Toxicity to the Sheepshead Minnow, *Cyprinodon variegatus*, in a Static System, AE F130060 Technical, 95.7% w/w. Unpublished study performed by Aventis CropScience, Pikeville, NC. Laboratory Study Identification CK99W506. Study submitted by Aventis CropScience, Research Triangle Park, NC. Study initiated June 1, 2000 and completed February 16, 2001.

*limit test*



2013017

**Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)**

PMRA Submission Number

EPA MRID Number 45386301

**EXECUTIVE SUMMARY:**

In a 96-hour acute toxicity study, juvenile Sheepshead minnow (*Cyprinodon variegatus*) were exposed to AE F130060 Technical (Mesosulfuron-methyl) at mean-measured concentrations of 0 (negative control) and 105 ppm a.i. under static conditions. Nominal concentrations were 0 (negative control) and 100 ppm (limit concentration). <sup>30 fish</sup>

No mortality or signs of toxicity were observed in the control or test groups during the 96-hour study. The 96-hour LC<sub>50</sub> is >105 ppm a.i., which categorizes AE F130060 Technical (Mesosulfuron-methyl) as practically non-toxic to juvenile Sheepshead minnow on an acute toxicity basis. The NOEC and LOEC observed for both mortality and sub-lethal effects were 105 and >105 ppm a.i., respectively, the only concentration tested.

Since the mean terminal fish weight of 0.307 g was less than the required initial weight range of 0.5 to 5 g, this study does not fulfill guideline requirements for an acute toxicity study with the Sheepshead minnow [§72-3(a)] and is classified SUPPLEMENTAL.

**Results Synopsis**

Test Organism Size/Age (mean Weight or Length): Age not specified; 0.307 ± 0.091 g and 2.2 ± 0.20 cm (means of 30 control fish at study termination)

Test Type (Flow-through, Static, Static Renewal): Static

**96-Hour**

LC<sub>50</sub>: >105 ppm a.i.

NOEC: 105 ppm a.i.

LOEC: >105 ppm a.i.

Endpoints affected: None

**I. MATERIALS AND METHODS**

**GUIDELINE FOLLOWED:** The study protocol was based on procedures outlined in the OECD Guideline No. 203 (1989), and the U.S. EPA Pesticide Assessment Guidelines, Series §72-3 (1982). Deviations from U.S. EPA FIFRA Guideline §72-3a include:

1. The wet fish weight (0.307 g) was determined from control organisms at study termination and was less than the recommended initial range of 0.5-5g.
2. Water hardness was not reported.

These deviations do not affect the validity of the study. However, this study does not fulfill guideline requirements.

**COMPLIANCE:**

Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided. This study was conducted in accordance with standards set forth in 40 CFR 160 with the following exceptions: routine dilution water and fish food contaminant screening analyses were not collected in accordance

with GLP procedures and an in-life inspection was not conducted for the contaminant analyses; and a range-finder test was conducted prior to the signed protocol (p. 3).

**A. MATERIALS:**

**1. Test Material**

AE F 130060 Technical (Mesosulfuron-methyl)

**Description:**

Light beige powder

**Lot No./Batch No. :**

Pfl. 35316

**Purity:**

95.7% (w:w)

**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 96 hours. Results are presented in Table 3, p. 19.

**Storage conditions of test chemicals:**

25 ± 5°C in the dark

*OECD requires water solubility, stability in water and light, pK<sub>a</sub>, P<sub>ow</sub>, and vapor pressure of the test compound. OECD requirements were not reported.*

**2. Test organism:**

**Species:**

Sheepshead minnow (*Cyprinodon variegatus*)

**Age at test initiation:**

Juvenile, not otherwise specified

**Weight at test initiation:**

Initial weights were not reported. Mean terminal weights were 0.307 ± 0.091 g (mean of 30 control fish at study termination)

**Length at test initiation:**

Initial lengths were not reported. Mean terminal lengths were 2.2 ± 0.20 cm (mean of 30 control fish at study termination)

**Source:**

Aquatic Bio-Systems, Fort Collins, CO

**B. STUDY DESIGN:**

**1. Experimental Conditions**

a. Range-finding Study: A 72-hour static range-finding study was conducted with Sheepshead minnow and AE F130060 Technical at nominal concentrations of 0 (negative control), 1, 10, and 100 ppm. After 72 hours, there were no mortalities observed in the control or treatment groups.

b. Definitive Study:

Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)

PMRA Submission Number

EPA MRID Number 45386301

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period:	14 days	EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.
Conditions: (same as test or not)	Same as test	
Feeding:	Rangen Salmon Starter and <i>Artemia nauplii</i> provided, <i>ad libitum</i> .	
Health: (any mortality observed)	No mortalities during the 14-day acclimation period.	
Duration of the test	96 hours	EPA/OECD requires: 96 hours
<u>Test conditions</u> static/flow through	Static	EPA: Must provide reproducible supply of toxicant, with a consistent flow rate of 5-10 vol/24 hours, and meter systems calibrated before study and checked twice daily during test period
Type of dilution system- for flow through method.	N/A	
Renewal rate for static renewal	N/A	
Aeration, if any	No aeration during testing.	EPA requires: no aeration; OECD permits aeration
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass 20 L 15 L (19.0-cm depth)	EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm Fill volume: 15-30 L of solution

Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)

PMRA Submission Number

EPA MRID Number 45386301

Parameter	Details	Remarks
		Criteria
Source of dilution water	The dilution water was synthetic seawater prepared with synthetic sea salts (Lobster Life Systems, E. Rutherford, NJ) and well water.	<p>Results of bi-weekly testing of the well water for nitrate, ammonia, salinity, pH, and DO are provided in Appendix 2, p. 35.</p> <p>Results of bi-annual testing of the well water for a broad range of contaminants and water quality parameters are provided in Appendix 2, pp. 36-39.</p> <p><i>EPA 1975; Soft reconstituted water or water from a natural source, not de-chlorinated tap water; OECD permits de-chlorinated tap water.</i></p>

Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)

PMRA Submission Number

EPA MRID Number 45386301

Parameter	Details	Remarks
		Criteria
<b>Water parameters:</b>		
Hardness	Not reported.	The water hardness was not reported.
pH	7.4-8.1	
Dissolved oxygen	78-112% saturation	
Total Organic Carbon	<1.0 mg/L (bi-annual analysis)	
Particulate Matter	<11.0 mg/L (TSS, bi-annual analysis)	
Metals	See Appendix 2, pp. 36-39	
Pesticides	Not detected	
Chlorine	Not reported	
Temperature	21.6-22.1 °C	
Salinity	17‰	
Intervals of water quality measurement	DO, pH, salinity, and temperature were determined daily in all test tanks. The temperature was also measured continuously in the control chamber.	
		<p><b>Hardness and pH</b>                      EPA requires hardness of 40-48 mg/L as CaCO<sub>3</sub>, and pH of 7.2-7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes; monthly range &lt;0.8. OECD allows hardness of 10-250 mg/L as CaCO<sub>3</sub>, and pH between 6 and 8.5.</p> <p><b>Dissolved Oxygen</b>  <u>Renewal:</u> ≥60% during 1<sup>st</sup> 48 hrs and ≥40% during 2<sup>nd</sup> 48 hrs  <u>Flow-through:</u> ≥60% through out test.                      OECD requires at least 80% saturation value.</p> <p><b>Temperature</b>                      EPA requires 22 ± 1 °C for estuarine/marine. OECD requires range of 21 - 25 °C for bluegill and 13-17 °C for rainbow trout.</p> <p><b>Salinity</b>                      30-34 ‰ (parts per thousand) salinity for marine-stenohaline fishes; 10-17‰ for estuarine-euryhaline fishes, weekly range &lt; 6 ‰</p> <p><b>EPA water quality</b>                      measured at beginning of test and every 48 hours</p>

6

Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)

PMRA Submission Number

EPA MRID Number 45386301

Parameter	Details	Remarks
		Criteria
<u>Concentration of test material:</u> nominal:  measured:	0 (negative control) and 100 ppm  0 (negative control) and 105 ppm a.i.	This study was designed as a limit test.  Recoveries were adjusted for the purity of the test material (Table 3, p. 19).  <i>EPA/OECD requires: Control and five treatment levels. Each conc. should be 60% of the next highest conc., and should be in a geometric series</i>
Solvent (type, percentage, if used)	None used.	<i>EPA requires: Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests; OECD requires solvent, exceed 100 mg/L.</i>
<u>Number of fish/replicates:</u> negative control:  solvent control:  treated:	30 fish, divided into three replicates containing 10 fish each  N/A  30 fish, divided into three replicates containing 10 fish each	<i>EPA: ≥ 10/concentration;                      OECD requires at least 7 fish/concentration</i>
Biomass loading rate	0.205 g fish/L (instantaneous)	<i>Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at &gt; 17°C; flow-through: ≤ 1 g/L/day; OECD requires maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through</i>
Lighting	16-hours light/8-hours dark	Light intensity was approximately 93 foot candles at the level of the test solution.  <i>EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.</i>



**Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)**

PMRA Submission Number

EPA MRID Number 45386301

Parameter	Details	Remarks
		Criteria
Feeding	Animals were not fed during testing.	<i>EPA/OECD requires: No feeding during the study</i>
Recovery of chemical	104-109% of nominal	Based on matrix spikes analyzed concurrently with the samples on Days 0 and 4 (Table 2, p. 19).
Level of Quantitation	5 ppm	
Level of Detection	Not reported	
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	N/A	

**2. Observations:**

**Table 2: Observations**

Criteria	Details	Remarks/Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	3, 6, 24, 48, 72, and 96 hours of exposure	<i>EPA/OECD requires: minimally every 24 hours</i>
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

**II. RESULTS AND DISCUSSION:**

**A. MORTALITY:**

No mortalities were observed in the control or 100 ppm treatment groups.

8

Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Sheepshead Minnow (*Cyprinodon Variegatus*)

PMRA Submission Number

EPA MRID Number 45386301

Table 3: Effect of AE F130060 Technical on Mortality of Bluegill Sunfish (*Lepomis macrochirus*).

Treatment, ppm, measured and (nominal conc.)	No. of fish at start of study	0-24 Hours		48-72 Hours		96 Hours	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Negative control	30	0	0	0	0	0	0
105 (100)	30	0	0	0	0	0	0
NOEC (mortality)	100 ppm						
LC <sub>50</sub> (95% C.I.)	>100 ppm						
Positive control, if used mortality: LC <sub>50</sub> :	N/A	N/A	N/A	N/A	N/A	N/A	N/A

**B. NON-LETHAL TOXICITY ENDPOINTS:**

No sublethal effects were observed during the study in the control or 100 ppm treatment groups.

**C. REPORTED STATISTICS:**

The 96-hour LC<sub>50</sub> value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. Nominal concentrations were reported.

**96-Hour**

LC<sub>50</sub>: >100 ppm

NOEC: 100 ppm

LOEC: >100 ppm

Endpoints affected: None

**D. VERIFICATION OF STATISTICAL RESULTS:**

The 96-hour LC<sub>50</sub> value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. Mean-measured concentrations were reported.

**96-Hour**

LC<sub>50</sub>: >105 ppm a.i.

NOEC: 105 ppm a.i.

LOEC: >105 ppm a.i.

Endpoints affected: None

**E. STUDY DEFICIENCIES:**

This study is scientifically valid. However, the mean fish weight of 0.307 g was determined from the 30 control fish at study termination, and was less than the required initial weight range of 0.5-5 g. As a result, this study does not fulfill guideline requirements for an acute toxicity study with the Sheepshead minnow [§72-3(a)] and is classified SUPPLEMENTAL.

**F. REVIEWER'S COMMENTS:**

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

**G. CONCLUSIONS:**

This study is scientifically sound, but does not satisfy the guideline requirements for an acute toxicity study with an estuarine fish (§72-3a) because the mean weight of the organisms, determined at study termination, was 0.307 g, which is less than the required initial weight range of 0.5 to 5 g. This study provides useful information, and is classified SUPPLEMENTAL. Based on the results of this study, AE F130060 Technical (Mesosulfuron-methyl) is categorized as practically non-toxic to juvenile Sheepshead minnow (*Cyprinodon variegatus*) on an acute toxicity basis.

**96-Hour**

LC<sub>50</sub>: >105 ppm a.i.

NOEC: 105 ppm a.i.

LOEC: >105 ppm a.i.

Endpoints affected: None

**III. REFERENCES:**

- Organization for Economic Co-operation and Development. 1989. *OECD Guideline for Testing of Chemicals; Guideline No. 203: Fish Acute Toxicity Test.*
- U.S. Environmental Protection Agency (EPA). 1982. *Pesticide Assessment Guidelines. Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms.* Guideline §72-3, EPA 540/9-82-024. Washington, DC.
- U.S. Environmental Protection Agency (EPA). 1989. Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), Federal Register Vol. 54, Good Laboratory Practice Standards, Final Rule (40 CFR Part 160). No. 158:34052-34074. Washington, DC.
- Eddy, S. 1978. *How to Know the Freshwater Fishes.* Third Edition. Wm. C. Brown Company, Dubuque, IO.

---

Page \_\_\_ is not included in this copy.

Pages 11 through 14 are not included in this copy.

---

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) \_\_\_\_\_.
- The document is not responsive to the request.

---

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---