

DATA EVALUATION RECORD
ACUTE LC₅₀ TEST WITH AN ESTUARINE/MARINE ORGANISM
§72-3(C) - SHRIMP

1/9/04

1. **CHEMICAL:** Mesosulfuron-methyl

PC Code No.: 122009

2. **TEST MATERIAL:** AE F130060 Technical

Purity: 95.7%

3. **CITATION:**

Author: Abedi, J., *et al.*

Title: 96 Hour Acute Toxicity to the Mysid Shrimp, *Mysidopsis bahia*, in a Static System, AE F130060, Technical, 95.7% w/w

Study Completion Date: February 16, 2001

Laboratory: Aventis CropScience
703 NOR-AM Road
Pikeville, NC 27863

Sponsor: Aventis CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Laboratory Report ID: CK99W507

MRID No.: 45386303

DP Barcode: D284719

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

Signature: Rebecca Bryan

Date: 8/22/03

APPROVED BY: Christie E. Padova, B.S., Staff Scientist, Dynamac Corporation

Signature: C. E. Padova
C. E. Padova

Date: 8/22/03

5. **APPROVED BY:** Tim Bargar, Biologist, OPP/EFED/ERB - III

Signature:

Jo LHA

Date: 01/09/04

6. STUDY PARAMETERS:

Scientific Name of Test Organism: *Mysidopsis bahia* (*Americamysis bahia*)

Age or Size of Test Organism: <24 hours old

Definitive Test Duration: 96 hours

Study Method: Static

Type of Concentration: Mean-measured

7. CONCLUSIONS:

Note: This is a range/limit test 30 mysids (control)
30 mysids (100 ppm)

The 96-hour acute toxicity of AE F130060 Technical (Mesosulfuron-methyl) to the saltwater mysid (*Mysidopsis bahia*) was studied under static conditions. Mysids were exposed to the test material at nominal concentrations of 0 (negative control) and 100 ppm (limit concentration). Mean-measured concentrations were <5.0 (LOQ; control) and 111 ppm a.i. Sym

No mortality or sub-lethal effects were observed in the control or test group during the 96-hour study. The 96-hour LC₅₀ value was 111 ppm a.i., which categorizes AE F130060 Technical (Mesosulfuron-methyl) as practically non toxic to the saltwater mysid, *Mysidopsis bahia*, on an acute toxicity basis. Based on mortality and sub-lethal effects, the NOEC was 111 ppm a.i.

This study is scientifically valid and fulfills the requirements of an acute LC₅₀ test with an estuarine/marine organism (Subdivision E, §72-3(C) [shrimp]). This study is classified as CORE.

Results Synopsis

96-Hour:

LC₅₀: >111 ppm a.i.

NOEC: 111 ppm a.i.

LOEC: >111 ppm a.i.

8. ADEQUACY OF THE STUDY:

A. Classification: Core

B. Rationale: The guideline deviations were considered to be minor and did not impact the acceptability or validity of the study. Missing information should be provided to U.S. EPA.

C. Repairability: N/A

9. BACKGROUND:

10. GUIDELINE DEVIATION:

1. The acclimation period of the adult gravid females was 24 hours, which is significantly less than the 10 days recommended.
2. The salinity (21‰) was less than recommended (30-34‰).
3. The temperature (25.0-25.7°C) was greater than recommended (22 ± 1°C).
4. The pH range (7.1-8.1) was less than recommended (8.0-8.3).
5. The test aquaria (1 L) and fill volume (800 mL) were less than recommended (3.9 L and 2-3 L, respectively).
6. The photoperiod (14 hours light and 10 hours dark) was less than recommended (16 hours light and 8 hours dark).

11. SUBMISSION PURPOSE: This study was submitted to provide data on the toxicity of AE F130060 Technical (Mesosulfuron-methyl) to mysids for the purpose of chemical registration.

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

Guideline Criteria	Reported Information
Species Preferred species are <i>Americamysis bahia</i> , <i>Penaeus setiferus</i> , <i>P. duorarun</i> , <i>P. aztecus</i> and <i>Palaemonetes sp.</i>	<i>Mysidopsis bahia</i> (same as <i>Americamysis bahia</i>)
Age Juvenile (≤ 24 hours old) mysids should be used	<24 hours old
Supplier	Gravid females were supplied by Aquatic BioSystems, Inc., Ft. Collins, CO.
All shrimp are from same source?	Yes
All shrimp are from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 10 days	Approximately 24 hours
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported.
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A

Guideline Criteria	Reported Information
<p><u>Feeding</u> No feeding during the study and no feeding for 24 hours before the beginning of the test if organisms are over 0.5 g each. Mysids should be fed throughout the study.</p>	<p>Fed concentrated <i>Artemia</i> nauplii during acclimation and testing.</p>
<p><u>Pretest Mortality</u> <3% mortality 48 hours prior to testing</p>	<p>0% mortality in the 24 hours prior to testing.</p>

C. Test System

Guideline Criteria	Reported Information
<p><u>Source of dilution water</u> Soft reconstituted water or water from a natural source, not dechlorinated tap water</p>	<p>Synthetic seawater prepared by adding synthetic sea salts (Lobster Life Systems, E. Rutherford, NJ) to well water.</p> <p>Results of bi-weekly testing of the well water for nitrate, ammonia, salinity, pH, and DO are provided in Appendix 2, p. 32.</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. 33-36.</p>
<p>Does water support test animals without observable signs of stress?</p>	<p>Yes</p>
<p><u>Salinity</u> 30-34 ‰ (parts per thousand) for marine (stenohaline) shrimp and 10-17 ‰ for estuarine (euryhaline) shrimp, weekly range <6 ‰</p>	<p>21‰</p>
<p><u>Water Temperature</u> Approx. 22 ± 1 °C</p>	<p>25.0-25.7 °C</p>

Guideline Criteria	Reported Information
<p>pH 8.0-8.3 for marine (stenohaline) shrimp, 7.7-8.0 for estuarine (euryhaline) shrimp, monthly range < 0.8</p>	7.1-8.1
<p>Dissolved Oxygen Between 60 and 105% saturation. If needed, aerate prior to introduction of chemical.</p>	78-99% saturation
<p>Total Organic Carbon Should be <5 mg/L in reconstituted seawater</p>	<1.0 mg/L (bi-annual analysis, p. 34)
<p>Test Aquaria</p> <ol style="list-style-type: none"> 1. <u>Material</u>: Glass or stainless steel 2. <u>Size</u>: 19.6 L is acceptable for organisms ≥ 0.5 g (e.g. pink shrimp, white shrimp, and brown shrimp), 3.9 L is acceptable for smaller organisms (e.g. mysids and grass shrimp). 3. <u>Fill volume</u>: 15 L is acceptable for organisms ≥ 0.5 g, 2-3 L is acceptable for smaller organisms. 	<ol style="list-style-type: none"> 1. Pyrex® beakers covered with glass sheets. 2. 1.0 L 3. 800 mL (10-cm depth).
<p>Type of Dilution System Must provide reproducible supply of toxicant</p>	N/A; Static
<p>Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period</p>	N/A
<p>Biomass Loading Rate Static: ≤ 0.8 g/L at $\leq 17^\circ\text{C}$, ≤ 0.5 g/L at $> 17^\circ\text{C}$; flow-through: ≤ 1 g/L/day (N/A for mysids)</p>	10 mysids/800 mL (organism loading)

Guideline Criteria	Reported Information
<u>Photoperiod</u> 16 hours light, 8 hours dark	14 hours light, 10 hours dark.
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	N/A

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $LC_{50} > 100$ mg/L with 30 shrimp, then no definitive test is required.	A 96-hour static range-finding study was performed at nominal test concentrations of 0 (negative control), 1, 10, and 100 ppm. By 96 hours, there was 0% mortality in the control and treatment groups.
<u>Nominal Concentrations of Definitive Test</u> Control & 5 treatment levels; a geometric series in which each concentration is at least 60% of the next higher one.	0 (negative control) and 100 ppm (limit concentration)
<u>Number of Test Organisms</u> Minimum 20/level, may be divided among containers	30 mysids/level, divided into three replicates of 10 mysids each.
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes. Mortality and sub-lethal effects were observed at 3, 6, 24, 48, 72, and 96 hours.

Guideline Criteria	Reported Information
<p><u>Water Parameter Measurements</u></p> <p>1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary >1°C</p> <p>2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control</p>	<p>1. Measured daily in each aquarium and continuously in the environmental chamber.</p> <p>2. Measured daily in each aquarium.</p>
<p><u>Chemical Analysis</u> needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used</p>	<p>Analytical determination of test substance was performed on samples collected from each test vessel at the beginning and end of the test.</p>

13. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
<p>Quality assurance and GLP compliance statements were included in the report?</p>	<p>Yes</p>
<p><u>Recovery of Chemical</u></p>	<p>111-112% of applied, based on fortification samples run concurrently with the concentration verification samples (Table 2, p. 19).</p>
<p><u>Control Mortality</u> Not more than 10% of control organisms may die or show abnormal behavior.</p>	<p>No mortality was observed.</p>
<p>Raw data included?</p>	<p>Yes</p>
<p>Signs of toxicity (if any) were described?</p>	<p>Yes</p>

Mortality

Concentration (ppm)		Number of Shrimp	Mean cumulative mortality (%)			
Nominal	Mean Measured		Hours of Study			
			24	48	72	96
Negative Control	ND	30	0	0	0	0 ¹
100	111	30	0	0	0	0

ND=Not detected

¹ One mysid in the control was not found due to cannibalism at 96 hours.

By 96 hours, no mortality or sub-lethal effects were observed in the control or 100 ppm treatment group.

B. Statistical Results

The 96-hour LC₅₀ and NOEC were estimated by visual interpretation of the mortality and clinical observation data. The nominal concentration was reported.

96-Hour:LC₅₀: >100 ppm

NOEC: 100 ppm

LOEC: >100 ppm

Endpoints affected: None

14. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC₅₀ and NOEC were estimated by visual interpretation of the mortality and clinical observation data. The mean-measured concentration was reported.

96-Hour:LC₅₀: >111 ppm a.i.

NOEC: 111 ppm a.i.

LOEC: >111 ppm a.i.

Endpoints affected: None

15. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to the study authors. The LC_{50} was >111 ppm a.i., which categorizes AE F130060 Technical (Mesosulfuron-methyl) as practically non-toxic to the Mysid shrimp [72-3(c)] on an acute toxicity basis.

There were numerous minor deviations from Subdivision E guidance. However, it is evident that repeating this study with strict adherence to guidance would not alter the study results, and this study is acceptable in fulfilling the guideline requirement. In future studies conducted by this laboratory, where the toxicity of the test material may be much higher, it is strongly recommended that Subdivision E guidance be followed.

This study was conducted in accordance with USEPA Good Laboratory Practice Regulations with the following exceptions: routine dilution water contaminant screening analyses were not collected in accordance with GLP procedures, and an in-life inspection was not conducted for this study (p. 3). A Quality Assurance Statement was included.

16. REFERENCES

- U.S. Environmental Protection Agency. 1982. Pesticides Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, Office of Pesticide Programs, Guideline 72-3, EPA-540/9-85-024, NTIS Document PB83-153908, Washington, DC.
- U.S. Environmental Protection Agency. 1989. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Register Vol. 54, Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160), No. 158:34052-34074, Washington, DC.
- Price, W.W. 1982. Key to the Shallow Water Mysidacea of the Texas Coast with notes on Their Ecology. *Hydrobiologia* 93, 9-21.

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.
