DP Barcode: D319377 MRID No.: 465789-52

DATA EVALUATION RECORD
ACUTE LC_{50} TEST WITH AN ESTUARINE/MARINE SHRIMP
• 72-3(C)

1. **CHEMICAL**: Orthosulfamuron PC Code No.: 108209

2. **TEST MATERIAL**: IR5878 Purity: 98.56%

3. **CITATION**

Authors:	Palmer, S., Kendall, T., and Krueger, H
Title:	IR5878: A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (*Americamysis bahia*)
Study Completion Date:	August 12, 2002
Laboratory:	Wildlife International, Ltd, Easton, Maryland \
Sponsor:	ISAGRO S.p.A., Milano, Italy
Laboratory Report ID:	544A-108
MRID No.:	465789-52
DP Barcode:	D319377

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

Signature: Rebecca L. Bryan **Date:** 2/13/06

APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental Inc.

Signature: Teri S Myers **Date:** 3/17/06

5. **APPROVED BY**: Christopher J. Salice

Signature: **Date: 7/31/06**

6. **DISCLAIMER**: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to shrimp. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

7. STUDY PARAMETERS

Scientific Name of Test Organism:	*Americamysis bahia*
Age or Size of Test Organism:	Juveniles, <24 hours old
Definitive Test Duration:	96 hours
Study Method:	Static
Type of Concentrations:	Mean measured

8. CONCLUSIONS:

The 96-hour acute toxicity of Orthosulfamuron (Syn. IR5878) to the saltwater mysid, *Americamysis bahia*, was studied under static conditions. Mysids were exposed to the test material at nominal concentrations of 0 (negative control), 16, 26, 43, 72, and 120 mg ai/L; mean measured concentrations were <5.0 (<LOQ; control), 16, 26, 43, 73, and 122 mg ai/L. During the 96-hour test, there were 5, 5 and 10% mortality in the 43, 73, and 123 mg ai/L treatment groups, respectively. No other mortalities occurred and no sub-lethal effects were observed in the treatment or control groups. The **96-hour LC_{50} value was > 122 mg ai/L**, which categorizes Orthosulfamuron as **practically non-toxic** to the saltwater mysid, *Americamysis bahia*, on an acute toxicity basis. Based on mortality, the **NOAEC and LOAEC values were 26 and 43 mg ai/L**, respectively.

This study is scientifically sound and fulfills the requirements of an acute LC_{50} test with an estuarine/marine organism. This study is classified as **ACCEPTABLE**.

Results Synopsis

96-hr LC_{50}: >122 mg ai/L	95% C.I.: Not applicable
Probit Slope: Not applicable	NOAEC: 26 mg ai/L

9. ADEQUACY OF THE STUDY

A. Classification: ACCEPTABLE

B. Rationale:

C. Repairability:

10. BACKGROUND

11. GUIDELINE DEVIATIONS

The pretest mortality/health of the mysids was not reported.

12. **SUBMISSION PURPOSE:**

13. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species are *Mysidopsis bahia*, *Penaeus setiferus*, *P. duorarun*, *P. aztecus* and *Palaemonetes sp.*	*Americamysis bahia*
Age Juvenile, mysids should be # 24 hours old	Juveniles, <24 hours old
Supplier	Wildlife International, Ltd., Easton, Maryland
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	14 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
Feeding No feeding during the study and no feeding	Live brine shrimp, *Artemia nauplii*, was provided daily.

Guideline Criteria	Reported Information
for 24 hour before the beginning of the test if organisms are over 0.5 g each. Mysids should be fed throughout the study.	
Pretest Mortality <3% mortality 48 hours prior to testing	No mortality reported prior to testing.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Natural seawater collected at Indian River Inlet, DE was filtered (25 µm) and diluted (to a salinity of approximately 20‰) with well water. Diluted seawater was aerated and filtered (0.45 µm) to remove microorganisms and fine particles.
Does water support test animals without observable signs of stress?	Yes
Salinity 30-34 ★(parts per thousand) for marine (stenohaline) shrimp and 10-17 ★for estuarine (euryhaline) shrimp, weekly range < 6 ★	20 to 21★
Water Temperature Approx. 22 ± 1 EC	24.7 to 25.9 EC
pH 8.0-8.3 for marine (stenohaline) shrimp, 7.7-8.0 for estuarine (euryhaline) shrimp, monthly range < 0.8	8.1 to 8.3
Dissolved Oxygen Static: ∃ 60% during 1st 48 hrs and ∃ 40% during 2nd 48 hrs, Flow-through: ∃ 60%	5.7-7.2 mg/L(≥78% saturation)
Total Organic Carbon Should be <5 mg/L in reconstituted seawater	Not reported

Guideline [illegible]	
Test Aquaria 1. Material: Glass or stainless steel 2. Size: 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. Fill volume: 15 L is acceptable for organisms ∃ 0.5 g, 2-3 L is acceptable for smaller organisms.	Glass beakers 2 L 1.5L
Type of Dilution System Must provide reproducible supply of toxicant	N/A
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	N/A
Biomass Loading Rate Static: # 0.8 g/L at # 17EC, # 0.5 g/L at > 17EC; flow-through: # 1 g/L/day (N/A for mysids)	N/A for mysids
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark.
Solvents 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
Range Finding Test If LC_{50} >100 mg/L with 30 shrimp, then no definitive test is required.	The nominal definitive test concentrations were based on a range-finding study. However, the results of this range-finding study were not reported.
Nominal Concentrations of Definitive Test Control & 5 treatment levels; a geometric series in which each concentration is at least 60% of the next higher one.	16, 26, 43, 72, and 120 mg ai/L (mean measured concentrations were 16, 26, 43, 73, and 122 mg ai/L)
Number of Test Organisms Minimum 20/level, may be divided among containers	20/level
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1EC 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	Every 24 hours
Chemical Analysis 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	Analytical determination of test substance was performed on samples collected from each test vessel at the beginning (0-hour), at 48 hours, and at end of the test (96-hours).

14. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Recovery of Chemical	98.0-103 %
Control Mortality Not more than 10% of control organisms may die or show abnormal behavior.	0%
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of toxicity were observed.

Mortality

Concentration (mg a.i./L)						
			Number Dead at Study			
Nominal	Mean Measured		24	48	72	96
Control	<LOQ (<5.00 mg/L)	20	0	0	0	0
16	16	20	0	0	0	0
26	26	20	0	0	0	0
43	43	20	0	1	1	1
72	73	20	0	1	1	1
120	122	20	0	1	2	2

During the 96-hour test, there were 5, 5 and 10% mortality in the 43, 73, and 123 mg ai/L treatment groups, respectively. No other mortalities occurred and no sub-lethal effects were observed in the treatment or control groups.

B. Statistical Results

Method: The 96-hour LC_{50} WAS visually determined due to a lack of 50% mortality and sub-lethal effects in the controls and treatment groups. The NOAEC was determined visually as the highest concentration not to exhibit mortality.

96-hr LC_{50}: >122 mg ai/L 95% C.I.: Not applicable
Probit Slope: Not applicable NOAEC: 26 mg ai/L

14. VERIFICATION OF STATISTICAL RESULTS

Parameter	
Binomial Test LC_{50} (C.I.)	>122 mg ai/L
Moving Average Angle LC_{50} (95% C.I.)	>122 mg ai/L
Probit LC_{50} (95% C.I.)	>122 mg ai/L
Probit Slope	Not applicable
NOAEC	26 mg ai/L

15. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to those of the study author.

Based on the LC_{50} value (>123 mg a.i./L), Orthosulfamuron (Syn. IR5878) is categorized as practically non-toxic to saltwater mysids *(Americamysis bahia)* on an acute toxicity basis.

It was not clear if the concentrations were corrected for purity, but the reviewer assumed that they were.

This study was conducted in accordance with USEPA (40 CFR Parts 160 and 792) Good Laboratory Practice Regulations. Quality Assurance and No Data Confidentiality Statements were included.

16. REFERENCES:

U.S. Environmental Protection Agency. 1996. Series 850 - Ecological Effects Test Guidelines (draft), OPPTS Number 850.1035: *Mysid Acute Toxicity Test.*

U.S. Environmental Protection Agency. 1985. *Standard Evaluation Procedure, Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test).* Hazard Evaluation Division. Office of Pesticide Programs. EPA-540/9-85-010. Washington, DC.

ASTM Standard E 729-88a. 1994. *Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.* American Society for Testing and Materials.