Record

Data Evaluation ~~Report~~ on the Acute Toxicity of Orthosulfamuron (IR5878) to Crayfish

PMRA Submission Number {.....} EPA MRID Number 465789-55

Data Requirement:

PMRA Data Code	{.....}
EPA DP Barcode	D319377
OECD Data Point	{.....}
EPA MRID	465789-55
EPA Guideline	Nonguideline (OPPTS 850.1075)

Test material: Orthosulfamuron
Common name: IR5878 Technical
Chemical name: IUPAC:
CAS name:
CAS No.: 213464-77-8
Synonyms:

Purity: 98.56%

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation

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

Secondary Reviewer: Teri S. Myers
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Date: 3/17/06

Primary Reviewer: Christopher Salice
EPA/OPP/EFED/ERB – IV

Date: 6/30/06

Secondary Reviewer(s): Christopher Salice
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Date: 7/31/06

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
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Use Site Category:	{.....}	[For PMRA]
EPA PC Code	108209	

Date Evaluation Completed: 31-07-2006

CITATION: Sutherland, C., Kendall, T., and Krueger, H. 2002. IR5878: A 96-Hour Static Acute Toxicity Test with the Crayfish (*Procambarus clarkii*). Unpublished study performed by Wildlife International, Ltd., Easton Maryland. Laboratory Report Number: 544A-124. Study submitted by ISAGRO S.p.A., Milano, Italy. The final report was issued July 14, 2003.

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 freshwater invertebrates. 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.

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EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, crayfish, *Procambarus clarkii*, were exposed to Orthosulfamuron (IR5878) at nominal concentrations of 7.5, 15, 30, 60, and 120 mg ai/L. Mean measured concentrations were 8.2, 16, 32, 64, and 129 mg ai/L under static conditions. No mortalities or sublethal effects were observed during the study at any treatment level. The 96-h LC_{50} was >129 mg ai/L. The EC_{50} and NOAEC values, based on mortality/sub-lethal effects, were >129 mg ai/L and 129 mg ai/L, respectively.

This study is scientifically sound, but it is classified as SUPPLEMENTAL, because crayfish are not a US EPA-recommended species for toxicity testing with freshwater invertebrates, and guidelines do not exist for this species. The results of this study, however, are useful for risk assessment purposes.

Results Synopsis

Test Organism Size/Age (mean weight or length): Juvenile (Age not specified); 3.7 cm and 1.2 g (mean of ten control crayfish at test termination).
Test Type (Flow-through, Static, Static Renewal): Static

LC_{50}: >129 mg ai/L 95% C.I.: Not applicable
NOAEC: 129 mg ai/L Probit Slope: Not applicable
EC_{50}: >129 mg ai/L
Endpoint(s) Affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This is a nonguideline study.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Confidentiality statements were provided. This study was conducted in accordance with GLP standards set forth by the U.S. EPA (1989), the OECD (1998), and the Japan MAFF (1999, p. 3).

A. MATERIALS:

1. Test material Orthosulfamuron (IR5878)

Description: White powder

Lot No./Batch No. : G009/02

Purity: 98.56%

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, 48, and 96 hours. Recoveries at the 7.5 to 120 mg ai/L (nominal) levels were 106-108% of nominal concentrations in 0-hour samples, 107-112% in 48-hour samples, and 106-110% in 96-hour samples, with no pattern of decline.

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

Storage conditions of test chemicals: Test material was stored under ambient conditions.

Physicochemical properties of Orthosulfamuron.

Parameter	Values	Comments
Water solubility at 20EC	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Species: Crayfish, *Procambarus clarkii*
Age at test initiation: Juvenile (Age not specified)
Weight at study initiation: 1.2 g and 0.83-1.6 g (mean and range of ten control crayfish at test termination).

Length at study initiation: 3.7 cm and 3.2-4.1 cm (mean and range of ten control crayfish at test termination).

Source: W. Ray McClain, Crowley, Louisiana.
EPA recommends that all organisms be from the same source

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study
The nominal definitive test concentrations were based on a range-finding study. However, the results of this range-finding study were not 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)	14 days Same as test Frozen brine shrimp were provided daily. No mortalities occurred and there were no signs of disease or stress.	*The recommended acclimation period is a minimum of 14 days; OECD guideline recommends a minimum of 12 days. Pretest mortality should be < 3% 48 h. prior to testing. OECD pretest mortality criteria: >10% = rejection of entire batch; ≥ 5 and ≤ 10% = continued acclimation for 7 days; <5% = acceptable.*
Duration of the test	96 hours	*The recommended test duration is 96 hours.*
Test condition Static/flow-through Type of dilution system - for flow-through method. Renewal rate for static renewal	Static Not applicable Not applicable	*A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.*
Aeration, if any	Gentle aeration was added after 48 hours and continued until test termination.	*Aeration is not recommended; OECD guideline recommends aeration. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.*

Parameter	Details	Remarks *Criteria*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Stainless steel aquaria 54 L 40 L	The aquaria contained 5 PVC tiles each to minimize aggressive encounters between crayfish. *Test vessel size is usually 250 ml or 3.9 L Fill volume is usually 200 ml of solution.*
Source of dilution water Quality:	The dilution water was filtered and aerated laboratory well water.	*Recommended source of dilution water is soft, reconstituted water or water from a natural source. EPA does not recommend the use of dechlorinated tap water; however, its use may be supportable if the biological responses for the organisms and chemical analyses of residual chlorine meet conditions in the Agency's 850.1010 guidelines for dilution water (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Draft/850.1010.pdf) Dilution water should be intensely aerated before the study. OECD permits dechlorinated tap water.*

Parameter	Details	Remarks *Criteria*
Water parameters: Hardness pH Dissolved oxygen Total Organic carbon Particulate Matter Metals Pesticides Chlorine Temperature Intervals of water quality measurement	128 mg/L 8.3-8.7 4.7-8.6 mg/L (slightly below 60% saturation) Not reported Not reported Not detected Not detected Not reported 21.3-22.7°C Every 24 hours	Pesticides and organics were not detected at levels of concern (<50 ppb). No heavy metals were detected. *Hardness:* *EPA recommends 40 - 48 mg/L as $CaCO_3$ (OECD recommends 10 - 250 mg a.i./L)* *pH:* *EPA recommends 7.2 - 7.6* *Dissolved Oxygen:* *EPA recommends: Static: ∃60% during first 48 hrs and ∃40% during second 48 hrs; flow-through: ∃60%; (OECD guideline recommends at least 80% saturation value).* *Temperature:* *EPA recommends 20°C (measured continuously or if water baths are used, every 6 hr, may not vary > 1°C* *Water quality should be measured at beginning of test and every 48 hours.*
Number of replicates/groups: control: solvent control: treated ones:	2 Not applicable 2	*Recommended number of replicates includes a control and five treatment levels. Each concentration should be 60% of the next highest concentration; concentrations should be in a geometric series.*
Number of organisms per replicate /groups: control: solvent control: treated ones:	10 Not applicable 10	*Number of organisms per replicate should be ∃10/concentration; OECD guideline recommends at least 7 fish/concentration.*
Biomass loading rate	0.30 g crayfish/L	*Recommended static conditions are # 0.8 g/L at # 17EC and # 0.5 g/L at > 17EC. Recommended flow-through conditions are # 1 g/L/day. OECD recommends a maximum of 1 g fish/L for static and semi-static, while higher rates are recommended for flow-through.*
Test concentrations:		

Parameter	Details	Remarks *Criteria*
nominal: measured:	7.5, 15, 30, 60, and 120 mg ai/L 8.2, 16, 32, 64, and 129 mg ai/L	
Solvent (type, percentage, if used)	Not applicable	*The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD recommends that the solvent not exceed 100 mg a.i./L.*
Lighting	16-hours light/8-hours dark, with a 30-minute transition period.	*The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12 -16 hours.*
Feeding	Frozen brine shrimp were provided daily.	
Recovery of chemical Frequency of determination Level of quantization Level of detection	99.3 ± 1.93% of nominal Concurrently with test samples 5.00 mg ai/L Not reported	Based on matrix spikes (at 7.00, 30.0, and 120 mg a.i./L) analyzed concurrently with the samples (Appendix 3.6, p. 36).
Positive control {if used, indicate the chemical and concentrations}	Not applicable	
Other parameters, if any	The whole body residues of crayfish were determined using tissue analysis.	

2. Observations:

Table 2: Observations

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and sublethal effects	
Observation intervals	Every 24 hours	*Observation intervals should be a minimum of every 24 hours.*
Were raw data included?	Yes, sufficient	
Other observations, if any	Tissue analysis for residues.	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

During the 96-hour test, no mortalities were observed. The NOAEC based on mortality was 129 mg ai/L, the highest concentration tested.

Table 3: Effect of Orthosulfamuron (IR5878) on Mortality of Crayfish.

Treatment (mg ai/L) measured and (nominal) concentration used	No. of fish at start of study	Observation period					
		Day 1		Day 2		Day 4	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control (dilution water only)	20	0	0	0	0	0	0
8.2 (7.5)	20	0	0	0	0	0	0
16 (15)	20	0	0	0	0	0	0
32 (30)	20	0	0	0	0	0	0
64 (60)	20	0	0	0	0	0	0
129 (120)	20	0	0	0	0	0	0
NOAEC		129		129		129	
LC_{50}		>129		>129		>129	
Positive control, if used mortality: LC_{50}:		NA		NA		NA	

NA= Not applicable

B. NON-LETHAL TOXICITY ENDPOINTS:

During the 96-hour test, no sublethal effects were observed. The NOAEC based on sublethal effects was 129 mg ai/L, the highest concentration tested.

Table 4: Sub-lethal Effect of Orthosulfamuron (IR5878) on Crayfish.

Treatment (mg ai/L) measured and (nominal) concentration used	Observation period		
	Day 1	Day 2	Day 4
	% affected	% affected	% affected
Control (dilution water only)	N	N	N
8.2 (7.5)	N	N	N
16 (15)	N	N	N
32 (30)	N	N	N
64 (60)	N	N	N
129 (120)	N	N	N
NOAEC	129	129	129
LOAEC	>129	>129	>129
EC_{50}	>129	>129	>129
Positive control, if used % sublethal effect: EC_{50}:	NA	NA	NA

N= Appears normal
NA= Not applicable

C. REPORTED STATISTICS:

The 96-hour LC_{50} and NOAEC were visually determined, due to the lack of treatment-related mortality or sub-lethal effects at any treatment level.

96-Hour

LC_{50}: >129 mg ai/L 95% C.I.: Not applicable

NOAEC: 129 mg ai/L

Probit Slope: Not applicable 95% C.I.: Not applicable

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: The LC_{50} based on mortality and the NOEC and LOEC values based on mortality and sub-lethal effects were determined visually due to a lack of treatment related effects at any level during the definitive exposure period.

LC_{50}: >129 mg ai/L 95% C.I.: Not applicable

NOAEC: 129 mg ai/L

Probit Slope: Not applicable 95% C.I.: Not applicable

E. STUDY DEFICIENCIES:

This is a nonguideline study. There were no study deficiencies.

F. REVIEWER'S COMMENTS:

The reviewer's LC_{50} estimate was identical to the study authors'.

The whole body residues of crayfish were determined using tissue analysis at test termination. The tissue samples for each treatment group were collected by combining 5 crayfish from each replicate. The measured concentrations of Orthosulfamuron in the crayfish tissues ranged from <LOQ (<0.500 µg ai/g) to 1.99 µg ai/g (Table 2, p. 21).

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

The experimental start date was May 19, 2003 and the experimental termination date was May 23, 2003.

G. CONCLUSIONS:

This study is scientifically sound, but it is classified as SUPPLEMENTAL, because crayfish are not a US EPA-recommended species for toxicity testing with freshwater invertebrates, so guidelines do not exist for this species. The results of this study, however, are useful for risk assessment purposes. The 96-hour LC/EC_{50} was >129 mg ai./L and the NOAEC was 129 mg ai/L.

III. REFERENCES:

Organization for Economic Cooperation and Development. 1984. Guideline 202: *Daphnia sp. Acute Immobilization Test and Reproduction Test*. OECD Guideline for the Testing of Chemicals. Updated Guideline, adopted April, 1984.

Organization for Economic Cooperation and Development. 1993. OECD Guidelines for the Testing of Chemicals Guideline 203: *Fish Acute Toxicity Test*. Adopted by the Council on 12 July 1992.

U.S. Environmental Protection Agency. 1996. Series 850 - Ecological Effects Test Guidelines (draft), OPPTS Number 850.1075: *Fish Acute Toxicity Test, Freshwater and Marine*.

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

APHA, AWWA, WPCF. 1998. Standard Methods for the Examination of Water and Wastewater. 20th Edition. American Public Health Association. American Water Works Association. Water Pollution Control Federation, New York.