Record

Data Evaluation ~~Report~~ on the Acute Toxicity of IR5878 Technical (Orthosulfamuron) to Bluegill Sunfish (*Lepomis macrochirus*)

PMRA Submission Number {.....}

EPA MRID Number 46219043

Data Requirement:

PMRA DATA CODE	
EPA DP Barcode	D304186
OECD Data Point	
EPA MRID	46219043
EPA Guideline	§72-1a

Test material: IR5878 Technical
Common name: Orthosulfamuron
Chemical name: IUPAC: Not Reported
CAS name: Not reported
CAS No.: 213464-77-8
Synonyms: N/A

Purity: 98.56%

Primary Reviewer: John Marton
Staff Scientist, Dynamac Corporation

Signature:
Date: 12/13/2004

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Date: 12/28/2004

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Date: 7/31/06

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Date Evaluation Completed: 31-07-2006

CITATION: Palmer, S.J., T.Z. Kendall, and H.O. Krueger. 2002. IR5878: A 96-Hour Static Acute Toxicity Test With The Bluegill (*Lepomis macrochirus*). Unpublished study performed by Wildlife International, Ltd., Easton, MD. Laboratory Project Identification No. 544A-111. Study submitted by ISAGRO S.p.A, Centro Uffici San Siro, I-20153 Milano Italy. Study initiated December 18, 2002 and completed February 5, 2003.

EXECUTIVE SUMMARY:

The 96-hour acute toxicity of IR5878 Technical (Orthosulfamuron) to Bluegill sunfish (*Lepomis marcrochirus*) was studied under static conditions. Fish were exposed to IR5878 Technical at nominal concentrations of 0 (negative control), 16, 26, 43, 72 and 120 ppm a.i. Mean-measured concentrations were <5.00 (<LOQ, negative control), 18, 34, 46, 84, and 142 ppm a.i., respectively.

After 96 hours of exposure, there were no mortalities in the control group or any of the treatment groups. The 96-hour LC_{50} was >142 ppm a.i., the highest concentration level tested, which classifies IR5878 Technical (Orthosulfamuron) as practically non-toxic to the Bluegill sunfish (*Lepomis macrochirus*) on an acute toxicity basis. No sub-lethal effects were observed during the exposure period in the control or any of the treatment groups. The NOEC for this study based on the mortality and sub-lethal effects data was 142 ppm a.i., the highest treatment concentration tested.

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with Bluegill Sunfish (*Lepomis macrochirus*)[§72-1(a)]. Although the blotted wet weight of the test fish, obtained from ten negative control fish at study termination (0.37-1.1 g) ranged lower than the recommended initial weight range of 0.5 to 5 g, fish were beyond the yolk-sac stage. Consequently, this study is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	Mean blotted-dry weight of ten negative control fish at test termination was 0.78 g (range of 0.37-1.1 g). Mean length of ten negative control fish at test termination was 4.1 cm (range of 3.4-4.5 cm).
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour
LC_{50}: >142 ppm a.i. 95% C.I.: N/A
Probit Slope: N/A
NOEC: 142 ppm a.i.
LOEC: >142 ppm a.i.
Endpoints affected: None
Most sensitive endpoint: N/A

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was based on procedures outlined in the OECD Guidelines for the Testing of Chemicals, 203: *Fish Acute Toxicity Test*; U.S. EPA Series 850- Ecological Effects Test Guidelines (draft), OPPTS Number 850.1075: *Fish Acute Toxicity Test, Freshwater and Marine* and ATM Standard E729-88a: *Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians*. Deviations from §72-1a included:

- The hardness (140 mg/L as $CaCO_3$) was higher than recommended (40-48 mg/L as $CaCO_3$).
- The total organic carbon, particulate matter, and chlorine concentrations in the dilution water were not

reported.

- The pH range (8.2-8.7) was higher than recommended (7.2-7.6).
- It was not reported whether or not aeration was used during the definitive test.
- The blotted wet-weights of ten negative control fish at test termination ranged (0.37-1.1 g) lower than recommended (0.5-5.0 g).

The above deviations did not affect the validity of the study.

COMPLIANCE: Signed and dated GLP, No Data Confidentiality, and Quality Assurance statements were provided. The study followed the U.S. EPA, Japan MAFF and OECD Good Laboratory Practice Guidelines.

A. MATERIALS:

1. Test Material IR5875 Technical (Orthosulfamuron)

Description: White Powder

Lot No./Batch No. : G009/02

Purity: 98.56%

Stability of Compound Under Test Conditions: Recoveries (all test levels) were 106-148% of nominal concentrations in 0-hour samples, 107-150% in 48-hour samples and 108-152% in 96-hour samples (Table 1, p. 17). Mean-measured recoveries were 107-131% of nominal. Note section **E. STUDY DEFICIENCIES:** below for further details.

Storage conditions of test chemicals: The test chemical was stored under ambient conditions.

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. The following OECD requirements were reported:

2. Test organism:

Species: Bluegill sunfish (*Lepomis macrochirus*)

Age at test initiation: Juvenile, age not specified.

Weight at test initiation: Not reported; Mean blotted-dry weight of ten negative control fish at test termination was 0.78 g (range of 0.37-1.1 g).

Length at test initiation: Not reported; Mean length of ten negative control fish at test termination was 4.1 cm (range of 3.4-4.5 cm).

Source: Osage Catfisheries, Inc., Osage Beach Missouri.

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: The definitive nominal test concentrations were selected in consultation with the Sponsor, and were based on the results of an exploratory range finding test. Results from the range finding test were not reported.

b. Definitive Study:

Table 1: Experimental Parameters

Parameter	Details	Remarks / Criteria
Acclimation period:	At least 14 days in test water from the same source. Acclimated to test conditions for approximately 55 hours prior to test initiation	
Conditions: (same as test or not)	Same as test.	*EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.*
Feeding:	Commercial fish food supplied by Zeigler Brothers, Inc., Gardners, PA. Fish were not fed at least two days prior to test initiation.	
Health: (any mortality observed)	All fish appeared normal and healthy.	
Duration of the test	96 hours	
		EPA/OECD requires: 96 hours
Test condition static/flow through	Static	
Type of dilution system- for flow through method.	N/A	*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*
Renewal rate for static renewal	N/A	
Aeration, if any	The study authors did not report	

Parameter	Details	Remarks
		Criteria
	whether aeration was used or not during testing.	*EPA requires: no aeration; OECD permits aeration*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Glass aquaria 25 L 20 L (23 cm depth for test solution)	
		EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm *Fill volume: 15-30 L of solution*
Source of dilution water	On-site well-water, 40 m deep.	The well water was sand filtered to remove particles greater than approximately 25 µm, aerated with spray nozzles, then filtered again (45 µm) to remove microorganisms and particles.
		*EPA 1975; Soft reconstituted water or water from a natural source, **not** dechlorinated tap water;* *OECD permits dechlorinated tap water.*

Parameter	Details	Remarks Criteria
Water parameters: Hardness	140 mg $CaCO_3$/L (test initiation)	The hardness (140 mg/L as $CaCO_3$) was higher than recommended (40-48 mg/L as $CaCO_3$). The pH ranged (8.2-8.7) higher than recommended (7.2-7.6).
pH	8.2-8.7	
Dissolved oxygen	7.8-9.9 mg O_2/L (≥72% saturation)	
Total Organic Carbon	Not reported	
Particulate Matter	Not reported	
Metals	<LOD; See Appendix 2, pp. 23-24	
Pesticides	<LOD	
Chlorine	Not reported	
Temperature	21.0-22.9°C	
{Salinity for marine or estuarine species}	N/A	
Intervals of water quality measurements	DO, temperature and pH were measured in each test chamber at test initiation, test termination and at 24 hour intervals. Hardness was measured at test initiation. Temperature was also measured continuously in one negative control chamber.	

Parameter	Details	Remarks Criteria
		Hardness and pH *EPA requires hardness of 40-48 mg/L as $CaCO_3$ 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 <0.8. OECD allows hardness of 10-250 mg/L as $CaCO_3$ and pH between 6 and 8.5.* ***Dissolved Oxygen*** *Renewal: ≥60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs* *Flow-through: ≥60% through out test. OECD requires at least 80% saturation value.* ***Temperature*** *EPA requires 22 ± 1 °C for estuarine/marine. OECD requires range of 21 - 25 °C for bluegill and 13-17 °C for rainbow trout.* ***Salinity*** *30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰* ***EPA water quality*** *measured at beginning of test and every 48 hours*
Concentration of test material: nominal: measured:	0 (negative control), 16, 26, 43, 72, and 120 ppm a.i. <5.00 (<LOQ, negative control), 18, 34, 46, 84, and 142 ppm a.i.	Measured concentrations were determined at 0, 48 and 96 hours; results are provided in Table 1, p. 17. Mean-measured recoveries were 107-131% of nominal. *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*
Solvent (type, percentage, if used)	N/A	*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.*
Number of fish/replicates: negative control:	20 fish, two replicates with 10 fish each.	*EPA: ≥ 10/concentration;*

Parameter	Details	Remarks
		Criteria
solvent control: treated:	N/A 20 fish, two replicates with 10 fish each.	*OECD requires at least 7 fish/concentration*
Biomass loading rate	0.39 g fish/L	
		Static: ≤ 0.8 g/L at ≤ 17 °C, ≤ 0.5 g/L at > 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
Lighting	16-hours light/8-hours dark with a 30 minute transition period	
		EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.
Feeding	Animals were not fed during testing.	
		EPA/OECD requires: No feeding during the study
Stability of chemical in the test system	Recoveries (all test levels) were 106-148% of nominal concentrations in 0-hour samples, 107-150% in 48-hour samples and 108-152% in 96-hour samples (Table 1, p. 17).	Note section **E. STUDY DEFICIENCIES:** below for further details.
Recovery of chemical Level of Quantitation Level of Detection	102-109% of nominal 5.00 ppm a.i. Not reported	Based on matrix spikes (at 15.0, 30.0 and 120 ppm a.i.) analyzed concurrently with the test samples (Appendix 3.5, p. 30).
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 sub-lethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	18, 24, 48, 72, and 96 hours	
		EPA/OECD requires: minimally every 24 hours
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

After 96 hours of exposure, no mortalities had occurred in the negative control group or any of the treatment groups. The 96-hour LC_{50} was >142 ppm a.i., the highest concentration tested. The NOEC for mortality was 142 ppm a.i.

Table 3: Effect of IR5878 Technical (Orthosulfamuron) on Mortality of Bluegill Sunfish (*Lepomis macrochirus*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	No. of Fish at Start of Study	Observation Period					
		18-24 Hours		48 Hours		96 Hours	
		No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality
Negative control	20	0	0	0	0	0	0
18 (16)	20	0	0	0	0	0	0
34 (26)	20	0	0	0	0	0	0
46 (43)	20	0	0	0	0	0	0
84 (72)	20	0	0	0	0	0	0
142 (120)	20	0	0	0	0	0	0
NOEC (mortality), ppm a.i.		142		142		142	
LC_{50} (95% C.I.), ppm a.i.		>142		>142		>142	
Positive control, if used mortality: LC_{50}:		N/A	N/A	N/A	N/A	N/A	N/A

B. NON-LETHAL TOXICITY ENDPOINTS:

After 96 hours of exposure, no sub-lethal effects were observed in the negative control or any of the treatment groups. The NOEC for sub-lethal effects was 142 ppm a.i.

Table 4: Sub-Lethal Effects of IR5878 Technical (Orthosulfamuron) on Bluegill Sunfish (*Lepomis macrochirus*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	Observation Period			
	Endpoint at 18-24 Hours	Endpoint at 48 Hours	Endpoint at 72 Hours	Endpoint at 96 Hours
	% Affected	% Affected	% Affected	% Affected
Negative control	N	N	N	N
17.98 (16)	N	N	N	N
34.15 (26)	N	N	N	N
46.18 (43)	N	N	N	N
83.50 (72)	N	N	N	N
142 (120)	N	N	N	N
NOEC	142			
LOEC	>142			
EC_{50}	Not reported			
Positive control, if used % sub-lethal effect: EC_{50}:	N/A	N/A	N/A	N/A

N - Appeared normal.

C. REPORTED STATISTICS:

The 96-hour NOEC and LC_{50} values were determined by visual interpretation of the mortality and sub-lethal effects data due to the lack of any treatment related effects. All toxicity values were determined in terms of the mean-measured treatment concentrations.

96-Hour
LC_{50}: >142 ppm a.i. 95% C.I.: N/A
Probit Slope: N/A
NOEC: 142 ppm a.i.
LOEC: >142 ppm a.i.
Endpoints affected: None
Most sensitive endpoint: N/A

D. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC_{50}, NOEC and LOEC values were determined visually due to a complete lack of mortality and sub-lethal effects at all treatment levels. All toxicity values were determined in terms of the mean-measured treatment concentrations.

96-Hour
LC_{50}: >142 ppm a.i. 95% C.I.: N/A
NOEC: 142 ppm a.i.
LOEC: >142 ppm a.i.
Endpoints affected: None
Most sensitive endpoint: N/A

E. STUDY DEFICIENCIES:

The blotted-dry weights of ten negative control fish at test termination (0.37-1.1 g) ranged lower than the US EPA recommended initial weight range of 0.5-5.0 g. However, fish of this size are beyond the yolk-sac stage and therefore are expected to respond similarly to toxicant exposure compared to fish within the recommended weight range.

The study authors noted that samples collected at test initiation, at 48-hours, and at test termination (96-hours) had measured concentrations that ranged from 106 to 121% of nominal concentrations, with the exception of one replicate in the nominal 26 ppm a.i. treatment group. These measured concentrations of samples collected from that replicate were 148-152% of nominal. Since the concentration was consistently high over the 96-hour period, the study authors believed an error occurred in the preparation of the test solution for that replicate. Since the measured concentrations (38.5-39.6 ppm a.i.) were all well below the experimentally determined NOEC value, the study authors concluded that these higher than expected recoveries did not affect the results of this study. The reviewer agrees with the above comments and concluded that the higher than expected recoveries at the nominal 26 ppm a.i. treatment level did not adversely affect this study. Consequently, this deviation was considered minor.

All other deficiencies/deviations from U.S. EPA guideline §72-1a were considered minor and did not affect the validity or acceptability of this study. This study is classified as ACCEPTABLE and fulfills guideline requirements for an acute toxicity study with the Bluegill Sunfish [§72-1(a)].

F. REVIEWER'S COMMENTS:

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

G. CONCLUSIONS:

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with Bluegill Sunfish (*Lepomis macrochirus*)[§72-1(a)]. his study is classified as ACCEPTABLE. on the results of this study (LC_{50} was >142 ppm a.i.), IR5878 Technical (Orthosulfamuron) is categorized as practically non-toxic to the Bluegill Sunfish (*Lepomis macrochirus*) on an acute toxicity basis. The NOEC based on the lack of mortality and sub-lethal effects was the highest treatment concentration tested, 142 ppm a.i..

96-Hour
LC_{50}: >142 ppm a.i. 95% C.I.: N/A
NOEC: 142 ppm a.i.
LOEC: >142 ppm a.i.
Endpoints affected: None
Most sensitive endpoint: N/A

III. REFERENCES:

Organization for Economic Cooperation and Development. 1993. OECD Guidelines for Testing of Chemicals. Guideline 203: *Fish, Acute Toxicity Test.* Updated Guideline adopted on 17 July 1992.

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

ASTM Standard E729-88a. 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.