Record

Data Evaluation Report on the Acute Toxicity of IR5878 Technical (Orthosulfamuron) to Rainbow Trout (*Oncorhynchus mykiss*)

PMRA Submission Number {.....} **EPA MRID Number 46219042**

Data Requirement:

PMRA DATA CODE	
EPA DP Barcode	D304186
OECD Data Point	
EPA MRID	46219042
EPA Guideline	§72-1c

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: 12/10/2004

QC Reviewer: Gregory S. Hess
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Date: 12/28/2004

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Date: 7/31/06

Reference/Submission No.:

Company Code:
Active Code:
EPA PC Code: 108209

Date Evaluation Completed: 31-07-2006

CITATION: Palmer, S.J., M.A. Stence, T.Z. Kendall, and H.O. Krueger, 2002. IR5878: A 96-Hour Static Acute Toxicity Test With The Rainbow Trout (*Onchorynchus mykiss*). Unpublished study performed by Wildlife International, Ltd., Easton, MD. Laboratory Project Identification No. 544A-107. Study submitted by ISAGRO S.p.A, Centro Uffici San Siro, I-20153 Milano Italy. Study initiated May 23, 2002 and completed August 19, 2002.

EXECUTIVE SUMMARY:

The 96-hour acute toxicity of IR5878 Technical (Orthosulfamuron) to Rainbow trout (*Oncorhynchus mykiss*) 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), 16, 26, 44, 74, and 122 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 >122 ppm a.i., the highest concentration tested, which classifies IR5878 Technical (Orthosulfamuron) as practically non-toxic to the Rainbow trout (*Oncorhynchus mykiss*) 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 122 ppm a.i., the highest concentration tested.

This study is scientifically sound, and satisfies the guideline requirements for an acute toxicity study with Rainbow trout (*Oncorhynchus mykiss*)[§72-1(c)]. This study is classified ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	Mean blotted-dry weight of ten negative control fish at test termination was 0.81 g (range of 0.36-1.3 g). Mean length of ten negative control fish at test termination was 4.5 cm (range of 3.8-5.1 cm).
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour
LC_{50}: >122 ppm a.i. 95% C.I.: N/A
Probit Slope: N/A
NOEC: 122 ppm a.i.
LOEC: >122 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;* U.S. EPA, Standard Evaluation Procedure: *Acute Toxicity Test for Freshwater Fish*; and ATM Standard E729-88a: *Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.* Deviations from §72-1c included:

- The hardness (124 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 ranged (8.3-8.7) higher than recommended (7.2-7.6).
- The temperature ranged (11.7-13.4°C) slightly lower than recommended (13-17°C).
- The study authors did not report whether or not aeration was used during the definitive test.
- The blotted wet-weights of ten negative control fish at test termination ranged (0.36-1.3 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 97.6-105% of nominal concentrations in 0-hour samples, 98.3-105% in 48-hour samples and 99.0-107% in 96-hour samples (Table 1, p. 17). Mean-measured recoveries were 97.6-107% of nominal.

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: Rainbow trout (*Oncorhynchus mykiss*)

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 0.81 g (range of 0.36-1.3 g).

Length at test initiation: Not reported; Mean length of ten negative control fish at test termination

was 4.5 cm (range of 3.8-5.1 cm).

Source: Thomas Fish Company; Anderson, California.

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 53 hours prior to test initiation	*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:	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; mortality was <1% during the acclimation period.	
Duration of the test	96 hours	*EPA/OECD requires: 96 hours*
Test condition 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	The study authors did not report whether aeration was used or not	

Parameter	Details	Remarks
		Criteria
	during testing.	*EPA requires: no aeration; OECD permits aeration*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Glass aquaria 38 L 15 L (12.5 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 great 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	124 mg $CaCO_3$/L	The hardness (124 mg/L as $CaCO_3$) was higher than recommended (40-48 mg/L as $CaCO_3$). The pH range (8.3-8.7) was higher than recommended (7.2-7.6). The temperature ranged (11.7-13.4°C) was lower than recommended (13-17°C).
pH	8.3-8.7	
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, pgs. 23-24	
Pesticides	<LOD	
Chlorine	Not reported	
Temperature	11.7-13.4°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), 16, 26, 44, 74, and 122 ppm a.i.	Measured concentrations were determined at 0, 48 and 96 hours; results are provided in Table 1, p. 17. *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; OECD requires at least 7*

Parameter	Details	Remarks
		Criteria
solvent control: treated:	N/A 20 fish, two replicates with 10 fish each.	*fish/concentration*
Biomass loading rate	0.54 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 transitional 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 97.6-105% of nominal concentrations in 0-hour samples, 98.3-105% in 48-hour samples, and 99.0-107% in 96-hour samples.	Results are provided in Table 1, p. 17.
Recovery of chemical Level of Quantitation Level of Detection	99.5-100% of nominal 5.00 ppm a.i. Not reported	Based on matrix spikes (at 10.0, 40.0, 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	Mortality and sub-lethal effects	

sub-lethal effects/toxicity symptoms		
Observation intervals	3, 24, 48, 72, and 96 hours of exposure	
		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 >122 ppm a.i., the highest concentration tested. The NOEC for mortality was 122 ppm a.i.

Table 3: Effect of IR5878 Technical (Orthosulfamuron) on Mortality of Rainbow trout (*Oncorhynchus mykiss*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	No. of Fish at Start of Study	Observation Period					
		3-24 Hours		48 Hours		96 Hours	
		No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality
Negative control	20	0	0	0	0	0	0
16 (16)	20	0	0	0	0	0	0
26 (26)	20	0	0	0	0	0	0
44 (43)	20	0	0	0	0	0	0
74 (72)	20	0	0	0	0	0	0
122 (120)	20	0	0	0	0	0	0
NOEC (mortality), ppm a.i.		122		122		122	
LC_{50} (95% C.I.), ppm a.i.		>122		>122		>122	
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 122 ppm a.i.

Table 4: Sub-Lethal Effects of IR5878 Technical (Orthosulfamuron) on Rainbow Trout (*Oncorhynchus mykiss*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	Observation Period			
	Endpoint at 3-24 Hours	Endpoint at 48 Hours	Endpoint at 72 Hours	Endpoint at 96 Hours
	% Affected	% Affected	% Affected	% Affected
Negative control	N	N	N	N
16 (16)	N	N	N	N
26 (26)	N	N	N	N
44 (43)	N	N	N	N
74 (72)	N	N	N	N
122 (120)	N	N	N	N
NOEC	122			
LOEC	>122			
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}: >122 ppm a.i. 95% C.I.: N/A
Probit Slope: N/A
NOEC: 122 ppm a.i.
LOEC: >122 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}: >122 ppm a.i. 95% C.I.: N/A
NOEC: 122 ppm a.i.
LOEC: >122 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 (0.36-1.3 g) ranged lower than the US EPA recommended initial weight range of 0.5-5.0 g.

This study is classified as ACCEPTABLE and satisfies the guideline requirements for an acute toxicity study with the Rainbow Trout [§72-1(c)].

All deficiencies/deviations from U.S. EPA guideline §72-1c were considered minor and did not affect the validity or acceptability of this study.

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 Rainbow trout (*Oncorhynchus mykiss*)[§72-1(c)]. Although the blotted wet-weight of the test fish, obtained from ten negative control fish at study termination (0.36-1.3 g) ranged lower than the recommended initial weight range of 0.5 to 5 g, fish of this size are juveniles and beyond the egg fry stage. Consequently, this study is classified as ACCEPTABLE. Based on the results of this study (LC_{50} >122 ppm a.i.), IR5878 Technical (Orthosulfamuron) is categorized as practically non-toxic to the Rainbow trout (*Oncorhynchus mykiss*) on an acute toxicity basis. The NOEC based on the lack of mortality and sub-lethal effects was the highest treatment concentration tested, 122 ppm a.i..

96-Hour
LC_{50}: >122 ppm a.i. 95% C.I.: N/A
NOEC: 122 ppm a.i.
LOEC: >122 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.*

U.S. EPA. 1985. Standard Evaluation Procedure: *Acute Toxicity Test for Freshwater Fish.* Hazard Evaluation Division. Office of Pesticide Programs. EPA-540/9-85-006. Washington, DC.

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.