Data Evaluation Report on the Acute Toxicity of AE F130060 Technical to Rainbow Trout (*Oncorhynchus Mykiss*)
PMRA Submission Number EPA MRID Number 45386231

Data Requirement:

PMRA DATA CODE	
EPA DP Barcode	D284719
OECD Data Point	
EPA MRID	45386231
EPA Guideline	§72-1b

1/9/04

Test material: AE F 130060 Technical **Purity:** 94.6%
Common name: Mesosulfuron-methyl
Chemical name: IUPAC: Methyl 2-[3-(4,6-dimethoxyprimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethylbenzoate
CAS name: Not reported
CAS No.: Not reported
Synonyms: Code: AE F130060 00 1C95 0001

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation

Signature: Rebecca Bryan
Date: 8/22/03

QC Reviewer: Christie E. Padova, B.S.
Staff Scientist, Dynamac Corporation

Signature: C. E. Padova
Date: 8/22/03

Primary Reviewer: ~~Tim Bargar~~, Biologist
OPP/EFED/ERB - III

Date: 01/09/04

Secondary Reviewer(s):
{EPA/OECD/PMRA}

Date:

Reference/Submission No.:

Company Code:
Active Code:
EPA PC Code: 122009

Date Evaluation Completed:

CITATION: Sowig, P., *et al.* 1999. Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*), AE F130060; substance, technical. Unpublished study performed by Hoechst Schering AgrEvo GmbH, Frankfort am Main, Germany. Laboratory Study Identification CE97/026. Study submitted by Aventis CropScience, Research Triangle Park, NC. Study initiated May 20, 1997 and completed July 30, 1999.

EXECUTIVE SUMMARY:

In a 96-hour acute toxicity study, 5-month old Rainbow Trout (*Oncorhynchus mykiss*) were exposed to AE F130060 Technical (Mesosulfuron-methyl) at mean-measured concentrations of 0 (negative control), 9.5, 17.4, 30.1, 48.1, and 91.5 ppm a.i. under static conditions. Nominal concentrations were 0 (negative control), 18, 32, 56, and 100 ppm (limit concentration).

No mortality or signs of toxicity were observed in the control or test groups during the 96-hour study. The 96-hour LC_{50} is >91.5 ppm a.i., which categorizes AE F130060 Technical (Mesosulfuron-methyl) as slightly toxic to Rainbow trout on an acute toxicity basis. The NOEC and LOEC observed for both mortality and sub-lethal effects were 91.5 and >91.5 ppm a.i., respectively, the highest concentration tested.

This study is scientifically sound and fulfills guideline requirements for an acute toxicity study with the Rainbow trout [§72-1(c)]. This study is classified CORE.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	5 months old; 1.64 g weight and 4.73 cm length (means of 10 fish at study initiation)
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour
LC_{50}: >91.5 ppm a.i.
NOEC: 91.5 ppm a.i.
LOEC: >91.5 ppm a.i.
Endpoints affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the U.S. EPA Pesticide Assessment Guidelines, Series §72-1 (1982), the OECD Guideline No. 203 (1992); and the EU Directive 92/69/EWG Annex Part C:C1. Deviations from U.S. EPA FIFRA Guideline §72-1 include:

1. The test material storage conditions were not reported.
2. De-chlorinated tap water is not recommended for use in aquatic studies.
3. Water hardness was not reported as mg $CaCO_3$/L.
4. Dissolved oxygen in terms of percent saturation was not reported.
5. The total organic carbon and particulate matter contents, and levels of metals, pesticides, and chlorine in the dilution water were not reported.

These deviations do not affect the validity or acceptability of the study.

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements

were provided. This study was conducted in accordance with OECD principles of GLP (p. 3).

A. MATERIALS:

1. **Test Material** AE F 130060 Technical (Mesosulfuron-methyl)

Description: Light beige powder

Lot No./Batch No. : Code: AE F130060 00 1C95 0001

Purity: 94.6%

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 and 96 hours. Corrected results are presented in Table 6.2.2, p. 21.

Storage conditions of test chemicals: Not reported.

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. OECD requirements were not reported.

2. **Test organism**:

Species: Rainbow trout (*Oncorhynchus mykiss*)

Age at test initiation: 5 months old

Weight at test initiation: 1.64 g (mean of 10 fish)

Length at test initiation: 4.73 cm (mean of 10 fish)

Source: Forellezuchtanlage Worbis des Forstamtes Leinefelden, Worbis, Germany

B. STUDY DESIGN:

1. **Experimental Conditions**

a. Range-finding Study: No range-finding study was 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)	Continuous laboratory culture Same as test Standard trout food was provided 6 times a week at 2% of fish weight (divided into two daily feeding) except during the 24 hours prior to testing. Mortality was 0.76% in the stock culture during the 14 days prior to test initiation.	*EPA requires: minimum 14 days: no feeding during test OECD requires minimum of 12 days.*
Duration of the test	96 hours	*EPA/OECD requires: 96 hours*
Test conditions static/flow through Type of dilution system- for flow through method. Renewal rate for static renewal	Static N/A 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*
Aeration, if any	No aeration during testing.	*EPA requires: no aeration; OECD permits aeration*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Stainless steel 50 L 50 L (15.8- to 17.4-cm depth)	*EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm* *Fill volume: 15-30 L of solution*

4

Parameter	Details	Remarks Criteria
Source of dilution water	Filtered tap water and deionized water were passed through sand- and activated charcoal filters prior to being combined at a 1:1 ratio. The dilution water was then well aerated prior to use.	*EPA 1975; Soft reconstituted water or water from a natural source, **not** de-chlorinated tap water;* *OECD permits de-chlorinated tap water.*
Water parameters: Hardness	1.52-1.56 mmol/L (Ca^{2+} + Mg^{2+})	The water hardness in terms of mg/L as $CaCO_3$ was not provided.
pH	7.7-8.1	Dissolved oxygen in terms of percent saturation was not reported.
Dissolved oxygen	7.7-10.4 mg/L	
Total Organic Carbon	Not reported	***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*
Particulate Matter	Not reported	
Metals	Not reported	
Pesticides	Not reported	
Chlorine	Not reported	
Temperature	13.2-13.4 °C	
{Salinity for marine or estuarine species}	N/A	
Intervals of water quality measurement	DO, pH, and temperature were determined daily in all test tanks. Water hardness was determined at the start and end of testing in unspecified dilution water.	

Parameter	Details	Remarks Criteria
Concentration of test material: nominal: measured:	0 (negative control), 10, 18, 32, 56, and 100 ppm 0 (negative control), 9.5, 17.4, 30.1, 48.1, and 91.5 ppm a.i.	The mean-measured test concentration was reviewer-calculated from adjusted (for purity) recoveries in Table 6.2.2). *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)	None used.	*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: solvent control: treated:	10 fish, one replicate N/A 10 fish, one replicate	*EPA: ≥ 10/concentration; OECD requires at least 7 fish/concentration*
Biomass loading rate	0.33 g fish/L (instantaneous)	*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	*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*
Recovery of chemical Level of Quantitation Level of Detection	98.0-100.6% of nominal 0.35 ppm 0.21 ppm	Based on matrix spikes analyzed concurrently with the samples on Days 0 and 4 (Table 6.2.2, p. 21).

6

Parameter	Details	Remarks / Criteria
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 sublethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	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:

No mortalities were observed in the control or treatment groups.

7

Table 3: Effect of AE F130060 Technical on Mortality of Rainbow Trout (*Oncorhynchus Mykiss*).

Treatment, ppm, measured and (nominal conc.)	No. of fish at start of study	0-24 Hours		48-72 Hours		96 Hours	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Negative control	10	0	0	0	0	0	0
9.5 (10)	10	0	0	0	0	0	0
17.4 (18)	10	0	0	0	0	0	0
30.1 (32)	10	0	0	0	0	0	0
48.1 (56)	10	0	0	0	0	0	0
91.5 (100)	10	0	0	0	0	0	0
NOEC (mortality)	100 ppm						
LC_{50} (95% C.I.)	>100 ppm						
Positive control, if used mortality: LC_{50}:	N/A	N/A	N/A	N/A	N/A	N/A	N/A

B. NON-LETHAL TOXICITY ENDPOINTS:

No sub-lethal effects were observed during the study in the control or treatment groups.

C. REPORTED STATISTICS:

The 96-hour LC_{50} value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. Nominal concentrations were reported.

96-Hour
LC_{50}: >100 ppm
NOEC: 100 ppm
LOEC: >100 ppm
Endpoints affected: None

D. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC_{50} value, NOEC, and LOEC were visually determined, based on observed treatment-related mortality or sub-lethal effects. Mean-measured concentrations were reported.

96-Hour
LC_{50}: >91.5 ppm a.i.
NOEC: 91.5 ppm a.i.
LOEC: >91.5 ppm a.i.
Endpoints affected: None

E. STUDY DEFICIENCIES:

There were no deviations from FIFRA guideline §72-1(c) that affected the acceptability or validity of the study.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions are identical to those reported by the study authors.

Since the highest mean-measured concentration was below the required limit level of 100 ppm, a more conservative Toxicity Category was assigned.

It was noted that 24 and 48 hours after starting the test substance appeared as fine sediment on the bottom of the test vessels, and that after 72 hours, the test substance was completely dissolved (p. 17). This did not appear to have any significant impact on the level of active ingredient in solution, as it was demonstrated that recoveries were ≥87.9% on Day 0.

G. CONCLUSIONS:

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with freshwater fish (§72-1). This study is classified as CORE. Based on the results of this study, AE F130060 Technical (Mesosulfuron-methyl) is categorized as slightly toxic to juvenile Rainbow trout (*Oncorhynchus mykiss*) on an acute toxicity basis.

96-Hour
LC_{50}: >91.5 ppm a.i.
NOEC: 91.5 ppm a.i.
LOEC: >91.5 ppm a.i.
Endpoints affected: None

III. REFERENCES:

Pesticide Assessment Guidelines. Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, §72-1. Acute toxicity test for freshwater fish.

U.S. Environmental Protection Agency (EPA). 1975. Committee on Methods for Toxicity Tests with Aquatic Organisms, Method for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. EPA-660/3-75-009.

Organization for Economic Co-operation and Development. 1992. OECD Guideline for Testing of Chemicals; Guideline No. 203: Fish. Acute Toxicity Test, adopted July 17, 1992.

EU Directive 92/69/EWG Annex Part C: Methods for the Determination of Ecotoxicity; C.1. Acute Toxicity to Fish.

U.S. Environmental Protection Agency (EPA). 1975. Brauhn, J.L., *et al.* Acquisition and Culture of Research Fish: Rainbow Trout, Fathead Minnow, Channel Catfish, and Bluegills. EPA-660/3-75-001.

Deutsches Institut fur Normung (DIN). 1989. German Standard Methods for the Examination of Water, Waste Water, and Sludge. Normenausschuß Wasserwesen (NAW) im DIN Deutsches Institut fur Normung e.V. Berlin.

Page ___ is not included in this copy.

Pages 11 through 15 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.