

Data Evaluation Report on the Acute Toxicity of AE 0317309 to Fish (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-2445

EPA MRID Number 468017-24

Data Requirement:	PMRA Data Code	9.5.2.1
	EPA DP Barcode	D328639
	OECD Data Point	IIA 8.2.1
	EPA MRID	468017-24
	EPA Guideline	850.1075 (72-1)

Test material: AE 0317309 **Purity:** 97.4% w/w
Common name: Pyrasulfotole
Chemical name: IUPAC: Not reported
CAS name: (5-hydroxy-1,3-dimethylpyrazol-4-yl)(2-mesyl-4-trifluoromethylphenyl)methanone
CAS No.: 365400-11-9
Synonyms: Not reported

Primary Reviewer: John Marton
Staff Scientist, Cambridge Environmental Inc.

Signature:
Date: 5/08/06

Secondary Reviewer: Teri S. Myers
Senior Scientist, Cambridge Environmental Inc.

Signature:
Date: 5/21/06

Primary Reviewer: Megan Thyng, EPA
EPA

Date: 8/28/06

Secondary Reviewer(s): Melissa Panger, EPA
EPA

Date: 8/31/06

Secondary Reviewer: J.D. Whall (Officer No. 1268)
PMRA

Date: 11/23/06

Secondary Reviewer: David McAdam **Date** 6 Nov 2006
Australian Government Department of the Environment and Heritage.

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

Company Code BCZ
Active Code PSA
Use Site Category: 13, 14
EPA PC Code 000692

Date Evaluation Completed: 12-05-2006

CITATION: Christ, M.T. 2005. The 96 Hour Acute Toxicity to the Rainbow Trout, *Oncorhynchus mykiss*, in a Static System; AE 0317309 Technical 97.4% w/w (Amended Report). Unpublished study performed by Bayer CropScience, Research Park Triangle, NC. Laboratory report number 02DT35541-a. Study sponsored by Bayer CropScience, RTP, NC. Study completed on October 11, 2005.

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 fish. 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



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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.

EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, Rainbow trout (*Oncorhynchus mykiss*) were exposed to AE 0317309 at nominal concentrations of 0 (negative control) and 100 mg a.i./L under static conditions; mean-measured concentrations were <1.0 (<LOQ; negative control) and 96.0 mg a.i./L. The 96-h LC₅₀ was >96.0 mg a.i./L. The EC₅₀ and NOAEC values, based on mortality and sub-lethal effects, were >96.0 and 96.0 mg a.i./L, respectively. No sub-lethal effects were observed in the negative control or in the mean-measured 96.0 mg a.i./L treatment level. AE 0317309 does not appear to be toxic to *Oncorhynchus mykiss* at a concentration of 96.0 mg a.i./L.

This toxicity study is scientifically sound, is classified as **ACCEPTABLE**, and does satisfy the guideline requirement for an acute toxicity study with Rainbow trout (*Oncorhynchus mykiss*).

Results Synopsis

Test Organism Size/Age(mean weight or length): 1.554 (1.151-2.091) g; 4.5 (3.9-5.0) cm- Based on control fish at test termination.

Test Type (Flow-through, Static, Static Renewal): Static

LC₅₀: >96.0 mg a.i./L 95% C.I.: N/A

NOAEC: 96.0 mg a.i./L Probit Slope: N/A

EC₅₀: >96.0 mg a.i./L

Endpoint(s) Affected: None

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

The study was conducted following guidelines outlined in OECD Guidelines for Testing of Chemicals, 203, Fish Acute Toxicity Test and; and U.S. EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, EPA 540/9-82-024. The following deviations were noted:

1. The physiochemical properties of the test material were not reported (but have been included by secondary reviewer).
2. The pH of the dilution water (8.0-8.4) ranged higher than the recommended values (7.2-7.6).
3. The percent dissolved oxygen was higher than recommended (supersaturated at 67-106%).

The deviations did not impact the acceptability of the study.

COMPLIANCE:

Signed and dated No Data Confidentiality, GLP and Quality Assurance statements were provided. This study was conducted in compliance with Good Laboratory Practice Standards as specified in 40 CFR 160 with the following exceptions: Routine well water and fish food contaminant screening analyses for pesticides, PCBs and toxic metals were conducted by Lancaster Laboratories, Lancaster, PA. These data were not collected in accordance with Good Laboratory Practice procedures (no protocol, study director, or in-life inspections). [40CFR160.90(g)]

A. MATERIALS:

1. Test material

AE 0317309

Description:

Yellow Crystals

Lot No./Batch No. :

H2235

Purity:

97.4% w/w

Stability of compound under test conditions:

Analytical verification of the test material yielded percent recoveries ranging from 95-97% of nominal with a mean recovery of 96%.

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

Storage conditions of test chemicals:

Stored at ambient room temperature in the dark.

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Physicochemical properties of AE 0317309.

Parameter	Value	Comment
Molecular weight	362.3 g/mol	
Water Solubility (g/L) at 20°C	4.2 at pH 4 69.1 at pH 7 49.0 at pH 9	Very soluble
Vapor Pressure/Volatility	2.7×10^{-7} Pa at 20°C 6.8×10^{-7} Pa at 25°C	Non-volatile
UV Absorption	water $\lambda_{\max} = 264$ 0.1M HCl $\lambda_{\max} = 241$ 0.1M NaOH $\lambda_{\max} = 216$	Not likely to undergo photolysis.
Pka	4.2 ± 0.15	
log K _{ow} at 23°C	0.276 at pH 4 -1.362 at pH 7 -1.58 at pH 9	Not likely to bioaccumulate
Stability of compound at room temperature, if provided		No significant degradation over 12 months at ambient temperatures.

Data obtained from pyrasulfatole chemistry review of Submission 2006-2445.

2. Test organism:

Species:

Rainbow Trout (*Oncorhynchus mykiss*) EPA recommends a cold water species (preferably rainbow trout *Oncorhynchus mykiss*) and a warm water species (preferably bluegill sunfish *Lepomis macrochirus*). OECD recommends choice of species at discretion of testing laboratory.

Age at test initiation:

Juveniles

Weight at study initiation:

1.554 (1.151-2.091) g; based on control fish at test termination
EPA recommends: mean 0.5 - 5 g.

Length at study initiation:

4.5 (3.9-5.0) cm; based on control fish at test termination. EPA recommends: Longest not > 2x shortest; OECD recommends 2.0 \forall 1.0 cm for bluegill and 5.0 \forall 1.0 cm for rainbow trout

Source:

Pierce Associates, Inc., West Buxton, Maine. EPA recommends that all organisms be from the same source

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: A non-GLP range-finding study was performed by exposing one replicate of five fish to nominal concentrations of 1.0, 10 and 100 mg/L of AE 0317309 for approximately 96-hours. A control treatment was also included in the preliminary test. No mortality was observed in the control or any treatment.

b. Definitive Study

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Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
<u>Acclimation</u>		
Period:	14 Days	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 $\leq 10\%$ = continued acclimation for 7 days; <5% = acceptable.
Conditions: (same as test or not)	Same as test	
Feeding:	Ranger Salmon Stater (Lot # SS19OCT01) was provided <i>ad libitum</i> . Fish were not fed 48 hours prior to use in the study.	
Health: (any mortality observed)	One mortality occurred during 48 hours prior to testing. Therefore, the fish were considered to be sufficiently healthy for testing.	
Duration of the test	96-hours	The recommended test duration is 96 hours.
<u>Test condition</u>		
Static/flow-through	Static	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.
Type of dilution system - for flow-through method.	N/A	
Renewal rate for static renewal	N/A	
Aeration, if any	No aeration was provided.	Aeration is not recommended; OECD guideline recommends aeration. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.

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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass 37 L 35 L	<p>The size and fill volume of the test vessels (37 and 35 L, respectively) were larger than recommended (19 and 15-30 L, respectively); the reviewer feels that this deviation does not deleteriously impact the acceptability of the study. Acceptable for OECD and OPPTS 850</p> <hr/> <p><i>Test vessel size is usually 19 L (5 gal) or 30 x 60 x 30 cm. Fill volume is usually 15-30 L of solution.</i></p>
Source of dilution water Quality:	The dilution water was blended, filtered well water. The well water was blended with softened well water to lower the hardness. The water was filtered to remove iron, trace organics and suspended particulates (including microbes). The water was analyzed for pesticides and heavy metal contaminants. There are no contaminants in the water believed to be at levels high enough to interfere with this study.	<hr/> <p><i>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.</i></p>

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Parameter	Details	Remarks
		Criteria
<u>Water parameters:</u>		
Hardness	176 mg/L as CaCO ₃	The reported hardness of the dilution water (176 mg/L as CaCO ₃) was higher than recommended (40-48 mg/L as CaCO ₃). The pH of the dilution water (8.0-8.4) ranged higher than the recommended values (7.2-7.6). The percent dissolved oxygen was higher than recommended (supersaturated) at study initiation for test group; however, levels normalized after 24 hours. These are acceptable to OECD and OPPTS 850.1057 Guidelines.
pH	8.0-8.4	
Dissolved oxygen	7.1-10.9 ppm (67-105% saturation)	
Total Organic carbon	<2.0 mg/L	
Particulate Matter	<12 mg/L	
Metals	Boron (0.0725 mg/L), Barium (0.312 mg/L), Calcium (60.2 mg/L), Magnesium (16.8 mg/L), Potassium (0.623 mg/L), and Vanadium (0.0295 mg/L) were the only metals detected.	<u>Hardness:</u> EPA recommends 40 - 48 mg/L as CaCO ₃ (OECD recommends 10 - 250 mg/L) <u>pH:</u> EPA recommends 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 recommends pH 6.0 - 8.5) <u>Dissolved Oxygen:</u> EPA recommends: Static: $\geq 60\%$ during first 48 hrs and $\geq 40\%$ during second 48 hrs; flow-through: $\geq 60\%$; (OECD guideline recommends at least 80% saturation value). <u>Temperature:</u> EPA recommends 12 EC for coldwater species, 17 or 22 EC for warmwater species, and 22 ± 1 EC for estuarine/marine organisms. (OECD recommends 21 - 25°C for bluegill and 13 - 17°C for rainbow trout). <u>Salinity:</u> EPA recommends 30-34‰ (parts per thousand) for marine, 10-17‰ for estuarine fish, weekly range < 6‰ Water quality should be measured at beginning of test and every 48 hours.
Pesticides	None detected	
Chlorine	126 mg/L as Chloride	
Temperature	12.4-13.6°C	
{Salinity for marine or estuarine species}	N/A	
Intervals of water quality measurement	Temperature, DO, pH and conductivity were determined at test initiation and every 24-hours thereafter. Temperature was also monitored daily in a control test chamber.	
<u>Number of replicates/groups:</u>		
control:	3	A solvent control was not used.
solvent control:	N/A	
treated ones:	3	
		Recommended number of replicates include a control and five treatment levels. Each concentration should be 60% of the next highest concentration; concentrations should be in a geometric series.

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Parameter	Details	Remarks
		Criteria
Positive control {if used, indicate the chemical and concentrations}	N/A; a positive control was not used	
Other parameters, if any	None	

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2. Observations:

Table 2: Observations

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and sub-lethal effects.	
Observation intervals	Day 0 (hours 3 and 6), 24-, 48-, 72 and 96-hours	Observation intervals should be a minimum of every 24 hours.
Were raw data included?	Yes	
Other observations, if any	None	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortality was observed in the control or in the mean-measured 96.0 mg a.i./L treatment level. The NOAEC and LC₅₀ values based on mortality were 96.0 and >96.0 mg a.i./L, respectively.

Table 3: Effect of AE 0317309 on Mortality of *Oncorhynchus mykiss*.

Treatment (mg a.i./L) Mean-Measured and (Nominal)	No. of fish at start of study	Observation period					
		Day 1		Day 2		Day 4	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
<1.0 (Negative Control)	30	0	0	0	0	0	0
96.0 (100)	30	0	0	0	0	0	0
NOAEC	96.0 mg a.i./L						
LC ₅₀	>96.0 mg a.i./L						
Positive control, if used mortality: LC ₅₀ :	N/A; a positive control was not used						

B. NON-LETHAL TOXICITY ENDPOINTS:

No sub-lethal effects were observed in the negative control or in the mean-measured 96.0 mg a.i./L treatment level. The NOAEC and EC₅₀ values based on sub-lethal effects were 96.0 and >96.0 mg a.i./L, respectively.

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Table 4: Sub-lethal Effect of AE 0317309 on *Oncorhynchus mykiss*.

Treatment (mg a.i./L) Mean-Measured and (Nominal)	Observation period		
	endpoint 1 at Day 1	Endpoint 2 at Day 2	endpoint 3 at Day 4
	% affected	% affected	% affected
<1.0 (Negative Control)	All Normal	All Normal	All Normal
96.0 (100)	All Normal	All Normal	All Normal
NOAEC	96.0 mg a.i./L		
LOAEC	>96.0 mg a.i./L		
EC ₅₀	>96.0 mg a.i./L		
Positive control, if used % sublethal effect: EC ₅₀ :	N/A; a positive control was not used		

C. REPORTED STATISTICS:

Due to a lack of mortality, no calculations of LC/EC₅₀ values were performed.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method(s): The lack of mortality and sub-lethal effects precluded the use of statistical analyses. All toxicity values were therefore determined visually based on the mean-measured concentration.

LC₅₀: >96.0 mg a.i./L 95% C.I.: N/A
NOAEC: 96.0 mg a.i./L
Probit Slope: N/A 95% C.I.: N/A

E. STUDY DEFICIENCIES:

There were no study deficiencies.

F. REVIEWERS' COMMENTS:

The reviewers' results were identical to those of the study author.

This study was conducted as a limit test with a nominal concentration of 100 mg/L. AE 0317309 does not appear to be toxic to *Oncorhynchus mykiss* at a concentration of 96.0 mg a.i./L.

The in-life portion of the definitive toxicity test was conducted between October 28 and November 1, 2002.

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G. CONCLUSIONS:

This study is scientifically sound and is classified as **ACCEPTABLE**. Due to the lack of mortality and sub-lethal effects in the negative control and mean-measured 96.0 mg a.i./L treatment level, the NOAEC, LC₅₀ and EC₅₀ values are 96.0, >96.0 and >96.0 mg a.i./L, respectively.

III. REFERENCES:

Organization for Economic Cooperation and Development. 1992. *OECD Guidelines for Testing of Chemicals*; "Guideline 203, Fish Acute Toxicity Test," Paris.

U.S. Environmental Protection Agency. 1982. Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms. Office of Pesticide Programs. Washington, D.C.; EPA 540/9-82-024. NTIS Document PB83-153908.

U.S. Environmental Protection Agency. 1989. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards, Final Rule (40 CFR Part 160). Federal Register Vol. 54, No. 158:34052-34074; Washington, D.C.

Eddy, S. 1978. How to Know the Freshwater Fishes Third Edition. Wm. C. Brown Company, Dubuque, Iowa.

**Nominal and Mean-Measured
Concentrations**

Nominal (mg/L)
0 (Negative Control)
100

x Purity
0.974
0.974

Nominal (mg a.i./L)
0
97.4

Mean-Measured (mg/L)
0 (Negative Control)
96

x Purity
0.974
0.974

Nominal (mg a.i./L)
<0.974
93.5

LOQ (mg/L)
1

x Purity
0.974

0.974