

US EPA ARCHIVE DOCUMENT

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

PMRA Submission Number {.....}

EPA MRID Number 468438-05

Data Requirement:

PMRA Data Code	9.5.2.1a
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468438-05
EPA Guideline	72-1a

Test material: XDE-570 **Purity:** 99.2%
Common name: florasulam
Chemical name: IUPAC 2',6',8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide
 CAS name N-(2,6-difluorophenyl)-8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide
 CAS No. 145701-23-1
 Synonyms

Primary Reviewer: Tamara Sheremata, Ph.D
 PMRA

Date: 9.14.2000

Primary Reviewer: Brian D. Kiernan, Biologist
 EPA

Date: 3.06.2007

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 10/2/07

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

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
Use Site Category: {.....} [For PMRA]
EPA PC Code 129108

Date Evaluation Completed: 3.06.2007

CITATION: Kirk, H.D.; Hugo, J.M.; Miller, J.A.; and D.C. Stahl (1995) Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Rainbow Trout, *Oncorhynchus mykiss* Walbaum. The Environmental Toxicology & Chemistry Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, MI). DECO-ES-2940, January 26, 1995. Unpublished, 30 pages.

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

PMRA Submission Number {.....}

EPA MRID Number 468438-05

EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, rainbow trout (*Oncorhynchus mykiss*, Walbaum) were exposed to XDE-570 at a concentration of 100 mg/L. Two groups of ten fish were exposed to a nominal concentration of 100 mg ai/L (mean measured concentration 96 mg ai/L). Test was conducted at 12.4 to 12.6 °C and pH 6.9-7.9 with dissolved oxygen levels of 9.3-10.3 mg O₂/L (90.3-100% saturation). The study was conducted in accordance with EPA GLP standards.

The test material was stable during the test. No mortality or other adverse reactions were observed. The 96-h LC₅₀ and NOEC values, based on mortality and non-lethal adverse effects, were >100 mg/L and 100 mg/L, respectively. No sublethal effects were observed in the groups exposed to 100 mg/L of XDE-570. XDE-570 is classified as practically nontoxic to rainbow trout (*Oncorhynchus mykiss*, Walbaum). The study is classified as acceptable. EFED accepts the PMRA DER in lieu of the generation of a new DER.

Results Synopsis

Test Organism Size/Age(mean weight or length):

Test Type: Static

LC₅₀: >96 mg a.i./L 95% C.I.: NA

NOAEC: 96 mg a.i./L

Endpoint(s) Affected: none

Appendix 9.5.2.1

PMRA Reviewer: Tamara Sheremata, Ph.D.

Date Evaluation Completed:

14-September-2000

STUDY TYPE: Cold Water Fish (Acute)
PMRA DATA CODE: 9.5.2.1
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.1

TEST MATERIAL (PURITY): XDE-570, 99.2 %

SYNONYMS: XR-570 (1990-Jan. 1994), XDE-570 (Jan. 94 - Jan. 97), DE-570 (Feb. 1997-?), Florasulam.

CITATION: Kirk, H.D.; Hugo, J.M.; Miller, J.A.; and D.C. Stahl (1995) Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Rainbow Trout, *Oncorhynchus mykiss* Walbaum. The Environmental Toxicology & Chemistry Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, MI). DECO-ES-2940, January 26, 1995. Unpublished, 30 pages.

SPONSOR: DowELanco, Indianapolis, IN.

EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, Rainbow Trout (*Oncorhynchus mykiss*, Walbaum) were exposed to XDE-570 at a concentration of 100 mg/L. Two groups of ten fish were exposed to a nominal concentration of 100 mg ai/L (mean measured concentration 96 mg ai/L). Test was conducted at 12.4 to 12.6 °C and pH 6.9-7.9 with dissolved oxygen levels of 9.3-10.3 mg O₂/L (90.3-100% saturation). The study was conducted in accordance with EEC Directive 91/414 Annex I 8.2.1, OECD guideline No. 203 and the EPA GLP standards.

The test material was stable during the test. No mortality or other adverse reactions were observed. The 96-h LC50, EC50 and NOEC values, based on mortality and non-lethal adverse effects, were greater than 100 mg/L. The maximum test concentration of XDE-570 (100 mg/L) was equivalent to [compare to EEC in water]. No sublethal effects were observed in the groups exposed to 100 mg/L of XDE-570. Based on the results of this study, XDE-570 would be classified as [classification] toxic to Rainbow Trout (*Oncorhynchus mykiss*, Walbaum) in accordance with the classification system of the U.S. EPA.

This toxicity study is classified acceptable and does satisfy the guideline requirement for an acute cold water fish toxicity study (DATA CODE 9.5.2.1).

COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging statements were provided.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: EEC Directive 91/414 Annex I 8.2.1, OECD guideline No. 203

“Fish Acute Toxicity Test”, The official Journal of the European Communities Directive 92/69/EEC C.1.

A. MATERIALS:

1. Test Material: XDE-570

Description: white crystalline solid

Lot/Batch No. : TSN100298

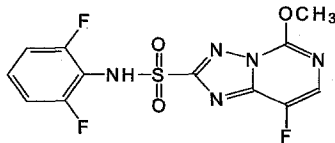
Purity: 99.2 % ai.

Stability of Compound: Not specified

CAS No.: 145701-23-1

IUPAC Name: 2',6',8'-trifluoro-5-methoxy-*s*-triazolo[1,5-*c*]pyrimidine-2-sulphonanilide

Structure:



2. Test organism:

Species: Rainbow trout, *Oncorhynchus mykiss* Walbaum

Weight at study initiation: 787.7 mg (548-1400 mg)

Length at study initiation: 37.2 mm (34-43 mm)

Source: Mt. Lassen Trout Farm, Red Bluff, CA.

Acclimation: 14 d

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study

Preliminary static acute test was conducted with exposure concentrations of 3, 10, 30, 100, and 300 mg XDE-570/L.

Results indicated that the 96 h LC50 value was greater than 300 mg XDE-570/L. Furthermore, incomplete solution was observed at 100 and 300 mg/L. Therefore, the

definitive test was set at 100 mg/L.

b) Definitive Study

Table 1 . Experimental Parameters.

Parameter	Value
Test system and number of replicates	12-L beakers with covers to reduce evaporation. Each vessel contained 10-L of water and 10 fish. There were 2 replicates.
Test concentrations	100 mg/L
Number of fish per replicate and loading	10 fish/vessel
Solvent	100 mg dimethylformamide per L
Photoperiod	16-hr light/8-hr dark transitional regimen
Temperature	12 ± 1 °C
Range for pH, dissolved oxygen	pH: 6.9-7.9 DO: 9.3-10.3 mg/L
Source of dilution water	Softened Lake Huron water that was minimally chlorinated, limed, and flocculated with FeCl ₃ by City of Midland Water Treatment Plant. The water was sand-filtered, pH-adjusted with CO ₂ , carbon-filtered, and UV-irradiated in the laboratory prior to use.

2. Observations:

Table 2: Observations

Criteria	Details
Test duration	96 h (4 d)
Test dates: start end	May 9, 1994 May 13, 1994
Observation intervals	3 h, 24 h, 48 h, 72 h, and 96 h
Renewal schedule	not applicable
Observations at each time interval	mortality (no response to touching of the caudal peduncle and no opercular movement) and sublethal effects.

No statistical methods were used to evaluate the data generated in this study.

II. RESULTS AND DISCUSSION & CONCLUSIONS:

No compound related effects were observed during the course of this study. Therefore, the LC50 value and the NOEC for XDE-570 in rainbow trout is greater than 100 mg XDE-570/L.

III. Study deficiencies: There were no deficiencies in this study.