Data Evaluation Report on the Acute Toxicity of Florasulam Degradate to Rainbow Trout

PMRA Submission Number {.....} EPA MRID Number 468083-12

Data Requirement:

PMRA Data Code	9.3.2
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468083-12
EPA Guideline	72-2

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-sulfonanilide
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: Peter Takacs
PMRA **Date:** 7.25.2000

Primary Reviewer: Brian D. Kiernan, Biologist **Date:** 3.06.2007
EPA

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 (1996) Evaluation of the Acute Toxicity of 5-Hydroxy XDE-570 to the Rainbow Trout, *Oncorhynchus mykiss* Walbaum. The Environmental Toxicology Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, MI). DECO-ES-3118, August 23, 1996. Unpublished, 43 pages.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 freshwater invertebrates. 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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EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, three groups of ten rainbow trout (*Oncorhynchus mykiss* Walbaum) were exposed to 5-Hydroxy XDE-570 at a nominal concentration of 100 mg/L (mean measured concentration of 91 mg ai/L). Test was conducted at 12.2 to 12.5 °C and pH 6.6-7.7 with dissolved oxygen levels of 8.7-10 mg O_2/L. The study was conducted in accordance with EC Method C1, Directive 92/69, OECD Guideline No. 203 and U.S. EPA FIFRA, Subdivision E, GGG Guideline 72-1(c) 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.

EF-1343 is classified as practically non-toxic to rainbow trout in accordance with the classification system of the U.S. EPA.

This study is classified supplemental and is consistent with the guideline requirement for an acute fish toxicity study.

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

EC_{50}: >100 mg a..i./L 95% C.I.: NA
NOAEC: 100 mg a..i./L
Endpoint(s) Affected: none

Appendix 9.5.2.1

PMRA Reviewer: Tamara Sheremata, Ph.D.
Date Evaluation Completed: 18-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): 5-Hydroxy XDE-570, 97.0 %; XDE-570 1.44 %

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 (1996) Evaluation of the Acute Toxicity of 5-Hydroxy XDE-570 to the Rainbow Trout, *Oncorhynchus mykiss* Walbaum. The Environmental Toxicology Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, MI). DECO-ES-3118, August 23, 1996. Unpublished, 43 pages.

SPONSOR: DowELanco, Indianapolis, IN.

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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 5-Hydroxy 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 5-Hydroxy XDE-570. Based on the results of this study, 5-Hydroxy XDE-570 would be classified as [*classification*] toxic to Rainbow Trout 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).

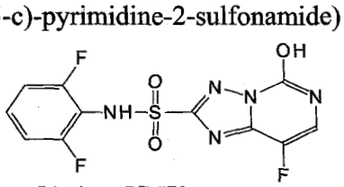
COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging statements were provided.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: EC Method C1, Directive 92/69, OECD Guideline No. 203 and U.S. EPA FIFRA, Subdivision E, GGGGuideline 72-1(c).

A. MATERIALS:

1. Test Material: 5-Hydroxy XDE-570
Description: white powder
Lot/Batch No. : DECO-393-053
Purity: 97.0 %5-Hydroxy XDE-570; 1.44 % XDE-570
Stability of Compound: <5 % degradation over 7 days at pH 4 and 9.
CAS No.: N/A
IUPAC Name: 5-Hydroxy (*N*-(2,6-difluorphenyl)-8-fluoro-5-hydroxy-(1,2,4)-triazolo-(1,5-c)-pyrimidine-2-sulfonamide)
Structure:



5-hydroxy DE-570

2. Test organism:
Species: Rainbow trout, *Oncorhynchus mykiss* Walbaum
Weight at study initiation: not indicated
Length at study initiation: not indicated
Source: Mt. Lassen Trout Farm, Red Bluff, CA.
Acclimation: 14 d

B. STUDY DESIGN:

1. Experimental Conditions

a) Probe Study

Preliminary static acute test was conducted with exposure concentrations of 1, 10, and 100 mg 5-Hydroxy XDE-570/L.

There were no adverse effects reported in the study.

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. Each test vessel was set in triplicate.
Test concentrations	100 mg/L
Number of fish per replicate and loading	10 fish/vessel
Solvent	none
Photoperiod	16-h light, 8-h dark, transition regimen.
Temperature	12.3 ± 0.10 °C
Range for pH, dissolved oxygen	pH: 6.6-7.7 DO: 8.7-10.0 mg/L
Source of dilution water	Lake Huron water that was 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 13, 1996 May 17, 1996
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 5-Hydroxy XDE-570 in rainbow trout is greater than 100 mg/L.

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