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TEXT SEARCHABLE DOCUMENT

Data Evaluation Report on the Acute Toxicity of Florasulam to *Menidia beryllina*

PMRA Submission Number {.....} EPA MRID Number 468083-17

Data Requirement:

PMRA Data Code	9.5.2.4
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468083-17
EPA Guideline	72-3a

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: Tamara Sheremata, Ph.D
PMRA **Date:** 9.21.2000

Primary Reviewer: Brian D. Kiernan, Biologist **Date:** 2.07.2007
EPA

10/8/07

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

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

Date Evaluation Completed: 2.07.2007

CITATION: Ward, T.J.; Magazu, J.P.; Boeri, R.L. 1995. XDE-570: Acute Toxicity to the Silverside, *Menidia beryllina*. T.R. Wilbury Laboratories, Inc. (Marblehead Massachusetts). T.R. Wilbury Study Number 645-DO; DOW study number ES-2924, October 2, 1995. Unpublished , 24 pages.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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EXECUTIVE SUMMARY:

In an acute static toxicity study, silverside (*Menidia beryllina*) were exposed to XDE-570 at a concentration of 130 mg/L (mean measured concentration 122 mg ai/L), prepared with filtered natural sea water. Test was conducted at 22 to 22.5 °C (mean 22.2 °C) and pH 7.6-8.0 under 16h light/8h dark photoperiod. Dissolved oxygen levels of 6.8-8.1 mg O2/L (mean 7.3 mg O2/L). The study was conducted in accordance with U.S. EPA - FIFRA, Subdivision E, Guideline 72-3 (a) and the EPA GLP standards.

The test material was stable during the test. No mortality or other adverse reactions were observed. The 96-h LC_{50}, EC_{50} and NOAEC values, based on mortality and non-lethal adverse effects, were all above 122 mg/L. Sublethal effects were not observed in the groups exposed to 122 mg/L of XDE-570. Based on the results of this study, XDE-570 is classified as "practically non-toxic" on an acute basis to marine/estuarine fish. This toxicity study is classified as **acceptable** and is sufficient to allow a risk assessment for acute toxicity of florasulam to estuarine/marine fish. 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

LC_{50}: >122.mg a..i./L 95% C.I.: NA
NOAEC: 122 mg a..i./L
Endpoint(s) Affected: none

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Appendix 9.5.2.4

PMRA Reviewer: Tamara Sheremata, Ph.D.
Date Evaluation Completed: 21-September-2000

STUDY TYPE: Marine/Estuarine Fish (Acute)
PMRA DATA CODE: 9.5.2.4
OECD Data Point: N.A.

TEST MATERIAL (PURITY): XDE-570 (Florasulam)

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

CITATION: Ward, T.J.; magazu, J.P.; Boeri, R.L. 1995. XDE-570: Acute Toxicity to the Solverside, *Menidia beryllina*. T.R. Wilbury Laboratories, Inc. (Marblehead Massachusetts). T.R. Wilbury Study Number 645-DO; DOW study number ES-2924, October 2, 1995. Unpublished , 24 pages.

SPONSOR: The Dow Chemical Company, Midand MI.

EXECUTIVE SUMMARY:

In an acute static toxicity study, Silverside (*Menidia beryllina*) were exposed to XDE-570 at a concentration of 100 mg/L (mean measured concentration 122 mg ai/L), prepared with filtered natural sea water. Test was conducted at 22 to 22.5 °C (mean 22.2 °C) and pH 7.6-8 under a 16 h light : 8 h dark photoperiod with dissolved oxygen levels of 6.8-8.1 mg O_2/L (mean 7.3 mg O_2/L). The study was conducted in accordance with U.S. EPA - FIFRA, Subdivision E, Guideline 72-3 (a) 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 all above 122 mg/L. Sublethal effects were not observed in the groups exposed to 122 mg/L of XDE-570. Based on the results of this study, XDE-570 would be classified as "practically non-toxic" (according to the study, but need to check this) to marine/estuarine fish 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 (PMRA DATA CODE: 9.5.2.4);

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

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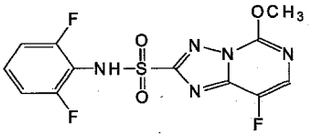
I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: U.S. EPA - FIFRA, Subdivision E, Guideline 72-3 (a)

A. MATERIALS:

1. Test Material: XDE-570
Description: white powder
Lot/Batch No. : TSN100298
Purity: 99.2 % ai.
Stability of Compound: test substance was stable in the test media at 0, 48, and 96 h during the course of the toxicity study.
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: silverside, *Menidia beryllina*
Weight at study initiation: 130 mg ?
Length at study initiation: 23 mm ?
Source: Aquatic Research Organisms, Hampton, NH
Acclimation: 14 d

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study

An initial range finding test was conducted under static conditions. The test was performed with a control and a single nominal concentration of XDE-570 (130 mg/L) to determine if the LC50 was greater than 100 mg/L. After 96-h, there was 100 % survival in the both the control and treatment groups.

b) Definitive Study

The definitive test was run at 130 mg/L XDE-570, and visual observations were made after 24, 48, 72, and 96 h.

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Table 1 . Experimental Parameters

Parameter	Value
Test system and number of replicates	20-L glass aquaria that contained 15-L of test solution (depth of 18 cm).There were three replicates for each treatment group.
Test concentrations	130 mg/L (nominal concentration)
Number of fish per replicate and loading	10
Solvent	none
Photoperiod	16-hour light/8-hr dark
Temperature	22.0-22.5 °C
Range for pH, dissolved oxygen, salinity	pH: 7.6-8.0 DO: 6.8-8.1 mg/L salinity: 17 ppt
Source of dilution water	Carbon filtered seawater (collected at T.R. Wilbury, Marblehead, MA) that was diluted with carbon filtered deionized water to obtain salinity of 11-17 ppt.

2. Observations:

Table 2: Observations

Criteria	**Details**
Test duration	96-h (4 d)
Test dates: start end	June 1, 1995 June 5, 1995
Observation intervals	3h, 24 h, 48 h, 72 h, and 96 h
Observations at each time interval	Number of surviving organisms and the occurrence of sublethal effects were determined visually.

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

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II. RESULTS, 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 silverside, *Menidia beryllina*, is greater than 130 mg XDE-570/L.

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

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