

Data Evaluation Report on the Acute Toxicity of Florasulam to Bluegill (*Lepomis macrochirus*)

PMRA Submission Number {.....}

EPA MRID Number 468438-04

Data Requirement:	PMRA Data Code	9.5.2.2
	EPA DP Barcode	D329529
	OECD Data Point	{.....}
	EPA MRID	468438-04
	EPA Guideline	72-1b

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: Not reported
PMRA

Date: 9.18.2000

Primary Reviewer: Brian D. Kiernan, Biologist
EPA

Date: 3.06.2007

BDK
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: 3.06.2007

CITATION: Kirk, H.D.; Hugo, J.M.; Miller, J.A.; Stahl, D.C. (1995) Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Bluegill, *Lepomis macrochirus* Rafinesque. The Environmental Toxicology & Chemistry Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, Michigan). Laboratory report number DECOES-2939, January 30, 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 Unpublished, 30 pages.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.



Data Evaluation Report on the Acute Toxicity of Florasulam to Bluegill (*Lepomis macrochirus*)

PMRA Submission Number {.....}

EPA MRID Number 468438-04

EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, two groups of ten bluegill sunfish (*Lepomis macrochirus* Rafinesque) were exposed to XDE-570 at a nominal concentration of 100 mg/L (mean measured concentration of 97.7 mg ai/L). Test was conducted at 22.5 to 22.7 °C and pH 7-8.1 with dissolved oxygen levels of 7.9-8.5 mg O₂/L (>94% saturation) in tap water of hardness 72 mg/L as CaCO₃. 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 >97.7 mg/L and 97.1 mg/L, respectively. No sublethal effects were observed. XDE-570 is classified as practically nontoxic to rainbow trout (*Oncorhynchus mykiss*, Walbaum). EFED accepts the PMRA DER in lieu of the generation of a new DER.

Acceptable
BOK
10/1/07

Results Synopsis

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

LC₅₀: >97.7.mg a.i./L 95% C.I.: NA
NOAEC: 97.7 mg a.i./L
Endpoint(s) Affected: none

Appendix 9.5.2.2**PMRA Reviewer:****Date Evaluation Completed:****18-September-2000**

STUDY TYPE: Warm Water Fish (Acute)
PMRA DATA CODE: 9.5.2.1
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.2

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

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.; Stahl, D.C. (1995) Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Bluegill, *Lepomis macrochirus* Rafinesque. The Environmental Toxicology & Chemistry Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company (Midland, Michigan). Laboratory report number DECO-ES-2939, January 30, 1995. Unpublished, 30 pages.

SPONSOR: DowElanco, Indianapolis, IN

EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, two groups of ten bluegill sunfish (*Elpomis macrochirus* Rafiinesque) were exposed to XDE-570 at a nominal concentration of 100 mg/L (mean measured concentration of 97.7 mg ai/L). Test was conducted at 22.5 to 22.7 °C and pH 7-8.1 with dissolved oxygen levels of 7.9-8.5 mg O₂/L (>94% saturation) in tap water of hardness 72 mg/L as CaCO₃. The study was conducted in accordance with EC Method C1, Directive 92/69 and 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 all greater than 100 mg/L. The 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 XDE-570. Based on the results of this study, XDE-570 would be classified as [classification] toxic to bluegill sunfish (*Elpomis macrochirus* Rafiinesque) 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 (?template says "cold" water fish, but this is a *warm* water fish ?!) water fish toxicity study (DATA CODE: 9.5.2.2).

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 and OECD Guideline No. 203

A. MATERIALS:

1. Test Material: XDE-570

Description: white crystalline solid

Lot/Batch No. : TSN100298

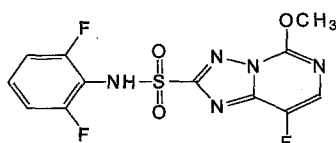
Purity: 99.2 % ai.

Stability of Compound: 121 mg/L

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: Bluegill sunfish (*Lepomis macrochirus*, Rafinesque)

Weight at study initiation: 354.8 mg ?

Length at study initiation: 25.4 cm ?

Source: "pond-reared" from Northeastern Biologists

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 glass beakers, filled to 10-L, fitted with covers to retard evaporation and loss of fish. Duplicate vessels for each dose were employed.
Test concentrations	100 mg/L
Number of fish per replicate and loading	10
Solvent	1 mL dimethylformamide in 10 L (0.1 %, w/w)
Photoperiod	16-hr light/8-hr dark
Temperature	22.5-22.7 °C
Range for pH, dissolved oxygen	pH: 7.0-8.1 DO: 7.9-8.5 mg/L (>94 % saturation)
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)
Observation intervals	3 h, 24 h, 48 h, 72 h, and 96 h
Observations at each time interval	mortality (no response to touching of the caudal peduncle and no opercular movement)

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

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 bluegill fish is greater than 100 mg XDE-570/L.

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