Data Evaluation Report on Acute EC_{50} Test With An Estuarine/Marine Mollusk; Shell Deposition Study

PMRA Submission Number {.....} EPA MRID Number 468083-19

Data Requirement:

PMRA Data Code	9.4.4
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468083-19
EPA Guideline	72-3b

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:** 10.04.2000

Primary Reviewer: Brian D. Kiernan, Biologist, ERBIV **Date:** 2.08.2007
EPA

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: 2.08.2007

CITATION: Ward, T.J., Magazu, J.P. and Boeri, R.L. (1995): XDE-570: Acute flow-through mollusc shell deposition test. Dow AgroSciences, unpublished report No. 644-DO, 27 September 1995.

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 aquatic species. 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.

EXECUTIVE SUMMARY:

A 96-h acute flow-through toxicity study with the eastern oyster (*Crassostrea virginica*) was conducted to determine the effects of XDE-570 on mollusc shell deposition. Two groups of fifteen oysters were exposed to a nominal concentration of 130 mg ai/L (mean measured 125 mg ai/L) prepared by mixing test material with unfiltered natural sea water. Test was conducted at 20.2 to 21 °C (mean 20.8 °C) and pH 7.7-7.9 under a 16h light:8h dark photoperiod with dissolved oxygen levels of 6.3-7.5 mg O_2/L (mean 6.9 mg O2/L). The study was conducted in accordance with US EPA FIFRA, Subdivision E, Guideline 72-3 (b) and the EPA GLP standards.

No mortality or other adverse reaction was observed. Control and test oyster groups both deposited an average of 2.9 mm of new shell growth during the 96-h exposure period. The 96-h are >125 mg/L and 125 mg/L, respectively. Sublethal effects were not observed at the test concentration of 125 mg/L. Based on the results of this study, XDE-570 is classified as practically non-toxic to *Crassostrea virginica*.

This toxicity study is classified as **acceptable** and is sufficient to allow a risk assessment for acute toxicity of florasulam to estuarine/marine invertebrates. EFED accepts the PMRA DER in lieu of the generation of a new DER.

Results Synopsis

Test Type: Flow-through

EC_{50}: >125.mg a.i./L 95% C.I.: NA
NOAEC: 125 mg a.i./L
Endpoint(s) Affected: none

Appendix 9.4.4

PMRA Reviewer: Peter Takacs **Date Report Completed: 4-October-2000**

STUDY TYPE: Mollusc Shell Deposition Study
PMRA DATA CODE: 9.4.4
OECD Data Point: IIA 8.11.1

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

SYNONYMS:DE-570, XR-570

CITATION: Ward, T.J., Magazu, J.P. and Boeri, R.L. (1995): XDE-570: Acute flow-through mollusc shell deposition test. Dow AgroSciences, unpublished report No. 644-DO, 27 September 1995.

SPONSOR: The Dow Chemical company, Midland, Michigan.

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No mortality or other adverse reaction was observed. Control and test oyster groups both deposited an average of 2.9 mm of new shell growth during the 96-h exposure period. The 96-h EC50 and NOEC could not be calculated due to a lack of effect on shell deposition, and were considered to be > 125 mg/L (measured a.i.) and ≥ 125 mg/L, respectively. Sublethal effects were not observed at the test concentration of 125 mg/L. Based on the results of this study, XDE-570 would be classified as practically non-toxic to the mollusc *Crassostrea virginica* in accordance with the classification system of the U.S. EPA.

This study is classified acceptable and does satisfy the guideline requirement for a mollusc shell deposition study toxicity study (PMRA DATA CODE: 9.4.4);

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

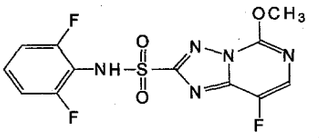
I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: US EPA FIFRA, Subdivision E, Guideline 72-3 (b).

A. MATERIALS:

1. Test Material: XDE-570 (99.2%) **Description:** technical herbicide, white powder.

Lot/Batch #: TSN 100298
Purity: 99.2 % a.i.
Stability of compound: not provided
CAS #:145701-23-1
IUPAC name: 2′,6′,8-trifluoro-5-methoxy-s-triazolo[1,5-c]pyrimidine-2-sulphonanilide
Structure:



2. Test organism: eastern oyster
Species: Juvenile *Crassostrea virginica*
Source: P. Cummins Oyster company
Acclimatization: 15 days

B. STUDY DESIGN:

1. Experimental conditions:

a) Range-finding Study: Not performed. Historical data was used to select test concentration.

b). Definitive Study: Conducted under flow through conditions for 96 hours with one treatment concentration (130 mg a.i./L) and one dilution water control group. Each group consisted of two replicates with 30 oysters each.

Table 1 . Experimental Parameters

Parameter	Value	Remarks

Test vessel and number of replicates	20 L glass aquaria 3 replicates per treatment	15 L unfiltered salt water solution
Test concentrations	130 mg a.i./L*	(125 mg/L, mean measured)
Number of organisms per replicate	30	
Solvent	natural sea water	32 ppt
Photoperiod	16 hour light, 8 hour dark	
Temperature	20.2-21.0 °C	
Range for pH, dissolved oxygen	pH: 7.7-7.9 DO: 6.3-7.5	
Other parameters		

* The concentration used in the study is five orders of magnitude greater than the EEC based on a single application of 7.5 g a.i./ha.

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
Test duration	96 hours	
Test dates: start end	2-June-1995 6- June-1995	
Observation intervals	days 0, 2 and 4 for exposure concentration, and 0, 24, 48, 72 and 96 hours for mortality and adverse effects. At the end of the study oysters shells were measured to the nearest 0.1 mm.	
Observations at each time interval	mortality and adverse effects	
Others		

II. RESULTS AND DISCUSSION:

A. Shell Deposition: One hundred percent survival occurred in the control and at 125 mg

a.i./L XDE-570 (mean measured concentration). No sublethal effects were observed during the study. Both control and treated oysters deposited an average of 2.9 mm of shell during the 96 hour exposure, with no significant differences between the two groups (unpaired t-test was used ($p = 0.05$)). The 96 hour EC50 for survival was > 125 mg a.i./L and the NOEC was ≥125 mg/L.

Table 3. Shell deposition at 96 hours.

Treatment (measured mg a.i. /L)	Shell Deposition (mm)	Percentage Index of Response
Negative control	2.9	100
125	2.9	100

II. Study deficiencies: The study authors stated that XDE-570 concentrations were measured during the study and that the compound was stable in the "static study", however, the study was a flow-through design. The analytical method used was not the one that was provided by the sponsor. These are considered to be minor deficiencies.