Data Evaluation Report on the Acute Toxicity of Florasulam to *Daphnia magna*

PMRA Submission Number {.....} EPA MRID Number 46843806

Data Requirement:

PMRA Data Code	9.3.2
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468438-06
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

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., Landre, A.M., Massaro, L.M., Hugo, J.M. and Stahl, D.C. (1995): Evaluation of the acute toxicity of XDE-570 herbicide to the daphnid, *Daphnia magna* Straus. Dow AgroSciences, unpublished report No. DECO-ES-2938, 22 May 1995.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 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.

EXECUTIVE SUMMARY:

An acute 48-hour static toxicity study was conducted to determine the effects of XDE-570 on daphnids (*Daphnia magna*). Four groups of five 1st instar daphnids were exposed to 0 (control), 38, 63, 104, 174 and 292 mg ai/L under a 16 h light (2045 ± 323 lux):8 h dark photoperiod at 19.5 - 20.2 °C with dissolved oxygen levels of 8.1-9 mg O_2/L (>91% saturation) at a pH 6.3 to 7.8. The raw water from Lake Huron was adjusted to a hardness of 166 mg/L as $CaCl_3$ prior to autoclaving, cooling and aerating. Exposure levels were monitored and found that the test material was stable during the test. The study was conducted in compliance with EPA GLP standards.

Lethal and sublethal effects only observed at the highest concentration tested, 292 mg ai/L. At 48 hours, there was 20% immobilization. Therefore, the 48-h LC50/EC50 values were >292 and the 48-h NOEC was 174 mg ai/L. XDE-570 is classified as practically non-toxic to daphnids.

This study is classified acceptable and is consistent with the guideline requirement for an acute daphnid 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}: >292.mg a..i./L 95% C.I.: NA
NOAEC: 174 mg a..i./L
Endpoint(s) Affected: none

Appendix 9.3.2

PMRA Reviewer: Peter Takacs **25-July-2000**

[redacted]

STUDY TYPE: Daphnia sp. Acute Study
PMRA DATA CODE: 9.3.2
OECD Data Point: IIA 8.3.1 and IIA 8.3.1.1

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

SYNONYMS: DE-570, XR-570

CITATION: Kirk, H.D., Landre, A.M., Massaro, L.M., Hugo, J.M. and Stahl, D.C. (1995): Evaluation of the acute toxicity of XDE-570 herbicide to the daphnid, *Daphnia magna* Straus. Dow AgroSciences, unpublished report No. DECO-ES-2938, 22 May 1995.

SPONSOR: Dow AgroSciences Canada Inc. Suite 201, 1144 - 29th Avenue, N.E. Calgary, Alberta T2E 7P1

EXECUTIVE SUMMARY:

An acute 48-hour static toxicity study was conducted to determine the effects of XDE-570 on daphnids (*Daphnia magna*). Four groups of five 1st instar daphnids were exposed to 0 (control), 38, 63, 104, 174 and 292 mg ai/L under a 16 h light (2045 ± 323 lux):8 h dark photoperiod at 19.5 - 20.2 °C with dissolved oxygen levels of 8.1-9 mg O_2/L (>91% saturation) at a pH 6.3 to 7.8. The raw water from Lake Huron was adjusted to a hardness of 166 mg/L as $CaCl_3$ prior to autoclaving, cooling and aerating. Exposure levels were monitored and found that the test material was stable during the test. The study was conducted in compliance with EC method C2, Directive 92/69 and OECD Guideline No. 202 Part I. And the EPA GLP standards.

Lethal and sublethal effects only observed at the highest concentration tested, 292 mg ai/L. At 48 hours, there was 20% immobilization. Therefore, the 48-h LC50/EC50 values were greater >292 and the 48-h NOEC was 174 mg ai/L.

The maximum concentration of XDE-570 tested (292 mg a.i./L, measure) was equivalent to 116800 times the EEC in water (0.0025 mg a.i./L), based on a single application at a rate of 7.5 g a.i./ha. Based on the results of this study, XDE-570 would be classified as practically non-toxic to daphnids in accordance with the classification system of the U.S. EPA.

This study is classified acceptable and does satisfy the guideline requirement for an acute daphnia sp. toxicity study (DATA CODE: 9.3.2).

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

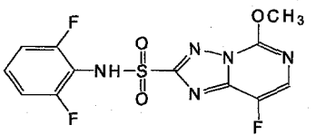
I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: EC method C2, Directive 92/69 and OECD Guideline No. 202 Part I.

A. MATERIALS:

1. Test Material:

Description: technical herbicide, white powder.
Lot/Batch #: TSN100298
Purity: 99.2% ai.
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:

Species: *Daphnia magna*
Source: not provided
Acclimatization: Instars (less than 24 hrs old) were separated from adults. Daphnids were kept under 16 hr light/8 hr dark cycles at 20 °C.

B. STUDY DESIGN:

1. Experimental conditions:

a) Range-finding Study:

A range finding study was conducted over a concentration range of 4.7 to 300 mg/L. The test material was stable in the test solutions with Daphnids and no significant decrease was observed over 48 hours.

b). Definitive Study

Table 1. Experimental Parameters

Parameter	Value	Remarks
Test vessel and number of replicates	4 replicates/treatment, 250 mL borosilicate jars were used	
Test concentrations (nominal)	38.9, 64.8, 108, 180, and 300 mg a.i./L.	Analysis of controls (reverse-phase HPLC with UV detection) confirmed the nominal to be within 96.3–97.7% of the theoretical concentrations.
Number of organisms per replicate	5	
Solvent	not provided	
Photoperiod	16 hr light/8 hr dark	
Temperature	19.5 to 20.2 °C	
Range for pH, dissolved oxygen	pH: 6.3 to 7.8 DO: 8.1 to 9.0 mg O_2/L	
Other parameters		

2. Observations:

Table 2: Observations

Criteria	**Details**	**Remarks**
Test duration	48 hrs	
Test dates: start end	April-13-1994 April-15-1994	
Observation intervals	day 0, 1, 2	
Observations at each time interval	mortality and immobility	
Others		

II. RESULTS AND DISCUSSION:

A. Mortality: Lethality (15%) and sublethal effects (20%) were only observed at the highest concentration tested, 292 mg/L, at 48 hours. Because of the low incidence of mortality and sublethal effects, the data was not statistically analyzed.

Table 3: Effect of XDE-570 on mortality of *Daphnia magna,* sp.

Treatment (measured concentration: mg a.i./L)	Observation period					
	Day 0		Day 1		Day 2	
	No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality
Negative control	0	0	0	0	0	0
38	0	0	0	0	0	0
63.0	0	0	0	0	0	0
104	0	0	0	0	0	0
174	0	0	0	0	0	0
292	0	0	1	5	3	15

III. Study deficiencies: No deficiencies were noted in the study.

IV. Comments: The 48 hour EC_{50} for XDE-570 must be in excess of 292 mg/L, the highest concentration tested. Since adverse effects were observed at this concentration, the NOEC is considered to be 174 mg/L.