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

PMRA Submission Number {.....} EPA MRID Number 468083-15

Data Requirement:

PMRA Data Code	9.3.2
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468083-15
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: Jenkins, C.A. (1996): EF-1343: Acute toxicity to Daphnia magna. Huntingdon Life Sciences, unpublished report No. 96/DES346/0352, 4 October, 1996.

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 EF-1343 (aformulated herbicide containing the active ingredient XDE-570 at 51.8 g ai/L) on daphnia(*Daphnia magna*). Six groups of five 1st instar daphnids were exposed to a nominalconcentration of 100 mg EF-1343/L. The mean measured concentration was 5.5 mg ai/L (110%of nominal). The test was conducted under a 16 h light : 8 h dark photoperiod at 18.7 to 19.9 °Cwith dissolved oxygen levels of 95-100% air saturation at a pH of 7.6-8. The study was conducted in accordence with the EC method C2, Directive 92/69 and OECD Guideline No. 202 Part I and the UK GLP standards.

No immobilisation or other sub-lethal reactions to exposure were observed in the treatment for 48 h. The 48-h LC50, EC50 and NOEC, based on mortality and sublethal adverse effects, could not be calculated due to lack of mortality. **The 48-h EC50, and NOEC were estimated to be >100 and 100 mg EF-1343/L (or 5.5 mg ai/L), respectively.** Non-lethal effects were not observed in this study. The mean measure concentration of the active ingredient XDE-570 in the test solutions was 5.5 mg a.i./L , which is 2200 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. The EEC of the formulated product was calculated to be 0.052 mg EF-1343/L, based on a single application at a rate of 7.5 g a.i./ha (using 150 mL of the 50g/L end use product/ha; density = 1.033 g/mL).

EF-1343 is classified as practically non-toxic to daphnids 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 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}: >100 mg a..i./L 95% C.I.: NA
NOAEC: 100 mg a..i./L
Endpoint(s) Affected: none

Appendix 9.3.5

PMRA Reviewer: Peter Takacs **August-14-2000**

STUDY TYPE: Daphnia sp. Acute Study
PMRA DATA CODE: 9.3.5
OECD Data Point: IIA 8.3.1 and IIA 8.3.1.1

TEST MATERIAL (PURITY): EF-1343 (51.8 g/L, measured)

SYNONYMS:DOW 81682 H

CITATION: Jenkins, C.A. (1996): EF-1343: Acute toxicity to Daphnia magna. Huntingdon Life Sciences, unpublished report No. 96/DES346/0352, 4 October, 1996.

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 EF-1343 (a formulated herbicide containing the active ingredient XDE-570 at 51.8 g ai/L) on daphnia (*Daphnia magna*). Six groups of five 1st instar daphnids were exposed to a nominal concentration of 100 mg EF-1343/L. The mean measured concentration was 5.5 mg ai/L (110% of nominal). The test was conducted under a 16 h light : 8 h dark photoperiod at 18.7 to 19.9 °C with dissolved oxygen levels of 95-100% air saturation at a pH of 7.6-8. The study was conducted in accordence with the EC method C2, Directive 92/69 and OECD Guideline No. 202 Part I and the UK GLP standards.

No immobilisation or other sub-lethal reactions to exposure were observed in the treatment for 48 h. The 48-h LC50, EC50 and NOEC, based on mortality and sublethal adverse effects, could not be calculated due to lack of mortality. **The 48-h EC50, and NOEC were estimated to be >100 and ≥100 mg EF-1343/L (or 5.5 mg ai/L), respectively**. Non-lethal effects were not observed in this study. The mean measure concentration of the active ingredient XDE-570 in the test solutions was 5.5 mg a.i./L , which is 2200 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. The EEC of the formulated product was calculated to be 0.052 mg EF-1343/L, based on a single application at a rate of 7.5 g a.i./ha (using 150 mL of the 50g/L end use product/ha; density = 1.033 g/mL). Based on the results of this study, EF-1343 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: 9.3.5).

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

I. MATERIALS AND METHODS

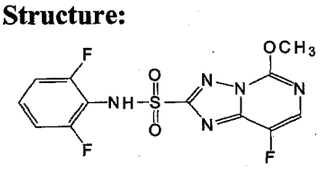
GUIDELINE FOLLOWED: EC method C2, Directive 92/69 and OECD Guideline No. 202 Part I.

A. MATERIALS:

1. Test Material: EF-1343

Description: Suspension concentrate containing DE-570 at 50 g/L nominal (51.8 g/L actual). Opaque, white, viscous liquid.

Lot/Batch #: B767-99
Purity: not provided
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: University of Sheffield, England.
Acclimatization: Instars (less than 24 hrs old) were separated from adults. Daphnids were kept under 16 hr light/8 hr dark cycles at 20 ± 2°C in 2L glass beakers.

B. STUDY DESIGN:

1. Experimental conditions:

a) Range-finding Study:

Two range finding studies were conducted over a concentration range of 0.01, 0.1, 1, and 10.0 mg concentrate/L (study 1) and 10.0 and 100.0 mg/L (study 2). No immobilization was observed in the test organisms, indicating that the EC50 of EF-1343 was > 100 mg/L (nominal).

b). Definitive Study: Based on the results of the range finding studies, a limit test was conducted at a single nominal concentration of 100 mg concentrate/L. A static design was used with six vessels containing five daphnids each which were exposed to EF-1343. The same number were used for a dilution water control. Vessels were not aerated during the experiment.

Table 1. Experimental Parameters

Parameter	Value	Remarks
Test vessel and number of replicates	6 replicates/treatment 150 mL crystallizing dishes were used	
Test concentrations (nominal)	100 mg/L.	Analysis of controls (reverse-phase HPLC with UV detection) confirmed the mean measured concentration to be within 108-112% of the nominal concentration.
Number of organisms per replicate	5	
Solvent	water	
Photoperiod	16 hr light/8 hr dark	
Temperature	18.7 to 19.8 °C	
Range for pH, dissolved oxygen, hardness, alkalinity	pH: 7.6 to 8.0 DO: 95-100% air saturation hardness: 236 mg/L as $CaCO_3$ alkalinity: 105 mg/L as $CaCO_3$	
Mean overall measured concentration of active ingredient	5.5 mg DE-570/L (110% nominal)	

2. Observations:

Table 2: Observations

Criteria	**Details**	**Remarks**
Test duration	48 hrs	
Test dates: start end	February-6-1996 February-8-1996	
Observation intervals	24 hrs and 48 hrs	
Observations at each time interval	mortality and immobility	
Others		

II. RESULTS AND DISCUSSION:

A. Mortality: No immobilities or effects were noted during the limit test. Therefore the LC50 and EC50 could not be calculated, however the 48-hour EC50 for EF-1343 must be > 100 mg EF-1343/L or 5.5 mg a.i./L in terms of mean measured XDE-570. The NOEC is considered to be ≥100 mg EF-1343/L.

Table 3: Effect of EF-1343 on mortality of *Daphnia magna,* sp.

Treatment (Nominal concentration: mg EF- 1343/L)	24 hours		48 hours	
	No Dead	% Mortality	No Dead	% Mortality
Negative control	0	0	0	0
100	0	0	0	0

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

IV. Comments: The 48 hour EC_{50} for EF-1343 must be in excess of 100 mg EF-1343/L, the highest concentration tested. Since adverse effects were not observed at this concentration, the NOEC is considered to be ≥100 mg/L.