Data Evaluation Report on the Acute Toxicity of Florasulam Formulation to Rainbow Trout

PMRA Submission Number {.....} EPA MRID Number 468083-13

Data Requirement:

PMRA Data Code	9.3.2
EPA DP Barcode	D329529
OECD Data Point	{.....}
EPA MRID	468083-13
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
EPA **Date:** 3.06.2007 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: J Jenkins, C.A. (1996): EF-1343: Acute toxicity to rainbow trout. Huntingdon LifeSciences, unpublished report No. 96/DES345/0351, 2 October, 1996.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:

In a 96-h acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to EF-1343 (a formulated product containing XDE-570 at 51.8 g ai/L) at a concentration of 100 mg concentrate/L (mean measured concentration 5.72 mg ai/L, or 114% of nominal) under semistatic condition. Test was conducted at 13 to 14.2 °C and pH 7.8 to 8.4 with dissolved oxygen levels of 79-103% of air saturation. The study was conducted in accordance with EC method C.1, 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 could not be calculated due to lack of mortality and adverse effects. The mean measure concentration of the active ingredient XDE-570 in the test solutions was 5.72 mg a.i./L , which is 2288 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). Sublethal effects were not observed in the groups exposed to 100 mg EF-1343/L.

EF-1343 is classified as practically non-toxic to rainbow trout 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 fish 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 9.5.4

PMRA Reviewer: Peter Takacs 13 **15-August-2000**

STUDY TYPE: Cold Water Fish (Acute)
PMRA DATA CODE: 9.5.4
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.1

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

SYNONYMS: DOW 81682 H

CITATION: Jenkins, C.A. (1996): EF-1343: Acute toxicity to rainbow trout. Huntingdon Life Sciences, unpublished report No. 96/DES345/0351, 2 October, 1996.

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

EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to EF-1343 (a formulated product containing XDE-570 at 51.8 g ai/L) at a concentration of 100 mg concentrate/L (mean measured concentration 5.72 mg ai/L, or 114% of nominal) under semi-static condition. Test was conducted at 13 to 14.2 °C and pH 7.8 to 8.4 with dissolved oxygen levels of 79-103% of air saturation. The study was conducted in accordance with EC method C.1, 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 could not be calculated due to lack of mortality and adverse effects. The mean measure concentration of the active ingredient XDE-570 in the test solutions was 5.72 mg a.i./L , which is 2288 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). Sublethal effects were not observed in the groups exposed to 100 mg EF-1343/L. Based on the results of this study, EF-1343 would be classified as practically non-toxic to *Oncorhynchus mykiss* 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: 9.5.4);

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

I. MATERIALS AND METHODS

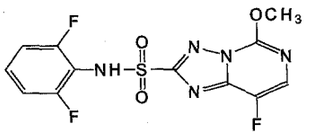
GUIDELINE FOLLOWED: EC method C.1, Directive 92/69 and OECD Guideline No. 203

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: 51.8 g/L, measured
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: *Oncorhynchus mykiss*
Weight at study initiation: mean weight: 0.82 g
Length at study initiation: mean fork length: 4.8 cm
Source: Aquatica, Surrey, Wilmington Trout Farm, Devon, UK.
Acclimation: Fish were held for 14 days prior to the definitive study at the performing laboratory in aerated flow-through tanks held at 12-13.8 °C. The pH ranged from 7.4-8.0, DO was 92-100% air saturation and water hardness ranged from 234 to 246 mg/L as $CaCO_3$. The fish were fed trout pellets daily (1-3% of total wet weight of the fish)

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: Groups of five fish were exposed for 96 hours under static conditions to nominal EF-1343 concentrations of 1, 10 and 100 mg/L or to dilution water alone. No mortality occurred in the fish and the intended chemical concentrations had been achieved and maintained (103-131% of nominal). The 96-hour LC50 for EF-1343 was found to be > 100 mg/L.

b. Definitive Study: A limit test was conducted under semistatic conditions in which two groups of ten fish were exposed to a nominal concentration of 100 mg/L. A control group of 15 fish was exposed to dilution water.

Table 1 . Experimental Parameters

Parameter	Value	Remarks
Test system and number of replicates	15 L aquaria were used two replicates per treatment	tanks were aerated
Test concentrations	100 mg EF-1343/L	the concentration of the active ingredient XDE-570 was 5.72 mg/L (mean measured) which exceeds the EEC (0.005 mg/L)
Number of fish per replicate and loading	10 fish per replicate loading rate was 0.59 g/L	one of the two control tanks had only 5 fish instead of 10, due to human error.
Solvent	water	
Photoperiod	16 hr light/8hr dark	
Temperature (°C)	13.0- 14.2	
Range for pH, dissolved oxygen	pH: 7.6-8.0 DO: 79-103% of air saturation	
Source of dilution water	dechlorinated tap water blended with reverse osmosis treated water	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
Test duration	96 hours	
Test dates: start end	29-February-1996 04-March-1996	
Observation intervals	during first 4 hours and every 24 hours	
Renewal schedule	once per day	fish were transferred to another vessel containing fresh solutions at 24, 48 and 72 hours.
Observations at each time interval	mortality and sublethal effects	
Others		

II. RESULTS AND DISCUSSION:

A. **Mortality:** No mortality or sublethal effects were observed during the test in either the control or test groups. The LC50 and NOEC could not be calculated, however, the 96-hour LC50 for EF-1343 must be > 100 mg/L (nominal) or > 5.72 mg a.i./L expressed in terms of the mean measured level of XDE-570. The NOEC is considered to be ≥100 mg EF-1343/L (5.72 mg a.i./L).

Table 3: Effect of EF-1343 on mortality of *Oncorhynchus mykiss*.

Treatment (nominal concentration: mg EF-1343/L)	**Observation period**							
	Day 1		**Day 2**		**Day3**		**Day 4**	
	No Dead	**% mortality**	**No Dead**	**% mortality**	**No Dead**	**% mortality**	**No Dead**	**% mortality**
Negative control	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0
NOEC	≥ 100							
LC_{50}	> 100							

B. Other toxicity endpoints: No other endpoints were assessed.

C. Other effects: There were no compound related effects.

IV. Study deficiencies: By error, only five fish were placed into one of the two control tanks instead of ten. This is thought to be a minor deficiency.