Data Evaluation Report on the Acute Toxicity of Florasulam to Earthworms

PMRA Submission Number {.....} EPA MRID Number 468083-31

Data Requirement:

PMRA Data Code	9.2.4.1
EPA DP Barcode	D329529
OECD Data Point	8.7.2
EPA MRID	468083-31
EPA Guideline	

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:** 13.07.2000

Primary Reviewer: Brian D. Kiernan, Biologist, ERBIV **Date:** 2.07.2007
EPA

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: Boeri, R.L., Magazu, J.P. and Ward, T.J., (1994): XDE-570 herbicide: acute toxicity to the earthworm, *Eisenia foetida*. Dow AgroSciences, unpublished report No. 464-DO, 5 July 1994.

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 bees. 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 an acute toxicity study, five groups of forty earthworms (*Eisenia foetida*) were exposed to XDE-570, at the measured rates of 95.7, 200, 336, 690, and 1320 mg a.i./kg soil (equivalent to 215.3, 450, 756, 1552.5, and 2970 kg a.i./ha) in an artificial soil (10% finely ground sphagnum peat, 20% koalin clay, 70% industrial sand, pH 6.2) for 14 days. Mean measured moisture content of soil was 27% on day 1 and 25% on day 14. Worms were maintained under continuous laboratory lighting at 750 lux at a temperature of 20 ± 2 °C. Mortality and sublethal effects were observed on days 0, 7 and 14. The study was conducted in compliance with the OECD Guideline No. 207 and the EPA GLP standards.

Analysis of soil samples confirmed that the test material was stable during the exposure period. At day 14, one of 40 worms were found dead in the control group, and 2 of the 40 worms dead in the treatment with the level of 95.7 mg a.i./kg, which is the lowest treatment level. No any mortalities were observed of worms exposed to 200 mg a.i./kg and higher. The LC_{50} and NOEC values could not be calculated as there was no mortality in all but the lowest treatment level. The LC_{50} and NOEC values were estimated to be >1300 mg a.i./kg soil and 1300 mg a.i./kg soil. Although there were significant differences in the mean body weight of worms exposed to concentrations of 690 mg/kg and above, these differences were due to greater body weight losses occurring in the control groups. This result is consistent with the results from a preliminary range finding study. XDE-570 is, therefore, considered non-toxic to earthworms up to 1320 mg a.i./kg soil and will not adversely affect the earthworms at this level.

This toxicity study is non-guideline and therefore classified as **supplemental**. EFED accepts the PMRA DER in lieu of the generation of a new DER.

Results Synopsis

LC_{50}: >1300 mg a.i./kg soil 95% C.I.: NA
NOAEC: 1300 mg a.i./kg soil
Endpoint(s) Affected: none

Appendix 9.2.3.1 a

PMRA Reviewer: **Peter Takacs, 13-07-2000**

STUDY TYPE: Earthworm Acute Toxicity (*Eisenia foetida*);
PMRA DATA CODE: 9.2.3.1;
OECD Data Point 8.9.1

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

SYNONYMS: DE-570, XR-570

CITATION: Boeri, R.L., Magazu, J.P. and Ward, T.J., (1994): XDE-570 herbicide: acute toxicity to the earthworm, *Eisenia foetida.* Dow AgroSciences, unpublished report No. 464-DO, 5 July 1994.

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

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This acute toxicity study is classified as acceptable and satisfies the guideline requirement of a earthworm acute toxicity study (DATA CODE: 9.2.3.1).

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

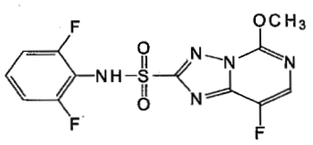
I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: OECD Guideline No. 207

A. MATERIALS:

1. Test Material: XDE-570

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 animals:

Species: *Eisenia foetida*
Weight at study initiation: minimum weight of 196 mg
Source: Carolina Biological Supply Company, Burlington, North Carolina
Housing: worms were not fed during the acclimation period or during the study
Acclimation period: 3 days

B. STUDY DESIGN:

1. Soil:

Table 1: Properties of artificial soil.

Property	Soil	Method
Soil type	artificial soil	70% industrial sand, 20% kaolin clay, 10% ground sphagnum peat
Soil preparation	-	-
pH	6.2	-
Moisture at 1/3 atm (%)	27	-

Experimental conditions:

Table 2: Experimental design.

Parameter		Soil	Remarks
Soil:		no details provided on weight	
Controls	Positive	chloracetamide	a 14 day study with the reference substance chloracetamide was conducted in February 1994. The LC_{50} was 13.0 mg/kg. No further details were provided.
	Negative	4 replicates	
Test organisms	Number of worms for each treatment	40	10 worms per replicate
	Initial weight for each group	control: 293.7 mg 1. 95.7 mg a.i./kg: 276.0 mg 2. 200 mg a.i./kg: 275.1 mg 3. 336 mg a.i./kg: 295.8 mg 4. 690 mg a.i./kg: 284.7 mg 5. 1320 mg a.i./kg: 271.1mg	After acclimation, worms were rinsed with deionized water, dried and weighed.
Application rates:		Nominal: 0, 99, 190, 360, 670, 1300 XDE-570/kg soil (dry weight) Actual: (mean measured concentrations were corrected for recovery loss of spiked samples) 95.7, 200, 336, 690, 1320 mg a.i./kg soil corresponding rates per hectare are: 215.3, 450, 756, 1552.5, and 2970 kg a.i./ha	No effects were found in a preliminary range finding study with maximal concentrations of 990 mg a.i./kg soil[1]
Pesticide application method:		Measured amounts of chemical were mixed into the dry artificial soils	
Replications:	controls treatments	4 4	
Test conditions	Apparatus	3.8L glass jars	
	Temperature (°C)	19.3-22.0	
	Moisture (%)	25-27	
	Lighting	continuous illumination	

[1] A range finding study was conducted with concentrations of 0, 0.99, 9.9, 99, and 990 mg/kg XDE-570. Greater than 90% survival was observed at all concentrations and weight loss was greatest in the control group.

2. Observations:

Table 3: Observations

Criteria	Details	Remarks
Test duration	14 days	
Test dates: start end	27-May-1994 10-June-1994	
Observation intervals	days: 0, 7, 14	
Observations at each time interval	day 0: survival and sublethal effects, time required to burrow, average wet weight day 7: survival and sublethal effects, time required to burrow day 14: survival and sublethal effects, average wet weight	
Others		

II. RESULTS AND DISCUSSION:

A. Mortality:

No significant mortalities or sublethal effects were observed in treatment and control groups during the 14 day exposure period. Worms burrowed below the soil surface within 10 minutes at all concentrations.

Table 4: Effect of XDE-570 on mortality of earthworms.

Treatment (measured or nominal concentration: mg a.i./kg soil)	Observation period					
	Day 0		Day 7		Day 14	
	Dead	% Mortality	Dead	% Mortality	Dead[1]	% Mortality
Negative control	0	0	0	0	1	2.5
Positive control (with *reference chemical*)	n.p.	-	-	-	-	-
Treatment 1	0	0	0	0	2	5
Treatment 2	0	0	0	0	0	0
Treatment 3	0	0	0	0	0	0
Treatment 4	0	0	0	0	0	0
Treatment *5*	0	0	0	0	0	0
NOEC	≥1300 mg XDE-570/kg soil					
LC_{50}	> 1300 mg XDE-570/kg soil					

[1] Mean % mortality per treatment. One organism was dead out of a total of 40 in the control group and two were dead (one in each of two jars) at 95.7 mg a.i./kg soil (treatment 1).
n.p.: not provided

B. Body weight and weight gain:

Table 5: Effect of XDE-570 on body weight loss of earthworm.

Treatment (measured concentration: mg a.i./kg soil)	Day 14
	% weight loss
Negative control	-19.2
Positive control	-
95.7	-11.8
200	-11.3
336	-11.3
690	-9.0
1320	-9.5
NOEC	≥1300 mg a.i./kg
EC_{50}	> 1300 mg a.i./kg

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

IV. Study deficiencies: The amount of soil used per replicate was not specified. The moisture content of the soil was below 35%. The stability of the test substance was assumed but not verified. The balance used to weigh the artificial soil was not calibrated before use. These are considered to be minor deficiencies.

Template name: *earthworm.wpd*

Study review filename: *X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.2.3.1 a florasulam earthworm tox.wpd*