Data Evaluation Report on the Acute Dietary Toxicity of Florasulam to Mallard Duck (*Anas platyrhynchos*)

PMRA Submission Number {.....} EPA MRID Number 468083-07

Data Requirement:	PMRA Data Code	9.6.2.5
	EPA DP Barcode	D329529
	OECD Data Point	{.....}
	EPA MRID	468083-07
	EPA Guideline	71-2

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: Tamara Sheremata, Ph.D
PMRA **Date:** 8.15.2000

Primary Reviewer: Brian D. Kiernan, Biologist **Date:** 3.05.2007 10/9/07
EPA

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
Active Code	{.....}	[For PMRA]
Use Site Category:	{.....}	[For PMRA]
EPA PC Code	129108	

Date Evaluation Completed: 3.05.2007

CITATION: Helsten, B.R., and A.M. Solatycki (1994) XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Mallard Ducklings. Bio-Life Associates Ltd. (Neillsville, WI). Dow study ID: ES-2796, July 15, 1994. Unpublished.

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 chronic toxicity of a pesticide to birds. 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:

The short-term dietary toxicity of technical XDE-570 to 11-d-old mallard duck (*Anas platyrhynchos*) was assessed over 8 d. XDE-570 was administered to the animals in the diet at nominal concentrations of 0, 312, 625, 1250, 2500, and 5000 mg ai/kg diet. During the quarantine, test, and recovery periods, the birds were maintained under 1 16 h light : 8 h dark light regime and at average temperature and RH of 36 °C and 29% (quarantine period), 35 °C and 41% (test period) and 35 °C and 40% (recovery period). Mortality and signs of reaction to treatment were recorded twice daily on day 0 and at least daily thereafter. Food consumption was estimated, and the gross pathological examinations were done at the end of recovery period.

The study was conducted in accordance with U.S. EPA Pesticide Assessment Guidelines of Subdivision E, Series 71-2 and OECD Guideline for Testing Chemicals No. 205, and the EPA GLP standards.

There were no compound-related toxic effects. The LC_{50} is greater than 5000 mg ai/kg diet, based on the fact that there were no differences in mortality, apparent toxicity and gross pathology. XDE-570 is classified as practically non-toxic to the mallard duck on a dietary basis.

This toxicity study is classified acceptable and does is contains sufficient information for the purpose of the guideline requirement for an avian dietary toxicity study.

The PMRA DER is accepted in lieu of generating a new DER.

Results Synopsis

LC50: >5000 mg ai/kg bw
NOAEC: 5000 mg ai/kg bw
Endpoint(s) Affected: none

Appendix 9.6.2.5

PMRA Reviewer: Tamara Sheremata, Ph.D. **17-August-2000**

STUDY TYPE: Mallard Duck Dietary LC_{50} Study;
PMRA DATA CODE: 9.6.2.5;
OECD Data Point IIA 8.1.2

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

SYNONYMS: XR-570 (1990-Jan. 1994), XDE-570 (Jan. 94 - Jan. 97), DE-570 (Feb. 1997-?), Florasulam.

CITATION: Helsten, B.R., and A.M. Solatycki (1994) XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Mallard Ducklings. Bio-Life Associates Ltd. (Neillsville, WI). Dow study ID: ES-2796, July 15, 1994. Unpublished.

SPONSOR: The Dow Chemical Company, Environmental Toxiciology & Chemistry Research Laboratory, Midland, MI.

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There were no compound-related toxic effects. The NOEC and LC_{50} of XDE-570 to the mallard duck were **both greater than 5000 mg ai/kg diet,** respectively. XDE-570 would be considered practically non-toxic to the mallard duck on a dietary basis.

This toxicity study is classified acceptable and does satisfy the guideline requirement for a mallard duck dietary LC_{50} study (DATA CODE 9.6.2.5).

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

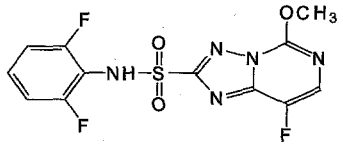
I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: U.S. EPA Pesticide Assessment Guidelines of Subdivision E, Series 71-2, "Acute Dietary LC50 Test for Waterfowl and Upland Game Birds", OECD Guideline for Testing Chemicals, "Avian Dietary Toxicity Test", No. 205.

A. MATERIALS:

1. Test Material: XDE-570

Description: grey powder
Lot/Batch #: 930910
Purity: 99.2 % ai.
Stability of compound: not specified
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: mallard duck (*Anas platyrhynchos*)
Age at study initiation: 11 d
Weight at study initiation: 184.84 ± 21.85 (SD) g (10 replicates from one group)
Source: Whistling Wings, Inc, Hanover IL.
Housing: indoor pen
Acclimation period: 9 d

B. STUDY DESIGN:

1. Experimental conditions:

Table 1: Experimental conditions.

Criteria	Details	Remarks
Nominal concentrations	0, 312, 625, 1250, 2500, and 5000 mg a.i./kg	
Measured concentrations	The nominal concentrations mentioned above were not verified by analytical methods.	Storage stability tests of spiked feed indicate that target concentrations of 500 and 5000 mg a.i. /kg yielded measured concentrations of 519 ± 34 (SD) and 4931 ± 165 (SD) mg a.i./kg.
Number of birds per concentration	10	
Number of birds in negative control group	10 each for 2 control groups	
Pen size	71.1 cm wide x 91.4 cm long x 27.9 cm high	
Photoperiod	16 h/d	natural daylight spectrum lighting
Temperature (°C)	23 °C for quartantine, 22 °C for the 5 d test period, and 21 °C for the 3 d recovery period.	
Relative humidity (%)	56 % for quarantine period; 71 % for 5 d test period; 62 % for 3 d recovery period.	
Diet preparation	XDE-570 (0 to ~35 g) was mixed with a small quantity of stock diet* (~ 200 g) in a blender for 3 min to prepare the "premix". This premix was combined with 2800.0 g of stock diet and mixed in a mixer for 15 min. Another 4000.0 g of stock diet was added, and the mixture was mixed for another 15 min.	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
Test duration	5 d test, followed by 3 d recovery	
Test dates: start end	May 20, 1994 May 28, 1994	
Observation intervals	daily	
Observations at each time interval	Presence/absence of clinical signs indicative of test material effect. Inspections were made for mortalities, abundance of feed and water, and feed spillage.	

II. RESULTS AND DISCUSSION:

A. Mortality:

No mortalities were recorded during the study. The results of the 8-d acute dietary LC50 study that was carried out with XDE-570 in mallard ducks indicate an acute dietary median lethal concentration (LC50) of the test material to be greater than 5000 mg a.i./kg.

The NOEL was considered to be in excess of 5000 mg a.i./kg.

B. Other toxicity endpoints:

No mortalities were recorded during the study. The results of the 8-d acute dietary LC50 study that was carried out with XDE-570 in mallard ducks indicate an acute dietary median lethal concentration (LC50) of the test material to be greater than 5000 mg a.i./kg.

The NOEL was considered to be in excess of 5000 mg a.i./kg.

C. Other effects:

No stastistically significant differences in body weights were noted at the 95 % confidence level.

It was reported that the feed consumption values were similar in all test and control groups during testing and recovery. However, there was no reported statistical basis for this conclusion.

Gross pathology examinations of 24 randomly selected birds revealed abnormal findings in

one bird in the 312 mg a.i./kg treatment group, where it was found that the liver was friable with a 1 cm^2 green spot on the right lobe. It was concluded that this abnormality was not related to the test iteself.

IV. Study deficiencies: There were no major/minor deficiencies in this study.
Template author: *M. Segstro*
Template dated: *October 20, 1998*
Template name: *av-dt-md.wpd*

Study review filename: *X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.6.2.5 Mallard duck_dietary.wpd*