

US EPA ARCHIVE DOCUMENT

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

PMRA Submission Number {.....}

EPA MRID Number 468083-09

Data Requirement:	PMRA Data Code	9.6.3.2
	EPA DP Barcode	D329529
	OECD Data Point	{.....}
	EPA MRID	468083-09
	EPA Guideline	72-3a

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-sulfonamide
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: 8.21.2000

Primary Reviewer: Brian D. Kiernan, Biologist
EPA

Date: 2.28.2007

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

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

Date Evaluation Completed: 2.28.2007

CITATION: Gallagher, S.P., Beavers, J.B., and M. Jaber (1995) XDE-570: A Reproduction Study with the Mallard (*Anas platyrhynchos*). Wildlife International Ltd. (Easton, MD). Dow study no. DECO-ES-2912, December 21, 1995. Unpublished. 180 pp.

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.



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EXECUTIVE SUMMARY:

The reproductive toxicity of technical XDE-570 to 28 week-old mallard duck (*Anas platyrhynchos*) was assessed over 23 wk. Three treatment groups, each comprising 16 pairs of adult mallard were fed diets containing XDE-570 at nominal concentrations of 0 (control), 240, 600 and 1500 mg ai/kg diet prepared with aid of acetone and corn oil. The photoperiod for the first nine weeks of the study was 8h light (441 lux) : 16h dark and thereafter was increased to 17h light : 7h dark. The average temperature in the adult study was 20.9 ± 1.6 °C (RH $45 \pm 15\%$), eggs were hatched at 37.5 °C (RH 56%) and the chicks maintained at 24.4 ± 2.7 °C (RH $63 \pm 19\%$). Effects on adult health, weight gain, feed consumption, egg production, development of eggs, egg shell thickness, viability of the embryos, percent hatchability and offspring survival were evaluated. The study was conducted in accordance with U.S. EPA, Pesticide Assessment Guidelines, FIFRA Subdivision E, Subsection 71-4 and OECD No. 206 and the EPA GLP standards. Analysis of test diet confirmed that XDE-570 was stable for at least seven days and homogeneity was also confirmed. There were no compound-related effects. The NOAEC of XDE-570 to the mallard duck was 1500 mg ai/kg diet.

This toxicity study is classified acceptable and does is contains sufficient information for the purpose of the guideline requirement for a mallard duck reproductive toxicity study.

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

Results Synopsis

NOAEC: 1500 mg a.i./kg diet

Endpoint(s) Affected: none

Appendix 9.6.3.2

PMRA Reviewer: Tamara Sheremata, Ph.D.

21-August-2000

STUDY TYPE: Mallard Duck Reproductive Toxicity Study;
PMRA DATA CODE: 9.6.3.2;
OECD Data Point IIA 8.1.4

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: Gallagher, S.P., Beavers, J.B., and M. Jaber (1995) XDE-570: A Reproduction Study with the Mallard (*Anas platyrhynchos*). Wildlife International Ltd. (Easton, MD). Dow study no. DECO-ES-2912, December 21, 1995. Unpublished.

SPONSOR: The Dow Chemical Company, Health & Environmental Sciences, Environmental Toxicology & Chemistry Research Laboratory, Midland, MI.

EXECUTIVE SUMMARY:

The reproductive toxicity of technical XDE-570 to 28 week-old mallard duck (*Anas platyrhynchos*) was assessed over 23 wk. Three treatment groups, each comprising 16 pairs of adult mallard were fed diets containing XDE-570 at nominal concentrations of 0, 240, 600 and 1500 mg ai/kg diet prepared with aid of acetone and corn oil. A control was included. The photoperiod for the first nine weeks of the study was 8 h light (441 lux) : 16 h dark and thereafter was increased to 17 h light : 7 h dark. The average temperature in the adult study was 20.9 ± 1.6 °C (RH 45 ± 15%), eggs were hatched at 37.5 °C (RH 56%) and the chicks maintained at 24.4 ± 2.7 °C (RH 63 ± 19%). Effects on adult health, weight gain, feed consumption, egg production, development of eggs, egg shell thickness, viability of the embryos, percent hatchability and offspring survival were evaluated. The study was conducted in accordance with U.S. EPA, Pesticide Assessment Guidelines, FIFRA Subdivision E, Subsection 71-4 and OECD No. 206 and the EPA GLP standards.

Analysis of test diet confirmed that XDE-570 was stable for at least 7 days and homogeneity was also confirmed. There were no compound-related effects. The NOEC of XDE-570 to the mallard duck was 1500 mg ai/kg in the diet, or more. XDE-570 would be considered non-toxic to the mallard duck at 1500 mg ai/kg diet and would not be expected to affect the reproductive success of the mallard duck.

This toxicity study is classified acceptable and does satisfy the guideline requirement for a mallard duck reproductive toxicity study (DATA CODE: 9.6.3.2).

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, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms, Subsection 71-4 and OECD No. 206, Guideline for Testing of Chemicals, Avian Reproduction Test.

A. MATERIALS:

1. Test Material: XDE-570

Description: white powder

Lot/Batch #: 7194360

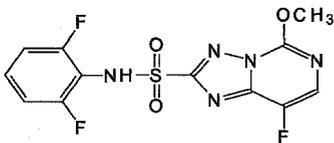
Purity: 99.2 % ai.

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: 28 wk

Weight at study initiation: 1122 ± 69 g (SD)

Source: Whistling Wings, Inc., Hanover, IL.

Housing: indoor pens

Acclimation period: 8 wks

B. STUDY DESIGN:**1. Experimental conditions:**

Table 1: Experimental conditions.

Criteria	Details
Nominal concentrations	240, 600, 1500 mg a.i./kg
Measured concentrations	228 ± 15 (SD), 580 ± 17 (SD), 1431 ± 49 (SD)
Number of birds per concentration [<i>male and female</i>]	16 pairs (1 male and 1 female) for each treatment group
Number of birds in negative control group [<i>male and female</i>]	16 pairs (1 male and 1 female) for each treatment group
Pen size	62 x 92 x 25.5 cm
Photoperiod	Adult mallards: 8 h (or less?) per day from wk 0-10, followed by 17 h per day until birds were euthanized. Hatchlings: 16 h per d.
Temperature (°C)	Adult mallards: 20.9 ± 1.6 °C (SD) Hatchlings: 38 °C from time of hatch until 5-7 days of age, afterwhich the temperature was reduced to 29 °C.
Relative humidity (%)	Adult mallards: 45 ± 15 % (SD) Hatchlings: 63 ± 19 % (SD)

Table 2: Feed preparation.

Description	Component	Nominal dose XDE-570, ppm			
		0	240	600	1500
Premix	XDE-570, g	0	48.9919	122.4798	306.1996
	acetone, mL	250	250	250	250
	corn oil, mL	180	180	180	180
	ration*, g	7938.0	7889.0	7815.5	7631.8
Final Diet	premix, g	2000	2000	2000	2000
	ration, Kg	45.50	45.50	45.50	45.50
	limestone, g	2500	2500	2500	2500

*"ration" refers to Wildlife International Ltd. Game Bird Ration.

2. Observations:

Table 3: Observations

Criteria	Details
Test duration	23 wk
Test dates: start end	January 18, 1995 June 29, 1995
Observation intervals	Mortality, abnormal behaviour, and signs of toxicity: daily observations. Body weights: 0, 2, 4, 6, and 8 wks, and at adult termination. Feed consumption was measured every 7 days.
Observations at each time interval	Mortality and signs of toxicity and abnormal behaviour. At end of the test, adults were euthanized and necropsied.

II. RESULTS AND DISCUSSION:**A. Toxicity endpoints:**

There were no mortalities associated with treatments applied, and no statistically significant differences in body weights, food consumption, and other endpoints associated with reproduction between treatment groups and controls.

IV. Study deficiencies: There were compound related effects.

Template author: M. Segstro

Template dated: October 20, 1998

Template name: av-re-md.wpd

Study review filename: X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.6.3.2 Mallard duck_reproduction.wpd