Data Evaluation Report on the Chronic Toxicity of Florasulam to Bobwhite Quail (*Colinus virginainus*)

PMRA Submission Number {.....} EPA MRID Number 468083-08

Data Requirement:	PMRA Data Code	9.6.3.1
	EPA DP Barcode	D329529
	OECD Data Point	{.....}
	EPA MRID	468083-08
	EPA Guideline	71-4a

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:** 8.18.2000

Primary Reviewer: Brian D. Kiernan, Biologist **Date:** 2.28.2007 10/3/07
EPA

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

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

Date Evaluation Completed: 2.28.2007

CITATION: Beavers, J.B., and M. Jaber (1995) XDE-570 herbicide: A reproduction study with the northern bobwhite (*Colinus virginianus*). Wildlife International Ltd. (Easton, MD). Dow Study No.: DECO-ES-2911, December 21, 1995. Unpublished. 178 pp.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.

EXECUTIVE SUMMARY:

The reproductive toxicity of technical XDE-570 to 20 week-old bobwite quail (*Colinus virginianus*) was assessed over 21 wks. Three treatment groups, each comprising 16 pairs of 20 adult quail 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 seven weeks of the study was 8h light (423 lux) : 16h dark and thereafter was increased to 17h light : 7h dark. The average temperature in the adult study was 21.8 ± 1.3 °C (RH 35 ± 15%), eggs were hatched at 37.5 °C (RH 56%) and the chicks maintained at 25.8 ± 2.3 °C (RH 50 ± 13%). 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 reported. The NOAEC of XDE-570 to the bobwhite quail 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 bobwhite quail 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 9.6.3.1

PMRA Reviewer: Tamara Sheremata, Ph.D. **18-August-2000**

STUDY TYPE: Bobwhite Quail Reproductive Toxicity Study;
PMRA DATA CODE: 9.6.3.1;
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: Beavers, J.B., and M. Jaber (1995) XDE-570 herbicide: A reproduction study with the northern bobwhite (*Colinus virginianus*). Wildlife International Ltd. (Easton, MD). Dow Study No.: DECO-ES-2911, December 21, 1995. Unpublished.

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

EXECUTIVE SUMMARY:

The reproductive toxicity of technical XDE-570 to 20-wk-old bobwhite quail (*Colinus virginianus*) was assessed over 21 wks. Three treatment groups, each comprising 16 pairs of 20 adult quail 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 seven weeks of the study was 8 h light (423 lux) : 16 h dark and thereafter was increased to 17 h light : 7 h dark. The average temperature in the adult study was 21.8 ± 1.3 °C (RH 35 ± 15%), eggs were hatched at 37.5 °C (RH 56%) and the chicks maintained at 25.8 ± 2.3 °C (RH 50 ± 13%). 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 any compound-related effects regarding toxicity. The NOEC of XDE-570 to the bobwhite quail was 1500 mg a.i/kg in the diet, or more. XDE-570 would be considered non-toxic to the bobwhite quail at 1500 mg ai/kg diet, the highest concentration tested, and would not be expected to affect the reproductive success of the bobwhite quail.

This toxicity study is classified acceptable and does satisfy the guideline requirement for a bobwhite quail reproductive toxicity study (DATA CODE: 9.6.3.1).

COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging

statements were provided.

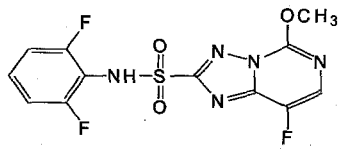
I. MATERIALS AND METHODS

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: bobwhite quail (*Colinus virginianus*)
Age at study initiation: 20 wks
Weight at study initiation: 191 g ± 9 (SD) (one of the control groups)
Source: Top Flight Quail Farm, Belvedere, New Jersey 07823
Housing: indoor pens
Acclimation period: 5 wks

B. STUDY DESIGN:

1. Experimental conditions:

Table 1: Experimental conditions.

Criteria	Details
Nominal concentrations	240, 600, and 1500 mg a.i./kg
Measured concentrations	228 ± 15 mg/kg, 580 ± 17 mg/kg, 1431 ± mg/kg
Number of birds per concentration [*male and female*]	16 pairs (1 male and 1 female) were used for each concentration.
Number of birds in negative control group [*male and female*]	16 pairs (1 male and 1 female) were used for each concentration.
Pen size	25 x 51 cm, with sloping floors that rresulted in ceiling height ranging from 20 to 26 cm
Photoperiod	1-7 wks: 8 h light/d 8-21 wks: 17 h light/d
Temperature (°C)	Room: 25.8 ± 2.3 °C (SD) Incubator: 37.5 ± 0.0 °C (SD) Hatcher: 37.2 ± 0.0 °C (SD)
Relative humidity (%)	Room: 50 ± 13 % Incubator: 56 % Hatcher: 76 %

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	21 wk
Test dates: start end	Feb. 22/95 July 3/95
Observation intervals	Adult birds were observed daily for mortality and signs of toxicity. Adult body weights were measured at 0, 2, 4, 6, and 8 wks. Feed consumption was measured for each pen for a 7 d period throughout the test. Chicks were observed daily throughout the rearing period for signs of toxicity or abnormal behaviour.
Observations made of adults at each time interval	Mortality and signs of toxicity and abnormal behaviour. At end of the test, adults were euthanized and.necropsied.
Observation of reproductive parameters	Eggs laid, eggs cracked, eggs set, viable embryo, live three-week embryos, hatchlings, body weight of hatchlings, 14-day old survivors, body weight of 14-day old survivors, egg shell thickness.

II. RESULTS AND DISCUSSION:

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

C. Other effects: There were compound related effects.

IV. Study deficiencies: There were no deficiencies in this study.

Template author: *M. Segstro*
Template dated: *October 20, 1998*
Template name: *av-re-bq.wpd*

Study review filename: *X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.6.3.1 Bobwhite quail_reproduction.wpd*