Data Evaluation Report on the Acute Dietary Toxicity of Florasulam to Japanese Quail (*Coturnix japonica*)

PMRA Submission Number {.....} EPA MRID Number 468279-20

Data Requirement:	PMRA Data Code	9.6.2.6
	EPA DP Barcode	D329529
	OECD Data Point	{.....}
	EPA MRID	468279-20
	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:** 8.17.2000

Primary Reviewer: Brian D. Kiernan, Biologist **Date:** 3.05.2007
EPA 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: 3.05.2007

CITATION: Helston, B.R. and A.M. Solatycki (1994) XDE-570 herbicide: 8-day acute dietary LC_{50} study in Japanese quail. The Dow Chemical Company, Environmental Toxiciology & Chemistry Research Laboratory, Midland, MI.

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 short-term dietary toxicity of technical XDE-570 to lld-old Japanese quail (*Coturnix coturnix japonica*) was assessed over 8 d. XDE-570 was administered to the animals in the diet at nominal levels of 0, 312, 625, 1250, 2500, and 5000 mg ai/kg diet. During the quarantine, test, and recovery periods, the birds were maintained under 16h light:8h dark light regime and at average temperature and RH of 38 °C and 25% (quarantine period), 37 °C and 31% (test period) and 38 °C and 31% (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 Japanese quail 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.

Results Synopsis

LD50: >5000 mg ai/kg bw
NOAEC: 5000 mg ai/kg bw
Endpoint(s) Affected: survival

Appendix 9.6.2.6

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

STUDY TYPE: Japanese quail Dietary LC_{50} Study;
PMRA DATA CODE: 9.6.2.6;
OECD Data Point IIA 8.1.3

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: Helston, B.R. and A.M. Solatycki (1994) XDE-570 herbicide: 8-day acute dietary LC_{50} study in Japanese quail.

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

EXECUTIVE SUMMARY:

The short-term dietary toxicity of technical XDE-570 to 11-d-old Japanese quail (*Coturnix coturnix japonica*) was assessed over 8 d. XDE-570 was administered to the animals in the diet at nominal levels 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 38 °C and 25% (quarantine period), 37 °C and 31% (test period) and 38 °C and 31% (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 NOEC and LC_{50} of XDE-570 to the Japanese quail, based on the fact that there were no differences in mortality, apparent toxicity and gross pathology, were both **greater than 5000 mg ai/kg diet**, respectively. XDE-570 would be considered practically non-toxic to the Japanese quail on a dietary basis.

This toxicity study is classified acceptable and does satisfy the guideline requirement for a Japanese quail dietary LC_{50} study (DATA CODE: 9.6.2.6).

COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging ? statements were *(not)* provided.

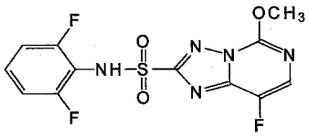
I. MATERIALS AND METHODS

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: Japanese quail (*Coturnix japonica*)
Age at study initiation: 11 d
Weight at study initiation: 55.83 ± 6.51 g (Control-I)
Source: Oak Ridge Game Farm, RR2, Gravette, AR, 72736
Housing: pen, indoors
Acclimation period: 2 d old birds were quarantined for 10-11 d to acclimate them to the laboratory conditions prior to test initiation.

B. STUDY DESIGN:

1. Experimental conditions:

Table 1: Experimental conditions.

Criteria	Details	Remarks
Nominal concentrations	312, 625, 1250, 2500, and 5000 mg DEX-570/kg feed	
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	Two control groups were used.
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 and 5 d test periods; 21 °C for 3 d recovery period.	
Relative humidity (%)	51 % for quarantine period; 64 % for 5 d test period; 65 % 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.	

*Purina® Game Bird Startena

2. Observations:

Table 2: Observations

Criteria	Details
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.

Four randomly selected birds (using random number generator) were selected from the control groups and each of the test groups. They were subjected to gross pathological examinations at the end of the project. The GI tract, liver, kidneys, heart, spleen, muscle, and subcutaneous fat were examined.

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 Japanese quail 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 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 no abnormal findings.

IV. Study deficiencies: No study deficiencies were noted.

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

Study review filename: *X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.6.2.6 (9624) Other avian species_dietary.wpd*