Data Evaluation Report on the Acute Toxicity of Florasulam to Honey Bees, *Apis mellifera*

PMRA Submission Number {.....} EPA MRID Number 468083-30

Data Requirement:

PMRA Data Code	9.2.4.1
EPA DP Barcode	D329529
OECD Data Point	8.7.2
EPA MRID	468083-30
EPA Guideline	[redacted]

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:** 07.19.2000

Primary Reviewer: Brian D. Kiernan, Biologist, ERBIV **Date:** 2.07.2007
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: 2.08.2007

CITATION: Palmer, S.J. & Beavers, J.B. (1994): XDE-570: An acute contact study with the honeybee. Dow AgroSciences, unpublished report No. 103-407, 3 August 1994.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.

2068759

EXECUTIVE SUMMARY:

In an acute toxicity study, four replicates of 25 honey bees (*Apis mellifera*) were exposed to XDE-570, administered topically (to the abdomen or thorax) at nominal rates of 6.3, 12.5, 25.0, 50.0, and 100 µg ai/bee. Control and solvent control were included. Once treated, bees were kept in the dark at 31°C and 46-58% relative humidity and fed on 50% sugar solution for the 48 hour observation period. This study was conducted in compliance with the FIFRA Subdivision L Guideline No. 141-1 and the EPA GLP standards.

Mortality ranged from 0% to 5% in the highest test concentration (100 µg ai/bee) and in the negative and solvent controls. The mortalities were not considered to be dose related by the study authors. The NOEC and LC_{50} values could not be calculated, but were visually estimated to be 100 µg ai/bee and >100 µg ai/bee, respectively. XDE-570 is classified as practically non-toxic to honey bees.

This toxicity study is classified as **acceptable** and is sufficient to allow a risk assessment for acute toxicity of florasulam to honey bees on a contact basis. EFED accepts the PMRA DER in lieu of the generation of a new DER.

Results Synopsis

LC_{50}: >100 µg ai/bee 95% C.I.: NA
NOAEC: 100 µg ai/bee
Endpoint(s) Affected: none

Appendix 9.2.4.1

PMRA Reviewer: **Peter Takacs, 19-July-2000**

STUDY TYPE: Honey bee acute contact toxicity study [*Apis mellifera*];
PMRA DATA CODE: 9.2.4.1;
OECD Data Point 8.7.2

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

SYNONYMS: DE-570, XR-570

CITATION: Palmer, S.J. & Beavers, J.B. (1994): XDE-570: An acute contact study with the honey bee. Dow AgroSciences, unpublished report No. 103-407, 3 August 1994.

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

EXECUTIVE SUMMARY:

In an acute toxicity study, four groups of 25 honey bees (*Apis mellifera*) were exposed to XDE-570, administered topically at the nominal rates of 0, 6.3, 12.5, 25.0, 50.0, and 100 µg a.i./bee. Control and solvent control were included. Once treated, bees were kept in the dark at 31 °C and 46-58% relative humidity and fed on 50% sugar solution for the 48 hour observation period. This study was conducted in compliance with the FIFRA Subdivision L Guideline No. 141-1 and the EPA GLP standards.

At the highest test concentration of 100 µg a.i./bee, 5% mortality was observed. The same level of mortality occurred in the negative and positive controls. The mortalities or other abnormal behavior were not considered to be dose related by the study authors. The NOEC and LC_{50} values could not be calculated, but were visually estimated to be ≥ 100 µg a.i./bee. XDE-570 is, therefore, relatively non-toxic to honey bees.

This acute toxicity study is classified acceptable, and does satisfy the guideline requirement for honey bee [*Apis mellifera*] acute contact toxicity study (DATA CODE: 9.2.4.1).

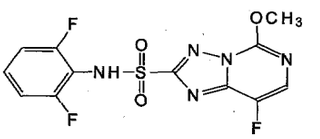
COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging statements were provided.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: FIFRA Subdivision L Guideline No. 141-1.

A. MATERIALS:

1. Test Material: XDE-570
Description: technical herbicide, white powder.
Lot/Batch #: TSN 100298
Purity: 99.2 % a.i.
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 organisms:
Species: *Apis mellifera*
Weight at study initiation: mean body weight ranged from 93 to 115 mg.
Source: Wildlife International Ltd.
Housing: Frames containing pupae were placed in acrylic boxes and were held for five days in an environmental chamber set to maintain a temperature of about 34°C. During this time, bees were allowed to feed *ad libitum* on honey and pollen stored in the hive frames. The test chambers were disposable one pint rolled paper containers measuring approximately 9 cm in diameter and 9 cm high. Each container was covered with a disposable plastic petri dish through which an inverted 20 ml glass vial containing a 50% sugar/water solution was inserted. This food source was available *ad libitum* to the test bees throughout the test period.
Acclimation period: 7 days. All bees were 1-5 days old at study initiation.

B. STUDY DESIGN:

Experimental conditions:

Table 1: Study design

Parameter		Details	Remarks
Cage size		9 cm x 9 cm	
Test conditions	Temperature (°C)	31.4-31.7	
	Relative humidity (%)	46-58	
	Lighting: intensity	continuous darkness	
Range finding test		not reported	
Controls	Positive	solvent (acetone) only	
	Negative	no treatment	handled in the same manner as treated bees
Test organisms	Number of bees per treatment	100 (4 replicates per treatment)	
	Number of bees per cage	25	
Solvent used		acetone	
Nominal dosages: µg a.i./bee		0, 6.3, 12.5, 25.0, 50.0, 100	
Measured dosage if appropriate		not reported	
Replications:	controls each treatment	4 4	
Feeding during test period		bees were fed *ad libitum* on a 50% sugar solution	
Test duration		48 hours	
Others			

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
Test dates: start end	June-20-1994 June-22-1994	
Test duration	48 hours	
Observation intervals	0.5, 1.5, 24 and 48 hrs.	
Parameters observed	immobility and mortality	
Others		

II. RESULTS AND DISCUSSION:

A. Mortality: The pattern of mortality in this study did not facilitate the calculation of an LD_{50} value. The percent mortality (5%) in both solvent and negative controls was equal to the mortality at the highest treatment concentration of 100 µg/bee.

B. Other effects: One bee in the negative control group was observed to have a loss of equilibrium on day 0 of the test, while one bee in the solvent control group was immobile on day 0. All surviving bees in the control groups appeared normal.

C. Toxicity: XDE-570 was classified as relatively nontoxic to honey bees according to the toxicity categories of Atkins et al. (1981).

Table 3: Effect of XDE-570 on cumulative mortality of honey bees.

Treatment (µg a.i./bee)	No of bees	Observation period							
		Hour 0.5		Hour 1.5		Hour 24		Hour 48	
		Dead	% Dead	Dead	%Dead	Dead	%Dead	Dead	%Dead
Negative control	100	0	0	2	2	5	5	5	5
Positive control	100	0	0	2	2	3	3	4	4
6.3	100	0	0	0	0	0	0	1	1
12.5	100	0	0	0	0	0	0	0	0
25.0	100	1	1	1	1	2	2	2	2
50.0	100	2	2	4	4	4	4	4	4
100.0	100	0	0	1	1	5	5	5	5
NOEC	48 hour: 100 µg a.i./bee								
LC_{50}	48 hour: > 100 µg a.i./bee								

IV. Study deficiencies: The dosing solutions were not analyzed to verify concentration, homogeneity or stability of the test substance in the carrier. Although these are potentially major deficiencies, it is the opinion of the reviewer that in this particular case they may be considered to be minor, since the test material is a herbicide and was non-toxic to earthworms in previous studies.

V. References:

Atkins, E.L., Kellum, D. and Atkins, K.W. 1981. Reducing Pesticide Hazards to Honey Bees: Mortality Prediction Techniques and Integrated Management Strategies. University of California Division of Agricultural Sciences. Leaflet 2883, 22 pp.

Template author: *R. Gangaraju*
Template dated: *September 4, 1998*

Template name: *bee-cont.wpd*

Study review filename: *X:\EDO\CRO\OECD\Review Exchange\MISC REVIEWS\Florasulam for EPA by DOW Request\Environment\9.2.4.1 florasulam bee contact.wpd*