DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.3150 ['82-1b] (non-rodent); Subchronic Oral Toxicity in Dogs

Work Assignment No. 4-01-128 D (MRID 46808223)

Prepared for
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Office of Pesticide Programs
U.S. Environmental Protection Agency
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Disclaimer

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XDE-570 (FLORASULAM)/129108

OPPTS 870.3150/ DACO 4.3/ OECD 409

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DATA EVALUATION RECORD - SUPPLEMENT

See TXR # 0054348 for previous DER

This supplement contains:
- New cover page
- New executive summary


PC CODE: 129108
TXR#: 0054348

TEST MATERIAL (PURITY): XDE-570 (Florasulam; 99.3% a.i.; Lot # 940714)

SYNONYMS: XR-570, XRD-570, DE-570, N-(2,6-difluorophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulfonamide


SPONSOR: Dow AgroSciences Canada, Inc., 2100- 450 1 St. SW, Calgary, AB, Canada

EXECUTIVE SUMMARY - In a 90-day oral toxicity study (MRID 46808223), XDE-570 (Florasulam; 99.3% a.i.; Lot # 940714) was administered to 4 Beagle dogs/sex/dose ad libitum in the diet at dose levels of 0, 5, 50, or 100 mg/kg/day (time-weighted average test substance intake was 0/0, 6/6, 56/55, and 104/94 mg/kg/day [M/F]) for 13 weeks.

There were no compound-related effects on mortality, clinical signs, body weight, body weight gain, food consumption, ophthalmoscopy, hematology, urinalysis, or gross pathology observed at any dose.

The target organ appeared to be the liver. At 100 mg/kg, the following effects were noted: (i) alkaline phosphatase activity was increased (p<0.05) by 213-451% in both sexes on Days 45 and 91; (ii) increased incidence of very slight to slight hepatic vacuolation (4/4 treated vs. 3/4 control males and 3/4 treated vs. 1/4 control females); and (iii) increased (p<0.05) absolute (incr. 22-29%) and relative (to body; incr. 26-27%) liver weight in both sexes.
At 50 mg/kg, alkaline phosphatase activity was only increased (p<0.05) by 59-112% in the males and 91-127% in the females on Days 45 and 91, and there was a slight increase in incidence of hepatic vacuolation (3/4 treated [very slight to slight severity] vs. 1/4 control [moderate severity] females).

The LOAEL is 100 mg/kg/day, based on increased alkaline phosphatase activity, increased absolute and relative liver weights, and increased incidence/severity of hepatic vacuolation in both sexes. The NOAEL is 50 mg/kg/day.

This study is classified as acceptable/guideline and satisfies the guideline requirement for Test Guideline OPPTS 870.3150; OECD 409 for a 90-day oral toxicity study in the dog.

**COMPLIANCE** - Signed and dated Data Confidentiality, GLP Compliance, and Quality Assurance statements were provided.

**Note to EPA reviewer:** The LOAEL has been changed from 50 mg/kg/day to 100 mg/kg/day, because the effects at 50 mg/kg/day were very minor.