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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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Disclaimer

This Data Evaluation Record my have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel

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See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: Subchronic Oral Toxicity [feeding] – [Dog]; OPPTS 870.3150 ['82-1b] (non-rodent); OECD 409.

PC CODE: 129108 **DP BARCODE:** D331116
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

CITATION: Stebbins, K.E. (1995) Amended report for XDE-570: Thirteen-week dietary toxicity study in Beagles. The Toxicology Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company, Midland, MI. Laboratory Project Study ID: DR-0312-6565-021, September 13, 1995 (Amended date: November 20, 1997). MRID 46808223. Unpublished.

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.