DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.3700a [§83-3a]; Prenatal Developmental Toxicity Study in Rats

Work Assignment No. 4-1-128 K (MRID 46808234)

Prepared for
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See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: Prenatal Developmental Toxicity Study - Rats; OPPTS 870.3700a [§83-3a]; OECD 414

PC CODE: 129108 **DP BARCODE:** D331116
TXR#: 0054348

TEST MATERIAL (PURITY): XDE-570 (99.3% a.i.)

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

CITATION: Liberacki, A. B., Carney, E. W., and R. J. Kociba (1997) XDE-570: oral gavage teratology study in CD rats. The Toxicology Research Laboratories, The Dow Chemical Company, Midland, MI. Laboratory Project Study ID: DR-0312-6565-027, June 12, 1997. MRID 46808234. Unpublished.

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

EXECUTIVE SUMMARY: In a developmental toxicity study (MRID 46808234), XDE-570 (Florasulam; 99.3% a.i.; Lot No. 940714) in aqueous 0.5% methylcellulose was administered daily via oral gavage to 25-27 time-mated CD (Sprague Dawley) rats/group at a dose volume of 4 mL/kg at dose levels of 0, 50, 250, or 750 mg/kg/day from gestation day (GD) 6-15. On GD 21, all surviving does were killed and a limited necropsy was performed. The kidneys and uterus were removed and weighed, and the fetuses were delivered by cesarean section.

No adverse treatment-related effects were observed on mortality, clinical signs, or gross pathology.

Four 750 mg/kg/day dams died on study. One female was found dead on GD 9; one female was killed for humane reasons on GD 10; and two females were found dead on GD 13. These animals did not display clinical signs of toxicity prior to death. In three of the dams, necropsy revealed dark or firm lungs, with gavage error noted as the probable cause of death.

At 750 mg/kg/day, body weights were decreased (p<=0.05) by 4-6% during GD 6-19, resulting in decreased (p<=0.05) body weight gains during treatment (GD 6-16; decr. 16%). Food consumption was also decreased (not statistically analyzed) by 6-13% during the treatment period. Additionally at this dose, absolute and relative (to body weight) kidney weights were increased (p<=0.05) by 8 and 12%, respectively.

The maternal LOAEL is 750 mg/kg/day, based on decreased body weights, body weight gains, and food consumption, and increased kidney weights. The maternal NOAEL is 250 mg/kg/day.

There were no effects of treatment on the numbers of implantations, live or dead fetuses, litters, or resorptions, or post-implantation loss.

There were no treatment-related external, visceral, or skeletal malformations.

At 750 mg/kg/day, a slight decrease (p<=0.05) was observed in fetal body weight (decr. 4%), accompanied by delayed ossification (not significant) of the skull, ribs, and sternebrae. However, these findings were considered to be a result of the decreased maternal weights in this dose group.

The developmental LOAEL was not observed. The developmental NOAEL is 750 mg/kg/day.

This study is classified **acceptable/ guideline** and satisfies the guideline requirements (OPPTS 870.3700a; OECD 414) for a developmental toxicity study in rats.

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