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DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: Non-guideline; Preliminary Developmental Toxicity Study in Rabbits

Work Assignment No. 4-1-128 I (MRID 46808232)

Prepared for
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U.S. Environmental Protection Agency
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 XDE-570 (FLORASULAM)/129108 Non-guideline

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DATA EVALUATION RECORD – SUPPLEMENT

See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: Preliminary Prenatal Developmental Toxicity Study - Rabbits; Non-guideline

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: Zablonty, C. L., and E. W. Carney (1997) XDE-570: oral gavage teratology probe study in New Zealand White rabbits. The Toxicology Research Laboratories, The Dow Chemical Company, Midland, MI. Laboratory Project Study ID: DR-0312-6565-023, 960014; August 12, 1997. MRID 46808232. Unpublished.

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

EXECUTIVE SUMMARY: In a preliminary developmental toxicity study (MRID 46808232), XDE-570 (Florasulam; 99.3% a.i.; Lot No. 940714) in aqueous 0.5% methylcellulose was administered daily via oral gavage to seven naturally mated New Zealand White rabbits/group at a dose volume of 4 mL/kg at dose levels of 0, 100, 300, 600, or 1000 mg/kg/day from gestation day (GD) 7-19. On GD 20, all surviving does were killed and necropsied. The liver and kidneys were removed and weighed, and a detailed examination of the uterus and ovaries was performed.

One 600 mg/kg/day doe died on GD 19, and one 1000 mg/kg/day doe died on each of GDs 10, 13, 17. These animals all exhibited decreased fecal output, body weight loss, and markedly lower food consumption. At necropsy, findings of congested, edematous lungs, decreased ingesta in the digestive tract, a gastric hairball, slight hemorrhage in the vaginal wall, and a distended bladder were noted. Due to increased mortality (43%), the remaining does from the 1000 mg/kg/day group were killed for humane reasons on GD 17, and no further data were collected from this group.

No treatment-related effects were observed on organ weights or gross pathological examinations of animals that survived to scheduled termination.

At 600 mg/kg/day, body weight gains were decreased (not significantly [NS]) during treatment (GD 7-19) by 16%, due to body weight loss during GD 7-10 (-33.1 g vs. 53.1g in controls) and decreased (NS) body weight gains during GD 13-16 (decr. 56%). Food consumption was decreased (NS) during GD 10-19 (decr. 7-36%).

The maternal LOAEL is 600 mg/kg/day, based on mortality and decreased body weight gains and food consumption. The maternal NOAEL is 300 mg/kg/day.

No treatment-related effects were observed on the numbers of implantations or resorptions, or litter size at up to 600 mg/kg/day. Cesarean section data were not reported for the 1000 mg/kg/day group. Fetuses were not examined in any dose group.

The developmental LOAEL and NOAEL were not determined.

This study is classified as an **acceptable/non-guideline** range-finding developmental toxicity study in rabbits.

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