DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.3100 [§82-1a]; Subchronic (90-day) Oral Toxicity Study in Mice

Work Assignment No. 4-1-128 C (MRID 46808222)

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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Template version 02/06

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See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: 90-Day Oral Toxicity [feeding]-[mice]; OPPTS 870.3100 [' 82-1a] (rodent); OECD 408.

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

TEST MATERIAL (PURITY): XDE-570 (Florasulam; 99.2% a.i.)

SYNONYMS: *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: Redmond, J. M., and K. A. Johnson. (1996) XDE-570: 13-week dietary toxicity in B6C3F1 mice. The Toxicology Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company, Midland, MI. Laboratory Project Study ID: DR-0312-6565-010, January 30, 1996. MRID 46808222. Unpublished.

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

EXECUTIVE SUMMARY: In a subchronic oral toxicity study (MRID 46808222), XDE-570 (Florasulam; 99.2% a.i.; Lot No. 930910) was administered in the diet to ten B6C3F1 mice/sex/dose at dose levels of 0, 20, 100, 500, or 1000 mg/kg/day (time-weighted intake was 0/0, 22/20, 110/101, 549/503, and 1125/1007 mg/kg/day [males/females]) for 13 weeks.

No adverse treatment-related effects were observed on mortality, clinical signs, body weights, body weight gains, food consumption, food efficiency, ophthalmoscopic examination, hematology, clinical chemistry, organ weights, or gross or microscopic pathology.

The LOAEL was not observed. The NOAEL is 1000 mg/kg/day (limit dose).

This study is classified as **acceptable/guideline** and satisfies the guideline requirements (OPPTS 870.3100; OECD 408) for a subchronic oral toxicity study in mice.

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

Note to EPA Reviewer: The LOAEL in the PMRA DER was set at 500 mg/kg/day, based on a microscopic pathological finding (very slight hypertrophy of the epithelial cells) in the kidney of the males. It is the opinion of the Dynamac reviewers that this single uncorroborated finding was insufficient to warrant setting the LOAEL at this dose, or at the high dose (1000 mg/kg/day, finding in both sexes).