

DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.3200 [§82-2]; Repeated-dose Dermal Toxicity Study in Rats

Work Assignment No. 4-01-128 E (MRID 46808225)

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Disclaimer

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

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OPPTS 870.3200/ DACO 4.3.5/ OECD 410

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See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: 28-Day Dermal Toxicity - Rats; OPPTS 870.3200 [' 82-2] (rodent); OECD 410.**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:** Scortichini, B.H. and R.J. Kociba (1997) XDE-570: 28-Day repeated dose dermal toxicity study in Fischer 344 rats. The Toxicology Research Laboratory, Health and Environmental Sciences, The Dow Chemical Company, Midland, MI. Laboratory Project Study ID: 971042, July 15, 1997. MRID 46808225. Unpublished.**SPONSOR:** Dow AgroSciences Canada, Inc., 2100- 450 1 St. SW, Calgary, AB, Canada**EXECUTIVE SUMMARY** - In a repeated-dose dermal toxicity study (MRID 46808225), XDE-570 (Florasulam; 99.3% a.i.; Lot # 940714) in aqueous 0.5% Methocel was applied to the shaved skin of 5 Fischer 344 rats/sex/dose at dose levels of 0, 100, 500, or 1000 mg/kg/day, 6 hours/day for 7 days/week during a 28-day period.

No compound related effects in mortality, clinical signs, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, organ weights, and gross or microscopic pathology parameters were observed in either sex.

At 1000 mg/kg/day, very slight (grade 1) edema and erythema at the treatment site were noted in 4/5 males beginning on Day 23. Dermal irritation was resolved by Day 28.

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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 requirement for Test Guideline OPPTS 870.3200; OECD 410 for a 28-day dermal toxicity study in rats.

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