US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.5395 [§84-2]; Micronucleus Assay in Mice

Work Assignment No. 4-01-128 Q (MRID 46808239)

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

XDE-570 (FLORASULAM)/129108	OPPTS 870.5395/ DACO 4.5.7 / OECD 474	
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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: *In Vivo* Mammalian Cytogenetics - Erythrocyte Micronucleus Assay in Mice; OPPTS 870.5395 ['84-2]; OECD 474.

<u>PC CODE</u>: 129108 <u>DP BARCODE</u>: D331116

TXR#: 0054348

TEST MATERIAL (PURITY): XDE-570 (Florasulam; 99.2% a.i.; Lot # 930910)

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

CITATION: Lick, S.J., B.B. Gollapudi, and B.E. Kropscott (1995) Evaluation of XDE-570 in the mouse bone marrow micronucleus assay. Health and Environmental Sciences, The Toxicology Research Laboratory, Midland, MI. Laboratory Project Study ID: DR-0312-6565-013, March 10, 1995. MRID 46808239. Unpublished.

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

EXECUTIVE SUMMARY - In a bone marrow micronucleus assay (MRID 46808239), young adult CD-1 mice (5/sex/dose/harvest time) were treated once via gavage (20 mL/kg) with XDE-570 (Florasulam; 99.2% a.i.; Lot # 930910) in corn oil at doses of 0, 1250, 2500, or 5000 mg/kg. Bone marrow cells were harvested at 24, 48, and 72 hours after dosing. Cyclophosphamide (120 mg/kg) served as the positive control.

No treatment-related clinical signs of toxicity were observed during the study. At 5000 mg/kg, two females died on Day 2; however, the cause of death and association with the test substance was not established. Both the MPCE frequency and the PCE:NCE ratio were comparable between vehicle controls and all treated groups at all sampling times in both sexes. Although there were no clinical signs and no apparent effect on marrow toxicity, dosing was considered to be adequate as XDE-570 was tested up to more than twice the limit dose of 2000 mg/kg. The positive control induced the appropriate response. There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time.

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This study is classified as **acceptable/guideline** and satisfies the guideline requirement for Test Guideline OPPTS 870.5395; OECD 474 for *in vivo* cytogenetic mutagenicity data.

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