DATA EVALUATION RECORD - SUPPLEMENT

XDE-570 (FLORASULAM)

Study Type: OPPTS 870.5375 [§84-2]; *In Vitro* Chromosomal Aberration Assay in Rat Lymphocytes

Work Assignment No. 4-01-128 O (MRID 46808237)

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See TXR # 0054348 for previous DER

This supplement contains:

- New cover page
- New executive summary

STUDY TYPE: *In vitro* Mammalian Cytogenetics (Chromosomal Aberration Assay in Rat Lymphocytes) OPPTS 870.5375 [§84-2]; OECD 473.

PC CODE: 129108 **DP BARCODE:** 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: Linscombe, V.A., D.W. Okowitt, and B.E. Kropscott (1995) Evaluation of XDE-570 in an *In Vitro* chromosome aberration assay utilizing rat lymphocytes. Health and Environmental Sciences, The Toxicology Research Laboratory, Midland, MI. Laboratory Project Study ID: DR-0312-6565-007, January 23, 1995. MRID 46808237. Unpublished.

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

EXECUTIVE SUMMARY - In two independent trials of a mammalian cell cytogenetics assay (chromosome aberration; MRID 46808237), primary rat lymphocyte cultures were exposed to XDE-570 (Florasulam; 99.2% a.i.; Lot # 930910) in dimethylsulfoxide (DMSO) for 4 hours in the presence of S9 and 24 hours in the absence of S9 at concentrations of 0, 3, 10, 30, 100, 300, 1000, or 3000 µg/mL (Trial 1, +/-S9); 0, 30, 100, or 300 µg/mL (Trial 2, –S9); and 0, 300, 1000, or 3000 µg/mL (Trial 2, +S9). Cells were harvested at 24 hours after initiation of treatment in Trial 1 and at 24 and 48 hours after initiation of treatment in Trial 2. The S9 fraction was derived from the livers of male Sprague-Dawley rats induced with Aroclor 1254. The positive controls were mitomycin C (-S9) and cyclophosphamide (+S9).

It was stated that XDE-570 was tested up to the limit of solubility (3000 µg/mL). Based on the observed cytotoxicity (as indicated by reduced mitotic index), cultures at concentrations of 30, 100, and 300 µg/mL (-S9, both trials, 24 hours); 300, 1000, and 3000 µg/mL (+S9, both trials, 24 hours); 300 µg/mL (-S9, Trial 2; 48 hours); and 3000 µg/mL (+S9, Trial 2, 48 hours) were selected for evaluation of chromosomal aberrations. No relevant increases in the number of metaphases with aberrations (excluding gaps) were observed at any concentration at the 24 or 48 hour harvest time in either the presence or absence of S9. The positive controls induced the appropriate response in the presence and absence of S9. **There was no evidence of chromosome aberrations induced over background in the presence or absence of S9-activation.**

This study is classified as **acceptable/guideline** and satisfies the guideline requirement for Test Guideline OPPTS 870.5375; OECD 473 for *in vitro* mutagenicity (chromosome aberration) data.

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