EPA Reviewer: Meta Bonner **Signature**: _____
RAB3, Health Effects Division (7509C) **Date**_____
EPA Secondary Reviewer: Steve Dapson **Signature**: _____
RAB3, Health Effects Division (7509C) **Date**_____

Template version 11/01

TXR#:0050232

Revised Executive Summary-
DATA EVALUATION RECORD
See TXR# 012328 for the original

STUDY TYPE: Prenatal Developmental Toxicity Study - Rat; OPPTS 870.3700a [§83-3a]; OECD 414.

PC CODE:128968 **DP BARCODE:** D284007
SUBMISSION NO.: S617981

TEST MATERIAL (PURITY): Fluroxypyr methylheptyl ester (MHE, 95.8% a.i.)

SYNONYMS: Fluroxypyr, ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl) oxy) acetic acid 1-methylheptyl ester

CITATION: Schroeder, R.E. (1994) A Developemtnal Toxicity Study in Rats with Fluroxypyr Methylheptyl Ester. Pharmaco LSR, Inc., Toxicology Services North America, NJ. Laboratory Project Study ID 93-4052, May 3, 1994. MRID 44094901. Unpublished.

SPONSOR: DowElanco

EXECUTIVE SUMMARY:

In a developmental toxicity study (MRID 44094901) [Fluroxypyr methylheptyl ester (95.8% a.i., batch/lot # Dec 03 93B)] was administered to 28 Spraque-Dawley CD rats/dose by gavage administered in Mazola corn oil at dose levels of 0, 100, 300 or 600 mg/kg bw/day from days 6 through 15 of gestation.

Treatment at the high dose (600 mg/kg/day) resulted in 8 deaths [following 4, 6, 7, 7, 8, 8, 10, 10 days of dosing] and decreased body weight gain [77% of control] and food consumption during the dosing period. There were no treatment-related effects on gross pathologic alterations. Comparable pregnancy rates were observed among groups, and there were no abortions, premature deliveries, or dams with 100% intrauterine deaths [except one mid-dose dam]. Fetal body weights and sex ratio were comparable among the groups, and there were no external malformations, visceral malformations or variations, or skeletal malformations that could be attributed to treatment. **The maternal LOAEL is 600 mg/kg bw/day, based on increased material**

deaths, decreased body weight gains and food consumption. The maternal NOAEL is 300 mg/kg bw/day.

The test material did not induce any fetal toxicity. **The developmental LOAEL is not established. The developmental NOAEL is 600 mg/kg bw/day (HDT).**

The developmental toxicity study in the rabbit is classified acceptable/guideline and satisfies the guideline requirement for a developmental toxicity study (OPPTS 870.3700; OECD 414) in rats.

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