

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUN 2 1994

011020

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fenoxycarb - Correction of Error in the Reevaluation of Toxicology Data Endpoints as a Result of the RfD/Peer Review Meeting held on 2/24/94

Tox. Chem. No.: 652C  
PC No.: 125301  
DP No.: NA  
Submission No.: NA

FROM: Marion P. Copley, D.V.M., Section Head  
Review Section IV, Toxicology Branch I  
Health Evaluation Division (7509C)

*Marion Copley*  
5/27/94

TO: Marion Johnson/Richard Mountford, PM #10  
Herbicide-Fungicide Branch  
Registration Division (7505C)

and

George Ghali  
Science Analysis Branch  
Health Evaluation Division (7509C)

THRU: Karl Baetcke, Ph.D., Chief  
Toxicology Branch I  
Health Evaluation Division (7509C)

*Karl Baetcke*  
5/31/94

The discussion of the rat developmental study (83-3a) in HED Doc. # 010870 was in error. It inadvertently was written as a repeat of the chronic dog comments. The corrected discussion and executive summary for the developmental rat study follow:

83-3a Developmental Study - Rat, MRID #00131346 (Original DER is in HED Doc # 004178).

The HED RfD/Peer Review Committee (RfDC) determined that the NOEL of 150 mg/kg/day for developmental toxicity should be 500 mg/kg/day since the effects observed at 500 mg/kg/day were not marked enough to be considered treatment related. This was concluded following a reevaluation of the incidence of resorptions in the original study. Although resorptions were statistically increased at the high dose, one litter

cc: William Greear, TB1



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

was responsible for half of them (see table 1 extracted from table 1, part 2 of the study report). The conclusions stated in this reevaluation of the study supersede those of the original DER.

TABLE 1 Number of resorptions, total (litters effected)

DOSE (mg/kg)	0	50	150	500
resorptions	18(8)	17	14	31(10) <sup>1</sup>

<sup>1</sup> 1 litter had 14 resorptions

EXECUTIVE SUMMARY - In a developmental (teratology) study,

20 Fu-Albino rats per dose group received 0, 50, 150 or 500 mg Fenoxycarb/kg/day by gavage from gestation days 7 through 16, inclusive. Each female was mated with one randomly selected male.

Maternal toxicity was not observed at any dose. The LEL for Maternal Toxicity is therefore greater than 500 mg/kg/day and the NOEL for maternal toxicity equal to or greater than 500 mg/kg/day.

Developmental toxicity was not observed at any dose. The LEL for Developmental Toxicity is therefore greater than 500 mg/kg/day and the NOEL for developmental toxicity equal to or greater than 500 mg/kg.

The study is classified as Core-Minimum Data even though there is no overt maternal toxicity at the highest dose tested (due to the high doses selected) and satisfies the requirement (Guideline 83-3a) for a developmental toxicity (teratology) study in rats.

FENOXYCARB\RFDUPDATE.2