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DICLORAN

Developmental Study (§83-3[b])

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Registration Action Branch 1/HED (7509C)

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DATA EVALUATION RECORD- SUPPLEMENTAL
See TXR NO. 002624 for Original DER

NOTE:

This study was previously reviewed and classified as Core Minimum. However, the format for the executive summary and the first page of the DER were different from the current format. This is to update the format and, at the same time, to add needed data to the DER for the ease of evaluating this study.

STUDY TYPE: Somers Test in Rabbits (A Special Study)
OPPTS Number: 870.3700

OPP Guideline Number: §83-3b

DP BARCODE: D241078
PC CODE 031301
MRID NO: 00080869,

SUBMISSION NO.: S541375
TOX. CHEM. NO.: 311

TEST MATERIAL (PURITY): Dicloran (Unspecified)

COMPOSITION/SYNONYM(S): 2,6-dichloro-4-nitroaniline; DCNA; Botran™

CITATION: Wazeter, F. X., Buller, R. H., and Geil, R. G. (1966). Somers Test in the Albino Rabbit: (unpublished study received March 31, 1966 under 6F0474; prepared by International Research and Development Corp., Report No. 100-037). The Upjohn Company. MRID Number 00080869 Unpublished.

SPONSOR: The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In a modified developmental toxicity study (MRID 00080869), dicloran (unspecified purity, Lot#: 13,964) in a diet was administered to pregnant New Zealand white rabbits (10/dose) at dose levels of 0, 100, or 1,000 ppm (0, 3, 30 mg/kg/day) on gestation days (GDs) 8 through 16. Pregnant females were allowed to deliver naturally. Two rabbits in the high dose group and one rabbit from the control group died during the study. Pathological examination indicate enteritis and diarrhea as the cause of death of the control rabbit; and pneumonia and mastitis as the cause of death of the two high dose rabbits.

No adverse treatment-related changes in behavior and appearance, food consumption and body

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weights were observed. With respect to parental females, no adverse effects were observed relative to fertility, fetal resorption, abortion or delivery of the pups. With respect to the pups, the number of live births, size of the litter, sex ratio, viability of the new born, 24 hour and 21 day survival, growth of the pups and pup weight at weaning were comparable between the control and treated groups. No teratologic changes were produced in offsprings by the feeding of dicloran to does during the gestation period. No other pathologic lesions attributable to the administration of dicloran were seen in parental females or offspring of the treated group.

The maternal Lowest Observed Adverse Effect Level (LOAEL) was not established. The maternal No Observed Adverse Effect Level (NOAEL) is 1000 ppm (equivalent to 30 mg/kg/day).

The developmental LOAEL was not established. The developmental NOAEL is 1000 ppm (equivalent to 30 mg/kg/day).

This developmental toxicity study is classified **Unacceptable/nonguideline (§83-3[b])**, and does not satisfy the guideline requirements for a developmental toxicity study in the rabbit. This study is a special study known as a Somers Test, which is not a classical test of teratogenicity or reproduction study. It measures maternal toxicity, reproductive parameters of mothers and limited developmental parameters. Number of animals used per dose is not sufficient. No individual animal data (maternal observations such as clinical signs, food consumption) nor fetal data were provided in the study report. In addition, the purity of the test material was not reported. This study **can not be upgraded** due to deficiencies mentioned above.

COMPLIANCE: Signed and dated GLP, Data Confidentiality, Quality Assurance and Flagging statements were not provided.