014663

DICLORAN

Reproduction Study (§83-4[a])

EPA Primary Reviewer: P. V. Shah, Ph.D.
Registration Action Branch 1/HED (7509C)

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3/22/01

DATA EVALUATION RECORD- SUPPLEMENTAL
See TXR N0. 002624 for Original DER

NOTE:
This study was previously reviewed and classified as Core Minimum Data. 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: Multigeneration Reproduction Study - Rat
OPPTS Number: 870.3800

OPP Guideline Number: §83-4a

DP BARCODE: D241078
P.C. CODE: 031301
MRID NO: 00102514, 0082269, 00082660, 00082673,

SUBMISSION CODE: S533857
TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Dicloran (Botran™ , purity not reported)

SYNONYMS: 2,6-dichloro-4-nitroaniline; DCNA; Botran™

CITATION: **NOTE:** MRID No.'s 0082269, 00082660 and 00102514 contains the same study results and MRID No. 00082673 contains the Interim report.

Lobdell, B. J., Johnston, C. D., and Cronin, M. T. I. (1965): U-2069: Effect on Reproductive Capacity through Three Generations in the Rat. Upjohn Co., Kalamazoo, MI, CDL:070503-AJ. MRID No. 00102514. Unpublished.

Lobdell, B. J., Johnston, C. D., and Cronin, M. T. I. (1965): U-2069: Effect on Reproductive Capacity through Three Generations in the Rat. Upjohn Co., Kalamazoo, MI, CDL:098141-A. MRID No. 00082269. Unpublished.

Lobdell, B. J., Johnston, C. D., and Cronin, M. T. I. (1965): U-2069: Effect on Reproductive Capacity through Three Generations in the Rat. Upjohn Co., Kalamazoo, MI, CDL:090471-M. MRID No. 00082660. Unpublished.

Johnston, C. D., and Lobdell, B. J., (1964): U-2069: Effect on Reproductive

(1)

Capacity through Three Generations in the Rat. Interim Report Upjohn Co., Kalamazoo, MI, CDL:090471-Z. MRID No. 00082673. Unpublished.

SPONSOR: Upjohn Co., Kalamazoo, MI.

EXECUTIVE SUMMARY: In a 3-generation reproduction study (MRID 00102514), dicloran technical (unknown purity, lot # 13964) was administered in the diet continuously to 3 generations of albino rats (20 rats/sex/dose) at dose levels of 0, and 100 ppm (equivalent to 0, and 5 mg/kg/day [M/F] in the P and F_1 animals). The P and F_1 animals were exposed to the test substance for approximately 75 days prior to mating.

The number of litters per group, total number of stillbirths, live births and the reproductive capabilities of the rats fed dicloran technical (U-2069) in the diet were comparable to those of the control rats.

Slight differences were observed with respect to stillbirth, percent of survival, and mean body weight at weaning. The difference did not indicate a compound dependence. The mean figures were comparable.

The Lowest Observed Adverse Level (LOAEL) for systemic parental toxicity was not established. No Observed Adverse Effect Level (NOAEL) is ≥100 ppm, HDT (5 mg/kg/day).

The LOAEL for systemic offspring toxicity was not established. NOAEL is ≥100 ppm, HDT (5 mg/kg/day).

The LOAEL for reproductive toxicity was not established. The reproductive NOAEL is ≥100 ppm, HDT (5 mg/kg/day).

The reproductive study is determined to be **unacceptable/guideline (§83-4[a])** and does not satisfy the guideline requirement for a multigenerational reproductive toxicity study in rats due to the lack of a systemic effects for parents and offspring. This study **can not be upgraded** due to numerous deficiencies (e.g. single dose, missing individual animal and litter data etc.) in the study report.

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

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