DICLORAN TECHNICAL

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

EPA Secondary Reviewer: William Dykstra, Ph.D.
Registration Action Branch 1/HED (7509C)

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

NOTE:
This study was previously reviewed and classified as 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: Acute Dermal Toxicity - Rat
OPPTS Number: 870.1200

DP BARCODE: D241078
PC CODE 031301
MRID NO: 00086894

OPP Guideline Number: §81-2
SUBMISSION NO.: S541375
TOX. CHEM. NO.: 311

TEST MATERIAL (PURITY): Dicloran Technical (96%)

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


SPONSOR: The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 00086894), five male and female New Zealand White rabbits were dermally exposed to dicloran technical (96.0% purity) at 2,000 mg/kg (limit dose) for 24 hours. The test substance was moistened with sterile physiological saline and applied to at least 10% of the body surface. The skin application site was abraded. Animals were observed for clinical signs of toxicity, skin irritation, and mortality for up to 14 days postdosing.

Dermal LD₉₀ Male and Female Rabbits = >2,000 mg/kg (observed)

Dicloran technical is classified as TOXICITY CATEGORY III based on the observed LD₉₀ values for both sexes.
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All animals survived the 14-day study. No treatment-related effects were observed on clinical signs of toxicity, dermal irritation or body weight gain.

This study is classified acceptable (§81-2) and satisfies the guideline requirement for an acute dermal study in the rabbit.

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