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DICLORAN TECHNICAL

Acute Dermal Toxicity Study (§81-2)

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3/15/01

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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

OPP Guideline Number: §81-2

DP BARCODE: D241078
PC CODE: 031301
MRID NO: 00086894

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

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

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

CITATION: Racznik, T. J. and Wood, D. R. (1980). Acute Dermal Toxicity Screen in New Zealand White Rabbits with Botran Technical (U-2069). Agricultural Research and Development Laboratories, The Upjohn Company, Kalamazoo, MI. Trial or Study Number 218-9610-1-TJR-79-466, Technical Report Number 218-9610-80-003, February 29, 1980. MRID Number 00086894. Unpublished.

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 LD₅₀ Male and Female Rabbits =>2,000 mg/kg (observed)

Dicloran technical is classified as **TOXICITY CATEGORY III** based on the observed LD₅₀ 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.