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DICLORAN TECHNICAL

Primary Dermal Irritation Study (§81-5)

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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 Guidelines. 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: Primary Dermal Irritation - Rabbit
OPPTS Number: 870.2500

OPP Guideline Number: §81-5

DP BARCODE: D241078
PC CODE 031301
MRID NO: 00086893,

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). Primary Dermal Irritation Study 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-79-465, Technical Report Number 218-9610-80-002, February 29, 1980. MRID Number 00086893. Unpublished.

SPONSOR: The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 00086893), 0.5 g of dicloran technical (96.0% a.i. Lot #: 12-05-9N) was dermally applied to 6 (3 male and 3 female) New Zealand white rabbits for 24 hours to two intact and two abraded sites. Dicloran was slightly moistened with sterile physiological saline. Animals were observed for dermal irritation for up to 14 days; irritation was scored by the Draize scale at 24 and 72 hours.

One animal had an application site (abraded) which showed signs erythema and edema at 24 hours posttreatment. However, the application site was normal 48 posttreatment. The Primary Skin Irritation Score (PIS) for the intact and abraded skin was 0 and 0.042, respectively. In this study, **dicloran technical is not a skin irritant**, and is classified as **TOXICITY CATEGORY**

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IV based on the degree of irritation.

This study is classified **acceptable/guideline (§81-5)** and does satisfy the requirements of the FIFRA Test Guideline for a primary dermal irritation study in the rabbit.

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