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DICLORAN TECHNICAL

Primary Eye Irritation Study (§81-4)

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

P. V. Shah
3/15/01

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

W. Dykstra
3/20/01

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 Eye Irritation - Rabbit
OPPTS Number: 870.2400

OPP Guideline Number: §81-4

DP BARCODE: D241078
PC CODE 031301
MRID NO: 00086892,

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

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

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

CITATION: Raczniak, T. J. and Wood, D. R. (1980). Primary Eye Irritation Evaluation 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-79-464, Technical Report Number 218-9610-80-001, February 29, 1980. MRID Number 00086892. Unpublished.

SPONSOR: The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 00086892), 0.1 g of dicloran technical (96.0% a.i. Lot #: 12-05-9N) was placed into the conjunctival sac of one eye (left eye) of 4 male and 5 female New Zealand white rabbits. The eye of 1 male and 1 female rabbit was washed with lukewarm sterile water 20-30 second after instillation. Animals were observed for ocular irritation for up to 14 days following instillation and irritation was evaluated using the guideline grades for ocular lesions at 24, 48 and 72 hours post instillation and at 4, 7, 10 and 14 days post instillation.

Ocular instillation of dicloran technical produced slight eye irritation consisting of injection of the conjunctival vasculature and edema of the nictating membrane. Irrigating of the treated eyes

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with sterile water reduced the injection of the conjunctival vasculature and duration of the conjunctival reaction. The Primary Eye Irritation Score (PIS) was 3.0 and 3.3 at 24 and 48 hours posttreatment, respectively. Ocular reactions were completely reversed by 7 days posttreatment. In this study, **dicloran technical is not an ocular irritant**, and is classified as **TOXICITY CATEGORY III** based on the degree of irritation.

This study is classified **acceptable/guideline (§81-4)** and does satisfy the requirements of the FIFRA Test Guideline for a primary eye irritation study in the rabbit.

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