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DICLORAN TECHNICAL

Dermal Sensitization Study (§81-6)

P.V. Shah 3/15/01

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3/20/01*

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: Dermal Sensitization - Guinea pig

OPPTS Number: 870.2600

OPP Guideline Number: §81-6

DP BARCODE: D241078

PC CODE: 031301

SUBMISSION NO.: S541375

MRID NO.: 00082721

TOX. CHEM. NO.: 311

TEST MATERIAL (PURITY): Dicloran Technical (Purity not specified)

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

CITATION: Johnson, R. L., and Schwikert, R. S. (1963) Letter sent to E. S. Feenstra dated Feb 21, 1963. U02069: 2, 6-dichloro-4-nitroaniline or Botran: Skin Sensitization in Guinea Pigs. Reference No. 5567-64-RLJ-106B. February 21, 1963. MRID Number 00082721. Unpublished.

SPONSOR: The Upjohn Company, Kalamazoo, MI.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 00082721) conducted with dicloran technical (purity not specified) 10 male guinea pigs were tested for sensitization. Dicloran suspension (0.1% in sodium chloride) was injected intracutaneously (0.1 mL suspension) every other day until a total of 10 had been made. First injection was of 0.05 mL. The challenge injection of 0.05 ml was applied 2 weeks after.

The average sensitization result of the challenge injections was higher than the average of the induction injections. Based on the results of this study, dicloran technical is a potential skin sensitizer.

This study is classified as **acceptable** (§81-6) and satisfies the guideline requirement for a dermal

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sensitization study in the guinea pig. This study **does not** meet the current guideline requirements, however, it is classified as acceptable/guideline study because the results of the study indicate that the test compound is a potential skin sensitizer. Therefore, the repeat test is not likely change the results and its Toxicity Category.