UNDATED

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Reregistration Branch I/HED (7509C)

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DATA EVALUATION REPORT

Note: This study is a discontinued study due to nutritional deficiency which led to an increase in mortality in the test animals. Therefore, a complete DER is not prepared for this study

Study Type: 90-Day dermal toxicity study in Micropigs®

Chemical: DEET (N, N-diethyl-m-toluamide) (98.3% purity)

Tox. Chem. 346 **DP Barcode**: D241775
MRID No. 44398601 **PC Code**: 080301

Sponsor: DEET Joint Venture/Chemical Specialties Manufacturers Association

Testing Facility: MPI Research (formerly International Research and Development Corp.)
500 N. Main
Mattawan, Michigan 49071

Citation: Goldenthal, E.I. (1997) Evaluation of DEET in a 90-day subchronic dermal toxicity study in Micropigs®: Discontinued study. MPI Research (formerly International Research and Development Corp.; Study No. 555-014. July 25, 1997. MRID No. 44398601. Unpublished.

Executive Summary: In a 90-day dermal toxicity study (MRID 44398601), groups of Micropigs®
(4/sex/dose) (approximately 2 months old) were dermally applied DEET (98.3%) at dose levels of 100, 300, and 1000 mg/kg/day. Each test animal received a dose volume of 1.0 ml/kg body weight, and the controls were treated in a similar manner except tap water was dermally applied. The application sites were not occluded, wiped, or washed after dosing. The highest dose, 1000 mg/kg, was the maximum level which could be applied without significant runoff. The test animals were treated 5 days/week for 13 weeks. The experimental design followed the EPA guidelines for a subchronic dermal toxicity study

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except the procedures for histology was not performed.

The test animals began to died on day 43, and by day 65, the death rates were 2/4,1/4, 1/4, and 1/4 for males and 1/4, 0/4, 0/4, and 2/4 for females in dose levels of 0, 100, 300, and 1000 mg/kg groups, respectively. The deaths were found to be due to vitamin E/selenium deficiency. The animals that died showed signs of decreased activity, trembling, and labored breathing during the week prior to death. When the survivors were supplemented with vitaminE/selenium, they survived to the end of the study.

The mean body weights, hematological and clinical chemistry parameters, and gross pathology of the DEET treated animals were comparable to those of the controls for the surviving animals. At the application sites of the test animals in all groups, the signs of dry skin, raised skin growth, and scrape were present. At the application sites of the DEET treated animals, erythema and scabbed lesions were also seen. Erythema was more severe in 1000 mg/kg group. The study was discontinued because of the increased death rates in both controls and treated groups. Histopathology was not conducted. However, the study provided useful information concerning the nutritional status of the Micropigs®. Subsequently, another 90-day dermal study was conducted successfully using similar dose levels and no systemic toxicity was seen at the highest dose level (1000 mg/kg/day) (MRID No. 41987401).

This study is an incomplete study and is classified as **unacceptable** for a 90-day dermal toxicity study (82-3).

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