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DATA EVALUATION RECORD

FENPYROXIMATE
(5% SC FORMULATION)

Study Type: §81-5, Primary Dermal Irritation

Work Assignment No. 2-01-56M (MRID 44781009)

Prepared for

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
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Prepared by

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Date: 2-11-00

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

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EPA Reviewer: Marion Copley
Registration Action Branch 1/HED (7509C)

EPA Work Assignment Manager: Marion Copley
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STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS Number: 870.2500 OPP Guideline Number: §81-5

DP BARCODE: D259079 SUBMISSION CODE: S564863
P.C. CODE: 129131 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): NNI-850 Flowable-R (5% fenpyroximate)

SYNONYMS: Fenpyroximate 5% SC Formulation

CITATION: Haynes, G. (1990) Fenpyroximate 5% SC: primary dermal irritation in rabbits. Toxicol Laboratories, Ltd., Herefordshire, England. Laboratory Report No. A/E 24652. May 1990. MRID 44781009. Unpublished.

SPONSOR: Nihon Nohyaku Company, Ltd., 2-5 Nihonbashi, 1-Chome, Chuo-ku, Tokyo 103, Japan.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44781009), six young adult New Zealand White female rabbits were dermally exposed to 0.5 mL of NNI-850 Flowable-R (5% fenpyroximate) for 4 hours. The test material was applied as received to a single intact 6.25-cm^2 site/animal. Animals were observed for dermal irritation for up to 7 days following patch removal, and irritation was scored by the Draize scale.

Very slight erythema was observed at 1/6 test sites 1 hour following patch removal. No other dermal irritation was observed during the 7-day study. In this study, **NNI-850 Flowable-R (5% fenpyroximate) is not a notable dermal irritant**, and is classified as **TOXICITY CATEGORY IV** for primary dermal irritation.

This study is classified **acceptable (§81-5)** and satisfies the guideline requirement for a primary dermal irritation study in the rabbit.

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

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I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: NNI-850 Flowable-R
   Description: White liquid
   Lot/Batch #: 900216
   Purity: 5% Fenpyroximate
   CAS #: Not provided

2. Vehicle and/or positive control: None employed

3. Test animals: Species: Albino rabbit
   Strain: New Zealand White
   Age: Approximately 10-12 weeks
   Weight: Approximately 2 kg (not further specified)
   Source: Ranch Rabbits, Crawley Down, Sussex, England
   Acclimation period: ≥5 Days
   Diet: SQC Standard Rabbit Pellets (Special Diets Services, Witham, Essex, England), ad libitum
   Water: Tap water, ad libitum
   Housing: Individually in grid-bottomed metal cages
   Environmental conditions:
   Temperature: 17-21 °C
   Humidity: 45-65%
   Air changes: Not specified
   Photoperiod: 12-hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: April 19-26, 1990

2. Animal assignment and treatment: Fur from the dorsal area of six young adult New Zealand White female rabbits was clipped 1 day prior to dermal administration with 0.5 mL of NNI-850 Flowable-R (5% fenpyroximate). The test material was applied as received to a single intact site per animal using a 6.25-cm^2 piece of surgical lint. The patches were held in place by wrapping the torso of each animal with Elastoplast elastic adhesive bandage. The coverings were removed 4 hours following application and residual test material was removed using warm water. Dermal irritation was observed at 1, 24, 48, and 72 hours and 7 days following patch removal. Erythema and edema were scored separately using the Draize scale.

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II. RESULTS AND DISCUSSION:

A. Clinical observations: Very slight erythema (score of 1) was observed at 1/6 test sites 1 hour following patch removal. No other dermal irritation was observed during the 7-day study. In this study, NNI-850 Flowable-R (5% fenpyroximate) is not a notable dermal irritant.

B. Deficiencies: There were no deficiencies that affected the validity of the study results.