MEMORANDUM:

SUBJECT: DIMILIN 2F; Delayed Contact Hypersensitivity Study in Guinea Pigs; [TOX CHEM. NO. 346A].

FROM: R. Bruce Jaeger, Section Head Review Section #1 Toxicology Branch/HED (TS-769)

TO: Paul Schroeder
PM Team #17 Insecticide/Rodenticide Branch Registration Division (TS-767)

Dimilin 2F tested positive in a guinea pig delayed contact hypersensitivity study (dated 8/28/87). The study is classified as CORE: Guideline. The detailed review is attached.
STUDY TITLE: Delayed Contact Hypersensitivity in the Guinea Pig with Dimilin 2F.

LABORATORY: Huntingdon Research Centre Ltd.
Huntingdon, Cambridgeshire PE18 6ES
United Kingdom

LABORATORY PROJECT I.D.: RG13890/PDR 454/SS

AUTHOR: S.R. Kynoch, B.I. Parcell

DATE of STUDY: August 28, 1977

SPONSOR: Duphar B.V.

TEST PROTOCOL: Magathor and Kligman Guinea Pig Maximization Test (1970)

TEST MATERIAL: DIMILIN 2F (2 lb/gal. formulation using 90% purity diflubenzuron); EPA Reg. No. 37100-ET

SPECIES: Hartley-Dunkin Albino Guinea Pigs

SEX: Females

NUMBER: Forty (40); 20 test/20 control animals

GLP: 40 CFR 160 GLPs were followed throughout with regard to animal husbandry, temperature, humidity control, housing conditions, storage of raw data, etc.

STUDY DESIGN: Animals were randomly divided among treated and control groups; tattooed and Individual body weights determined at the start and finish of the study. Animals had free access to tap water and Vitamin C enriched guinea pig diet. Daily cageside observations were conducted.

Preliminary investigations were conducted to identify the irritant concentration suitable for induction phase, and the non-irritant concentration suitable for the challenge phase. Positive control data were available on formalin as recent as 3/13 and 4/17/87 to verify the capability of the test method to detect a strong sensitizer.
A description of the test method is provided below from the Registrant's report (copied verbatim).
Diflubenzuron toxicology review

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Pages 4 through 7 are not included in this copy.

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Based on the preliminary results conducted on various concentrations the Sponsor selected the following concentrations of DIMILIN 2F for the hypersensitivity study:

**Induction Phase:**
- Intradermal injection: 1% v/v in water for irrigation
- Topical application: 50% v/v in distilled water

**Challenge Phase:**
- 1% and 0.5% v/v in distilled water

**RESULTS:** 12/20 treated guinea pigs elicited a positive reaction in comparison to the negative control animals. The remaining 8/20 g. pigs were comparable to the negative controls.

**CONCLUSION:** In accordance with the grading scale utilized for this test, 12/20 or 60% positive response classifies the DIMILIN 2F formulation as a Moderate (Grade III) sensitizer. Labeling for this product should reflect the precautionary labeling required for suspect human sensitizers.

**CORE:** Guideline