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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 4 1987

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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

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)

*RBJ 12/4/87*  
*file for 12/15/87*

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.

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**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.:** 861389D/PDR 454/SS

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

**DATE of STUDY:** August 28, 1977

**SPONSOR:** Duphar B.V.

**TEST PROTOCOL:** Magnusson and Kligman Guinea Pig Maximisation 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.

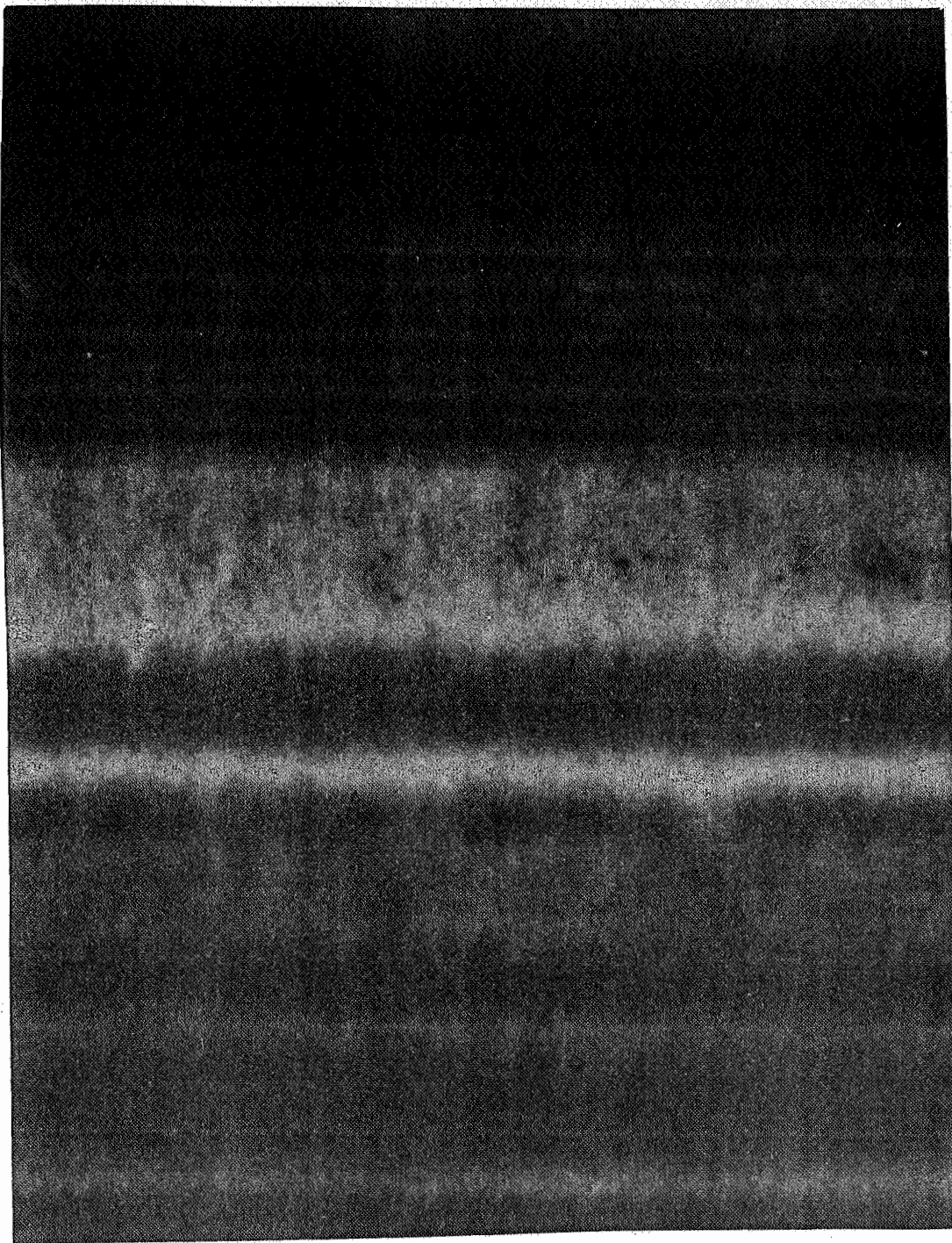
Preliminary investigations were conducted to identify the irritant concentration suitable for induction phase, and the non-irritant concentration suitable for the challenge phase. Positive control data were available on formalin as recent as 3/13 and 4/17/87 to verify the capability of the test method to detect a strong sensitizer.

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A description of the test method is provided below from the Registrant's report (copied verbatim).



FIFRA REGISTRATION DATA IS NOT INCLUDED

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Diflubenzuron toxicology review

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Pages 4 through 7 are not included in this copy.

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- Identity of product inert ingredients
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  - Description of the product manufacturing process
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  - Identity of the source of product ingredients
  - Sales or other commercial/financial information
  - A draft product label
  - The product confidential statement of formula
  - Information about a pending registration action
  - FIFRA registration data
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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 DIMILIIN 2F formulation as a Moderate (Grade III) sensitizer. Labeling for this product should reflect the precautionary labeling required for suspect human sensitizers.

CORE: Guideline

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