PB-1056
TXR-6489

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

DEC 4 1987

006489

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)

12/4/87

12/5/87

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.

006489

1 of 8

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 28,1987

SPONSOR: Duphar B.V.

TEST PROTOCOL: Magnusson and Kligman Guinea Pig Maxisation 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

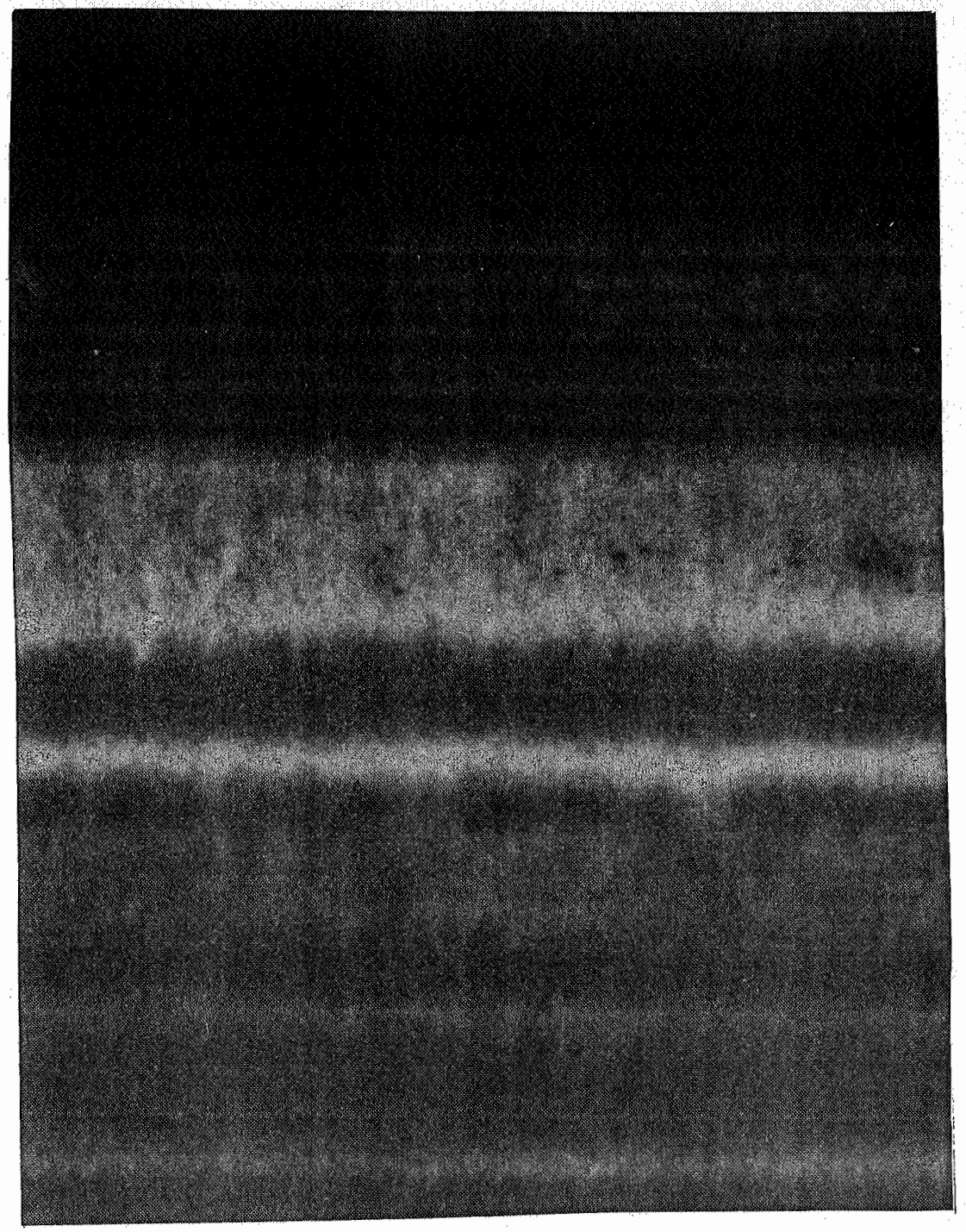
NUMBER: Forty (40); 20 test/20 control animals

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; tatooed 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

Page _____ is not included in this copy.

Pages 4 through 7 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ 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

X FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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