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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT--ETC(U)  
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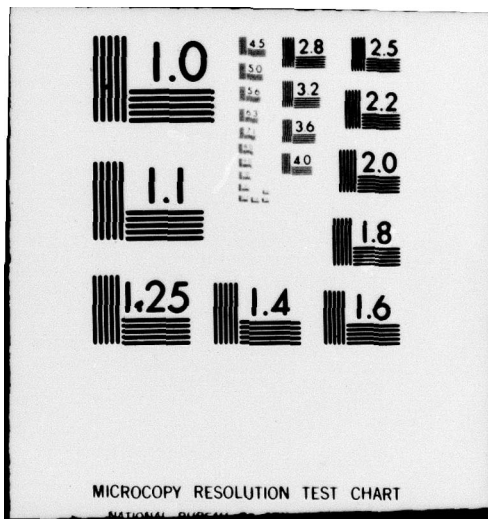
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**UNITED STATES ARMY  
ENVIRONMENTAL HYGIENE  
AGENCY**

**ABERDEEN PROVING GROUND, MD 21010**



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TOPICAL HAZARD EVALUATION PROGRAM  
OF CANDIDATE INSECT REPELLENT AI3-36437  
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND  
STUDY NUMBER 75-51-0895-79  
MAY 1976 - JUNE 1979

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A preliminary hazard evaluation of AI3-36437 was performed by means of laboratory studies using New Zealand White rabbits. The technical grade compound stained the skin of rabbits. This stain persisted at 7 days, and thus is considered unsuitable for use on human skin. K		



DEPARTMENT OF THE ARMY  
 U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY  
 ABERDEEN PROVING GROUND, MARYLAND 21010

CPT Singer/pj/AUTOVON  
 584-3980

HSE-LT-T/WP

12 SEP 1979

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent  
 AI3-36437, US Department of Agriculture Proprietary Compound, Study  
 No. 75-51-0895-79, May 1976 - June 1979

Executive Secretary  
 Armed Forces Pest Control Board  
 Forest Glen Section, WRAMC  
 Washington, DC 20012

A summary of the pertinent findings and recommendations of the inclosed report follows:

A preliminary hazard evaluation of AI3-36437 was performed by means of laboratory studies using New Zealand White rabbits. The technical grade compound stained the skin of rabbits. This stain persisted at 7 days, and thus is considered unsuitable for use on human skin. It is recommended that AI3-36437, US Department of Agriculture Proprietary Compound, not be approved for further testing as a candidate insect repellent. However, if this compound presents a significant improvement in pest repellent properties over existing compounds, it is suggested that it be purified with activated charcoal and resubmitted in its proposed use formulation and/or concentration.

FOR THE COMMANDER:

BRENDAN E. JOYCE, Ph.D.  
 LTC(P), MSC  
 Director, Laboratory Services

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CF:  
 HQDA (DASG-PSP)  
 Cdr, HSC (HSPA-P)  
 Supt, AHS (HSA-IPM)  
 Dir, Advisory Ctr on TOX, NRC  
 USDA, ARS - Southern Region  
 USDA, ARS (Dr. Terrence McGovern)

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TOPICAL HAZARD EVALUATION PROGRAM  
OF CANDIDATE INSECT REPELLENT AI3-36437  
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND  
STUDY NUMBER 75-51-0895-79  
MAY 1976 - JUNE 1979

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research Service, Southern Region, Insects Affecting Man Research Laboratory, Gainesville, Florida, 5 May 1976.

b. Memorandum of Understanding between the Department of the Army; Office of The Surgeon General; the US Army Health Services Command; the US Army Environmental Hygiene Agency; the Armed Forces Pest Control Board; and the US Department of Agriculture, effective 1970 with Amendment No. 1, effective August 1974.

2. REFERENCE. Toxicology Division Procedural Guide, USAEHA, 1972, revised 1976.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-36437.

4. SUMMARY OF FINDINGS. A hazard evaluation of the candidate insect repellent AI3-36437, US Department of Agriculture (USDA) Proprietary Compound, was conducted by this Agency using New Zealand White rabbits for a skin irritation study. A tabular presentation of animal toxicity data developed in this Agency follows:\*†

\* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education, and Welfare Publication No. (NIH) 74-23, revised 1972.

† The experiments reported herein were performed in animal facilities fully accredited by the American Association for Accreditation of Laboratory Animal Care.

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Study No. 75-51-0895-79, May 76 - Jun 79

Test	Results	Interpretation
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SKIN IRRITATION STUDIES

Rabbits

Single 24-hour application to intact and abraded skin of New Zealand White rabbits

Compound AI3-36437 stained the skin of all rabbits a yellow color which persisted longer than 7 days.

USAEHA Category V (ref Appendix)

0.5 ml of technical grade compound applied to each of six rabbits.

5. CONCLUSION. Technical grade compound AI3-36437 stained the skin of all rabbits tested and does not qualify as suitable for use on human skin. Apart from the staining, there did not appear to be any erythema or edema caused by AI3-36437.

6. RECOMMENDATION: Under the provisions of the Memorandum of Understanding (paragraph 1b), it is recommended that AI3-36437, USDA Proprietary Compound, not be approved for further testing as a candidate insect repellent. This is based strictly on the staining properties of AI3-36437. If this compound can be formulated for use in such a way so as to preclude this problem, it is suggested it be purified and resubmitted for acute testing.

*Allen W. Singer*

ALLEN W. SINGER  
CPT, VC  
General Veterinary Officer  
Toxicology Division

APPROVED:

*Arthur H. McCreesh*

ARTHUR H. MCCREESH, Ph.D.  
Chief, Toxicology Division

TOPICAL HAZARD EVALUATION PROGRAM  
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING  
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.