TOPICAL HAZARD EVALUATION PROGRAM
OF CANDIDATE INSECT REPELLENT A13-36437
US DEPARTMENT OF AGRICULTURE PROPRIETARY COMPOUND
STUDY NUMBER 75-51-0895-79
MAY 1976 - JUNE 1979

Approved for public release, distribution unlimited.
Final report, May 76 - Jun 79.

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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.

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

A preliminary hazard evaluation of A13-36437 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 A13-36437, 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:

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1. AUTHORITY.


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.


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.
SKIN IRRITATION STUDIES

Rabbits

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single 24-hour application to intact and abraded skin of New Zealand White rabbits</td>
<td>Compound A13-36437 stained the skin of all rabbits a yellow color which persisted longer than 7 days.</td>
<td>USAEHA Category V (ref Appendix)</td>
</tr>
<tr>
<td>0.5 ml of technical grade compound applied to each of six rabbits.</td>
<td></td>
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</tbody>
</table>

5. CONCLUSION. Technical grade compound A13-36437 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 A13-36437.

6. RECOMMENDATION: Under the provisions of the Memorandum of Understanding (paragraph 1b), it is recommended that A13-36437, USDA Proprietary Compound, not be approved for further testing as a candidate insect repellent. This is based strictly on the staining properties of A13-36437. 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.

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APPROVED:

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APPENDIX

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 prophylactic 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 prophylactic 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.