TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENTS AI3-3842 (U) ARMY ENVIRONMENTAL HYGIENE AGENCY ABERDEEN PROVING GROUND MD J V WADE JAN 83 USAEHA-75-51-0357-83
UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY
ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENTS
AI3-38421a, AI3-38422a, AI3-38423a, AI3-38424a, AI3-38420a,
AI3-38509a, AI3-38870a, AI3-38871a, AI3-38872a
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICALS
STUDY NOS. 75-51-0357-83 thru 75-51-0361-83,
75-51-0378-83, AND 75-51-0396-83 thru 75-51-0398-83
FEBRUARY 1982 - APRIL 1983

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<table>
<thead>
<tr>
<th>Key Word(s)</th>
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**20. ABSTRACT (Continue on reverse side IF necessary and identify by block number)**

Chemicals A13-38421a, A13-38422a, A13-38423a, A13-38424a, and A13-38420a produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, produced eschars at the site of application. Chemicals A13-38509a, A13-38870a, A13-38871a, and A13-38872a produced moderate primary irritation of the intact skin and the skin surrounding an abrasion.

Executive Secretary
Armed Forces Pest Management Board
Forest Glen Section, WRAMC
Washington, DC 20307

EXECUTIVE SUMMARY

The purpose, essential findings and recommendations of the inclosed report are as follows:

a. Purpose. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellents A13-38421a, A13-38422a, A13-38423a, A13-38424a, A13-38420a, A13-38509a, A13-38870a, A13-38871a, and A13-38872a by means of laboratory animal studies using New Zealand White rabbits.

b. Essential Findings. Chemicals A13-38421a, A13-38422a, A13-38423a, A13-38424a, and A13-38420a produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, produced eschars at the site of application. Chemicals A13-38509a, A13-38870a, A13-38871a, and A13-38872a produced moderate primary irritation of the intact skin and the skin surrounding an abrasion.

c. Major Recommendations. Recommend proprietary chemicals A13-38421a, A13-38422a, A13-38423a, A13-38424a, A13-38420a, A13-38509a, A13-38870a, A13-38871a, and A13-38872a be disapproved for further entomological testing.

FOR THE COMMANDER:

Joel C. Gaydos, M.D.
Colonel, MC
Director, Occupational and Environmental Health

1 Incl
as (5 cy)

CF:
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Dir, Advisory Cen on Tox, NRC
USDA, ARS (Dr. Terrence McGovern)
USDA, ARS-Southern Region (3 cy)
USDA, ARS-Southern Region (LTC Reinert)
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FEBRUARY 1982 - APRIL 1983

1. AUTHORITY.
   a. Letter, US Department of Agriculture - Agricultural Research, Southern
      Region, Insects Affecting Man and Animals Research Laboratory, Gainsville,
   b. Letter, US Department of Agriculture - Agricultural Research, Southern
      Region, Insects Affecting Man and Animals Research Laboratory, Gainsville,
      Florida, 29 April 1982.
   c. Letter, US Department of Agriculture - Agricultural Research, Southern
      Region, Insects Affecting Man and Animals Research Laboratory, Gainsville,
      Florida, 4 January 1983.
   d. Memorandum of Understanding between the US Army Environmental Hygiene
      Agency; the US Army Health Services Command; the Department of the Army,
      Office of the Surgeon General; the Armed Forces Pest Control Board; and the
      US Department of Agriculture, Agricultural Research, Science and Education
      Administrations; titled, Coordination of Biological and Toxicological Testing

2. REFERENCE. Toxicology Division Topical Hazard Evaluation Program

3. PURPOSE. The purpose of this program is to provide guidance for further
entomological testing of the candidate insect repellents A13-38421a,
A13-38422a, A13-38423a, A13-38424a, A13-38509a, A13-38870a,
A13-38871a, and A13-38872a, US Department of Agriculture (USDA) Proprietary
Chemicals.

4. SUMMARY OF FINDINGS. Hazard evaluation of the candidate repellents
A13-38421a, A13-38422a, A13-38423a, A13-38424a, A13-38509a, A13-38870a,
A13-38871a, and A13-38872a, USDA Proprietary Chemicals were
conducted by this Agency using New Zealand White rabbits for primary skin
irritation studies. 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) 80-23,
revised 1978.
† The studies reported herein were performed in animal facilities fully
accredited by the American Association for the Accreditation of Laboratory
Animal Care.

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TABLE. PRESENTATION OF DATA

Skin Irritation Studies

Rabbits

Single 24-hour application to intact and abraded skin of New Zealand White rabbits. 0.5 mL technical grade chemical applied to each of six rabbits.

Chemicals A13-38421a, A13-38422a, A13-38423a, and A13-38424a produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion, and additionally produced eschars. USAEHA Category IV

Chemicals A13-38509a, A13-38870a, A13-38871a, and A13-38872a produced moderate primary irritation of the intact skin and of the skin surrounding an abrasion. USAEHA Category III

5. CONCLUSION. Chemicals A13-38421a, A13-38422a, A13-38423a, A13-38424a, and A13-38420a produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, produced eschars. Chemicals A13-38509a, A13-38870a, A13-38871a, and A13-38872a produced moderate primary irritation of the intact skin and of the skin surrounding an abrasion. These studies were monitored by the Analytical Quality Assurance Office (see Appendix B).

6. RECOMMENDATION. Recommend proprietary chemicals A13-38421a, A13-38422a, A13-38423a, A13-38424a, A13-38420a, A13-38509a, A13-38870a, A13-38871a, and A13-38872a be disapproved for further entomological testing (under the provisions of the Memorandum of Understanding, para 1d, this report).

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CPT, VC
Laboratory Animal Veterinary Officer
Toxicology Division

APPROVED:

TIMOTHY B. WEYANDT, M.D., M.P.H
MAJ, MC
Acting 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.
Study Nos. 75-51-0357-83 thru 75-51-0361-83, 75-51-037R-83, 75-51-0396-83 thru 75-51-0398-83, Feb 82 - Apr 83

APPENDIX B

ANALYTICAL QUALITY ASSURANCE

The Analytical Quality Assurance Office certifies the following with regard to this study:

a. This study was conducted in accordance with:

(1) Standing Operating Procedures developed by the Toxicology Division, USAEHA.


b. Facilities were inspected during its operational phase to insure compliance with paragraph a above.

c. The information presented in this report accurately reflects the raw data generated during the course of conducting the study.

PAUL V. SNEERINGER, Ph.D.
Chief, Analytical Quality Assurance Office