UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY
ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENTS
A13-38305a, A13-38306a, A13-38313a, A13-38314a, and A13-38315a
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICALS
STUDY NOS. 75-51-0335-83, and 75-51-0339-83 thru 75-51-0342-83
JULY 1981 - APRIL 1983

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Chemical AI3-38305a was noninjurious to the skin of rabbits. Chemicals AI3-38306a, AI3-38313a, AI3-38314a, and AI3-38315a produced mild primary irritation of the intact skin and the skin surrounding an abrasion. Chemical AI3-38305a produced severe injury to the cornea and the conjunctiva. Chemicals AI3-38306a, AI3-38313a, AI3-38314a, and AI3-38315a produced moderate injury to the cornea and, in addition, produced some injury to the conjunctiva. 

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 A13-38305a, A13-38306a, A13-38313a, A13-38314a, and A13-38315a, by means of laboratory animal studies using New Zealand White rabbits.

b. Essential Findings. Chemical A13-38305a was noninjurious to the skin of rabbits. Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced mild primary irritation of the intact skin and the skin surrounding an abrasion. Chemical A13-38305a produced severe injury to the cornea and the conjunctiva. Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced moderate injury to the cornea and, in addition, produced some injury to the conjunctiva.

c. Major Recommendations. Recommend these chemicals be disapproved for further testing in their present form. If their insect repellent properties are distinctly superior to M-DET, based on a favorable response to skin irritation studies, recommend that these chemicals be purified and resubmitted.

FOR THE COMMANDER:

[Signature]

JOEL C. GAYDOS, M.D.
Colonel, MC
Director, Occupational and Environmental Health

CF:
HQDA (DASG-PSP) wo incl
Cdr, HSC (HSPA-P)
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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)
1. AUTHORITY.
   
   
   c. 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 of Pesticides, effective 23 January 1979.

2. REFERENCE. Toxicology Division Standing Operating Procedures, US Army Environmental Hygiene Agency (USAEM) 1981.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellents A13-38305a, A13-38306a, A13-38313a, A13-38314a, and A13-38315a, US Department of Agriculture (USDA) Proprietary Chemicals.

4. SUMMARY OF FINDINGS. Hazard evaluations of the candidate repellents A13-38305a, A13-38306a, A13-38313a, A13-38314a, and A13-38315a, USDA Proprietary Chemicals were conducted by this Agency using New Zealand White rabbits for skin and eye 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

TEST RESULTS INTERPRETATION

SKIN IRRITATION STUDIES

Rabbits

Single 24-hour application to intact and abraded skin of New Zealand White rabbits. Chemical A13-38305a, USAEHA Category I did not produce skin irritation. (ref Appendix A)

0.5 mL technical grade chemical applied to each of six rabbits. Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced mild primary irritation of the intact skin and of the skin surrounding an abrasion. USAEHA Category II (ref Appendix A)

EYE IRRITATION STUDIES

Rabbits

Single 24-hour application of 0.1 mL technical grade chemical to one eye of each of nine New Zealand White rabbits. Three of the nine rabbits had the eye flushed with warm water for 1 minute, 25 seconds after application. Chemical A13-38305a produced severe injury to the cornea and the conjunctiva. USAEHA Category F (ref Appendix A)

Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced moderate injury to the cornea and, in addition, produced some injury to the conjunctiva. USAEHA Category E (ref Appendix A)

5. CONCLUSION. The USDA Proprietary Chemical A13-38305a did not produce skin irritation. Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced mild primary irritation of the intact skin and of the skin surrounding an abrasion. Chemical A13-38305a produced severe injury to the cornea and the conjunctiva. Chemicals A13-38306a, A13-38313a, A13-38314a, and A13-38315a produced moderate injury to the cornea and, in
addition, produced some injury to the conjunctiva. These studies were monitored by Analytical Quality Assurance Officer (see Appendix B).

6. RECOMMENDATION. Recommend these chemicals be disapproved for further testing in their present form. If their insect repellent properties are distinctly superior to M-DET, based on a favorable response to skin irritation studies, recommend that these chemicals be purified and resubmitted (Memorandum of Understanding, paragraph 1c, this report).

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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.
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.

[Signature]

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