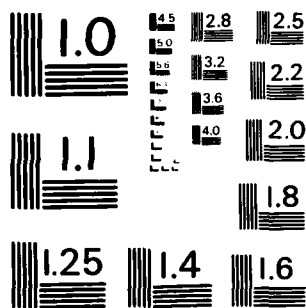


AD-A131 515 TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT 1 /
REPELLENTS A13-3830..(U) ARMY ENVIRONMENTAL HYGIENE
AGENCY ABERDEEN PROVING GROUND MD J V WADE 16 AUG 83
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**UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY**

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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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER 75-51-0335/0339-0342-83	2. GOVT ACCESSION NO. AD-A131515	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Topical Hazard Evaluation Program of Candidate Insect Repellents AI3-38305a, AI3-38306a, AI3-38313a, AI3-38314a, and AI3-38315, US Department of Agriculture Proprietary Chemicals, Study No 75-51-0335/0339-0342-83, July 1981 - April 1983		5. TYPE OF REPORT & PERIOD COVERED Final, July 1981 - April 1983
7. AUTHOR(s) John V. Wade, CPT, VC		6. PERFORMING ORG. REPORT NUMBER
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11. CONTROLLING OFFICE NAME AND ADDRESS Commander US Army Health Services Command Ft Sam Houston, TX 78234		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) 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.		

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REPLY TO
ATTENTION OF

HSMB-OT/WP

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

CPT Wade/orl/AUTOVON
584-3627

16 AUG 1983

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellents
A13-38305-a, 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.

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 A13-38305a, 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 A13-3815a 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:

1 Incl
as (5 cy)

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

CF:
HQDA (DASG-PSP) wo incl
Cdr, HSC (HSPA-P)
Comdt, AHS (HSHA-IPM)
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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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

REPLY TO
ATTENTION OF

HSHB-OT/WP

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

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research, Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 18 June 1981.

b. Letter, US Department of Agriculture - Agricultural Research Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 3 September 1981.

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 (USAEHA) 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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Study Nos. 75-51-0335-83 and 75-51-0339-83 thru 75-51-0342-83, Jul 81 - Apr 83

TABLE. PRESENTATION OF DATA

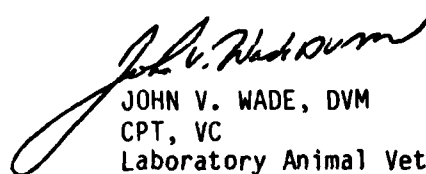
TEST	RESULTS	INTERPRETATION
<u>SKIN IRRITATION STUDIES</u>		
Rabbits		
Single 24-hour application to intact and abraded skin of New Zealand White rabbits.	Chemical A13-38305a, did not produce skin irritation.	USAEHA Category I (ref Appendix A)
0.5 mL technical grade chemical applied to each of six rabbits.	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)
<u>EYE IRRITATION STUDIES</u>		
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

Study Nos. 75-51-0335-83 and 75-51-0339-83 thru 75-51-0342-83, Jul 81 - Apr 83

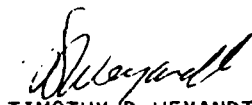
addition, produced some injury to the conjunctiva. These studies were monitored by Analytical Quality Assurance Officer (see Appendix B).

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).



JOHN V. WADE, DVM
CPT, VC
Laboratory Animal Veterinary Officer
Toxicology Division

APPROVED BY:



TIMOTHY B WEYANDT, M.D., M.P.H.
MAJ, MC
Acting Chief, Toxicology Division

APPENDIX A

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.

(2) Title 21, Code of Federal Regulations, 1981 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

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

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