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TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT  
REPELLENTS AI3-3842..(U) ARMY ENVIRONMENTAL HYGIENE  
AGENCY ABERDEEN PROVING GROUND MD J V WADE 24 FEB 84

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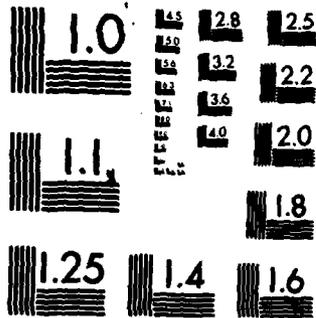
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**UNITED STATES ARMY  
ENVIRONMENTAL HYGIENE  
AGENCY**

**ABERDEEN PROVING GROUND, MD 21010**

TOPICAL HAZARD EVALUATION PROGRAM  
OF

CANDIDATE INSECT REPELLENTS  
AI3-38420b, AI3-38421b, AI3-38422b, AND AI3-38423b  
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICALS  
STUDY NOS. 75-51-0451-84 THRU 75-51-0454-84  
JUNE - OCTOBER 1983

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER 75-51-0451-84 thru 75-51-0454-84	2. GOVT ACCESSION NO. AD-A138 596	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Topical Hazard Evaluation Program of Candidate Insect Repellents AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b, US Department of Agriculture Proprietary Chemicals, Study No. 75-51-0451-84 thru 75-51-0454-84, June - October 1983		5. TYPE OF REPORT & PERIOD COVERED Final, June - October 1983
7. AUTHOR(s) John V. Wade, DVM, CPT(P), VC		6. PERFORMING ORG. REPORT NUMBER
9. PERFORMING ORGANIZATION NAME AND ADDRESS Commander US Army Environmental Hygiene Agency Aberdeen Proving Ground, MD 21010		8. CONTRACT OR GRANT NUMBER(s)
11. CONTROLLING OFFICE NAME AND ADDRESS Commander US Army Health Services Command Ft Sam Houston, TX 72834		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)		12. REPORT DATE June - October 1983
		13. NUMBER OF PAGES 6
		15. SECURITY CLASS. (of this report) Unclassified
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited.		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) AI3-38420b                      Topical Hazard Evaluation Program AI3-38421b                      USDA Proprietary Chemicals AI3-38422b AI3-38423b Skin Irritation		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Chemicals AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion. The response was characterized by ulceration, excoriation, acanthosis, and dermal thickening at the sites of application. ↑		



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U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY 584-3980  
ABERDEEN PROVING GROUND, MARYLAND 21010

REPLY TO  
ATTENTION OF

HSNB-OT/WP

24 FEB 1984

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellents  
AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b, US Department  
of Agriculture Proprietary Chemicals, Study Nos. 75-51-0451-84  
thru 75-51-0454-84, June - October 1983

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

EXECUTIVE SUMMARY

The purpose, essential findings and major recommendations of the inclosed report follow:

a. Purpose. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellents AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b by means of laboratory animal studies using New Zealand White rabbits.

b. Essential Findings. Chemicals AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion. The response was characterized by ulceration, excoriation, acanthosis, and dermal thickening at the sites of application.

c. Major Recommendations. Recommend proprietary chemicals AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b be disapproved for further entomological testing.

FOR THE COMMANDER:

1 Incl  
as (5 cy)

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HQDA (DASG-PSP) w/o Incl  
Cdr, HSC (HSPA-P)  
Comdt, AHS (HSHA-IPM)  
Dir, Advisory Cen on TOX, NRC (2 cy)  
USDA, ARS (Dr. Terrence McGovern)  
USDA, ARS-Southern Region (3 cy)  
Cdr, USAMRDC [SGRD-DPM/LTC(P) Reinert]



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  
AI3-38420b, AI3-38421b, AI3-38422b, AND AI3-38423b  
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICALS  
STUDY NOS. 75-51-0451-84 THRU 75-51-0454-84  
JUNE - OCTOBER 1983

1. AUTHORITY.

a. Letter, US Department of Agriculture, Agricultural Research Service, Northeastern Region, Beltsville Agricultural Research Center, Beltsville, Maryland, 10 June 1983.

b. 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 Topical Hazard Evaluation Program Procedural Guide, US Army Environmental Hygiene Agency (USAEHA), 1982.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellents AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b, US Department of Agriculture (USDA) Proprietary Chemicals.

4. SUMMARY OF FINDINGS. Hazard evaluation of the candidate insect repellents AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b, 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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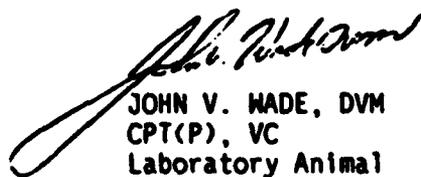
Study Nos. 75-51-0451-84 thru 75-51-0454-84, Jun-Oct 83

TABLE. PRESENTATION OF DATA

Test	Results	Interpretation
<u>Skin Irritation Studies</u>		
<u>Rabbits</u> 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 AI3-38420b, AI3-38421b, AI3-38422b and AI3-38423b produced moderate to severe primary irritation of the intact skin surrounding an abrasion. This response was characterized by ulceration, excoriation, acanthosis, and dermal thickening.	USAEHA Category IV (reference Appendix A)

5. CONCLUSION. Chemicals AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b produced moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion. This damage was apparent both grossly and microscopically at 7 days postapplication. These studies were monitored by the Analytical Quality Assurance Office (see Appendix B).

6. RECOMMENDATION. Recommend proprietary chemicals AI3-38420b, AI3-38421b, AI3-38422b, and AI3-38423b be disapproved for further entomological testing (under the provisions of the Memorandum of Understanding, paragraph 1b, this report).

  
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CPT(P), VC  
Laboratory Animal  
Veterinary Officer  
Toxicology Division

APPROVED:

  
MAURICE H. WEEKS  
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:

a. These studies were conducted in accordance with:

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

(2) Title 21, Code of Federal Regulations (CFR), 1983 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

(3) Proposed Rule, Pesticide Programs; Good Laboratory Practice Standards; Final Rule, 48 Federal Register (FR) 53946-539691, 29 November 1983.

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

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



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



The US Dept. of Agriculture Proprietary Chemical Study Numbers would not be known by anyone in the public domain who acquired this document. The document should remain for unlimited distribution per Capt. John V. Wade, AEHA

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