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UNITED STATES ARMY ENVIRONMENTAL HYGIENE AGENCY

ABERDEEN PROVING GROUND, MD 21010-5422

TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT AI3-70957-Ga US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL STUDY NO. 75-51-0517-85 AUGUST - SEPTEMBER 1984



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DEPARTMENT OF THE ARMY CPT RUSsell/slw/AUTOVON U.S. ARMY ENVIRONMENTAL HYGIENE AGENCY 584-3980 ABERDEEN PROVING GROUND, MARYLAND 210:0-5422

REPLY TO ATTENTION OF

HSHB-OT/WP

1 6 JAN 1985

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent AI3-70957-Ga, US Department of Agriculture Proprietary Chemical, Study No. 75-51-0517-85, August - September 1984

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 enclosed report follow:

a. <u>Purpose</u>. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70957-Ga by means of laboratory animal studies using New Zealand White rabbits.

b. <u>Essential Findings</u>. Subject chemical produced moderate to severe primary irritation of intact skin and skin surrounding an abrasion.

c. <u>Major Recommendation</u>. Recommend that chemical AI3-70957-Ga be disapproved for further testing as a candidate insect repellent as described in the Toxicology Division Topical Hazard Evaluation Program Procedural Guide (reference paragraph 2, this report).

FOR THE COMMANDER:

Encl

C. GAYDOS

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

CF: HQDA(DASG-PSP) (wo/encl Cdr, HSC (HSCL-P) (w/encl) Dir, Advisory Ctr on TOX, NRC (2 cy) (w/encl) Comdt, AHS (HSHA-IPM) (w/encl) USDA, ARS (Dr. Terrence McGovern) (w/encl) USDA, ARS-Southern Region (3 cy) (w/encl) Cdr, USAMRDC (SGRD-DPM/LTC Reinert) (wo/encl)

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1. AUTHORITY.

a. Letter, US Department of Agriculture – Agricultural Research Service, Southern Region, Insects Affecting Man and Animals Research Laboratory, Gainesville, Florida, 1 August 1984.

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), January 1982.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70957-Ga, US Department of Agriculture (USDA) Proprietary Chemical.

4. SUMMARY OF FINDINGS. Hazard evaluations of the candidate repellent AI3-70957-GA, USDA Proprietary Chemical were conducted by this Agency using New Zealand White rabbits for skin 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

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Single 24-hour application to intact and abraded skin of New Zealand White rabbits. Chemical AI3-70957-Ga produced moderate to severe primary skin irritation of the intact skin and of the skin surrounding an abrasion. USAEHA Category IV (ref Appendix A)

0.5 mL technical grade chemical applied to each of six rabbits.

5. CONCLUSION. Chemical AI3-70957-Ga produced moderate to severe primary irritation of intact skin and skin surrounding an abrasion. These studies were monitored by the Analytical Quality Assurance Office (see Appendix B).

6. RECOMMENDATION. Recommend that chemical AI3-70957-Ga be disapproved for further testing as a candidate insect repellent as described in the Toxicology Division Topical Hazard Evaluation Program Procedural Guide (reference paragraph 2, this report).

R. DAVID RUSSELL

CPT, VC Laboratory Animal Veterinary Officer Toxicology Division

APPROVED:

MAURICE H. WEEKS

Chief, Toxicology Division

Study No. 75-51-0517-85, Aug-Sep 85

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APPENDIX A

TOPICAL HAZARD EVALUATION PROGRAM DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING CONSIDERED FOR ACUTE SKIN APPLICATION

<u>CATEGORY I</u> - 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.)

<u>CATEGORY II</u> - 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.)

<u>CATEGORY III</u> - 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.)

<u>CATEGORY IV</u> - 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.)

<u>CATEGORY V</u> - 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.)

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Study No. 75-51-0517-85, Aug-Sep 85

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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) Final Rule, Pesticide Programs; Good Laboratory Practice Standards; 48 Federal Register (FR) 53946-53969, 29 November 1983.

(4) Final Rule, Toxic Substances Control; Good Laboratory Practice Standards; 48 Federal Register (FR) 53922-53944, 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

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