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TOPICAL HAZARD EVALUATION OF CANDIDATE INSECT REPELLENT AI3-365--ETC(U)
MAY 77 M H WEEKS, B J DESENA
USAEHA-51-0806-77

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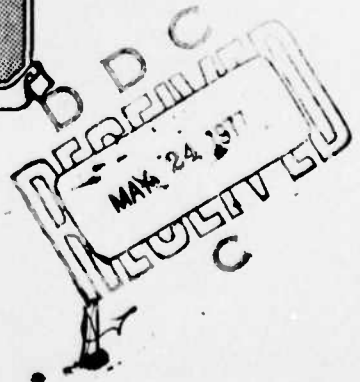
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TOPICAL HAZARD EVALUATION OF
CANDIDATE INSECT REPELLENT AI3-36581-aGa
USDA PROPRIETARY COMPOUND
STUDY NO. 51-0806-77
SEPTEMBER 1975 - OCTOBER 1976

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ABERDEEN PROVING GROUND, MD 21010

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A hazard evaluation of AI3-36581-aGa was conducted using New Zealand White rabbits for skin and eye studies, Hartley guinea pigs for a skin sensitization study and Sprague-Dawley, Wistar-derived rats for determination of acute oral toxicity. It is recommended that AI3-36581-aGa be approved for further testing as a candidate insect repellent. ↑ 038150 9/2			

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
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TOPICAL HAZARD EVALUATION OF
CANDIDATE INSECT REPELLENT AI3-36581-aGa
USDA PROPRIETARY COMPOUND
STUDY NO. 51-0806-77
SEPTEMBER 1975 - OCTOBER 1976

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research Service, Southern Region, Insects Affecting Man Research Laboratory, Gainesville, FL, 30 September 1975.

b. Memorandum of Understanding between the US Army Environmental Hygiene Agency; the US Army Health Services Command, the US Department of the Army, Office of The Surgeon General; the Armed Forces Pest Control Board; and the US Department of Agriculture, effective December 1970 with Amendment No. 1, effective August 1974.

2. REFERENCE. Toxicology Division Procedural Guide, USAEHA, 1972.

3. PURPOSE. The purpose of this study was to provide guidance for further entomological testing of the candidate insect repellent AI3-36581-aGa.

4. SUMMARY OF FINDINGS. A hazard evaluation of the candidate repellent AI3-36581-aGa (USDA Proprietary) was conducted by this Agency using New Zealand White rabbits for skin and eye studies, Hartley guinea pigs for a skin sensitization study and Sprague-Dawley, Wistar-derived rats for determination of oral toxicity. 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) 74-23, revised 1972 - second printing 1974. All experiments reported herein were performed in animal facilities, fully accredited by the American Association for Accreditation of Laboratory Animal Care.

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<u>TEST</u>	<u>RESULTS</u>	<u>INTERPRETATION</u>
<u>SKIN IRRITATION STUDIES</u> <u>Rabbits</u> Single 24-hr application to intact and abraded skin of New Zealand White rabbits. 0.5 ml technical grade compound applied to each of six rabbits.	Compound AI3-36581-aGa produced no primary irritation of the intact skin or the skin surrounding an abrasion.	USAHA Category I (reference Appendix)
<u>EYE IRRITATION STUDIES</u> <u>Rabbits</u> Single 24-hr application of 0.1 ml technical grade compound to one eye of each of six New Zealand White rabbits.	Compound AI3-36581-aGa produced very mild injury to the cornea in two of six rabbits and some slight irritation to the conjunctiva in five of six rabbits at 24 hr after application. Eyes appeared normal at 48 hr.	USAHA Category C (reference Appendix)
<u>APPROXIMATE LETHAL DOSE (ALD)</u> <u>Oral</u> Rats (male) - no diluent technical grade material.	ALD >2900 mg/kg	Presents little lethal hazard from acute accidental ingestion.
<u>SENSITIZATION STUDIES</u> <u>Guinea Pigs (Male)</u> Intradermal injections of 0.1 ml of a 0.1 percent solution (W/V) of AI3-36581-aGa or of an 0.1 percent suspension of dinitrochlorobenzene (DNCB)* in a mixture containing 1 volume of propylene glycol and 29 volumes of saline.		

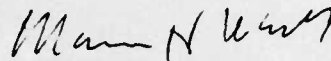
* A known skin sensitizer.

TEST	RESULTS	INTERPRETATION
Ten test guinea pigs received and challenged with an 0.1 percent solution of AI3-36581-aGa.	Challenge dose of test compound (last intradermal injection) produced no greater irritation reaction than that observed on the cage control animals.	Compound AI3-36581-aGa did not sensitize guinea pigs and is not expected to cause a sensitization reaction in humans.
Ten positive control guinea pigs received and challenged with an 0.1 percent suspension of DNCB.	Positive control (DNCB) produced a marked sensitization reaction in 10 out of 10 guinea pigs.	
Ten cage control guinea pigs.	Cage control guinea pigs showed no greater reaction to test compound and DNCB than were seen in original test group.	
Five received challenge dose of test compound without prior sensitizing doses.		
Five received challenge dose of DNCB without prior sensitizing doses.		
<u>PHOTOCHEMICAL SKIN IRRITATION STUDIES</u> <u>Rabbits</u>		
A single application (0.5 ml) of a 25-percent (W/V) solution of AI3-36581-aGa in 95 percent ethyl alcohol, a 10-percent (W/V) oil of Bergamot solution (positive control) in 95 percent ethyl alcohol and the diluent, 95 percent ethyl alcohol, were applied to the intact skin of six rabbits. Five minutes after application, the rabbits were exposed to UV light (365 nm) for 30 minutes at a distance of 10-15 cm.	AI3-36581-aGa did not cause a photochemical irritation reaction under test conditions.	Compound AI3-36581-aGa did not cause a photochemical irritation reaction under test conditions and is not expected to cause photochemical irritation reactions in humans.
<u>Control</u>		
Following UV exposure, 0.05 ml of the test compound, positive control and diluent were applied to additional skin areas of the rabbits.	Positive control application and irradiation caused greater irritant effects than in unirradiated areas.	

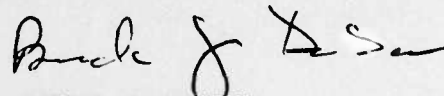
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5. CONCLUSIONS. The candidate insect repellent AI3-36581-aGa (USDA Proprietary) did not produce an irritant reaction in skin, eye, photochemical or sensitization tests and is not expected to be an acute topical toxic hazard when handled by humans.

6. RECOMMENDATION. Under the provisions of the Memorandum of Understanding (reference paragraph 1b), it is recommended that AI3-36581-aGa be approved for further testing as a candidate insect repellent.

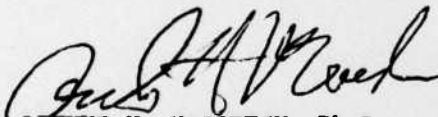


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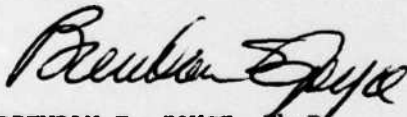


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APPENDIX

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

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, prior to human testing.

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.

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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.

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