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IRRITATION POTENTIAL OF COMPONENTS OF THE M-258A-1 DECONTAMINAT--ETC(U)
NOV 81 W W JEDERBERG, J T FRUIN

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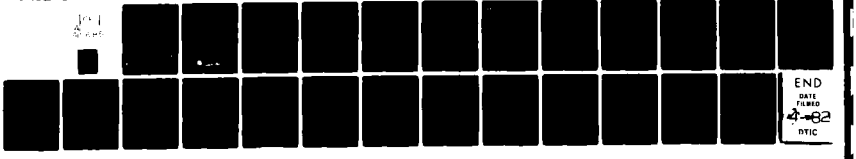


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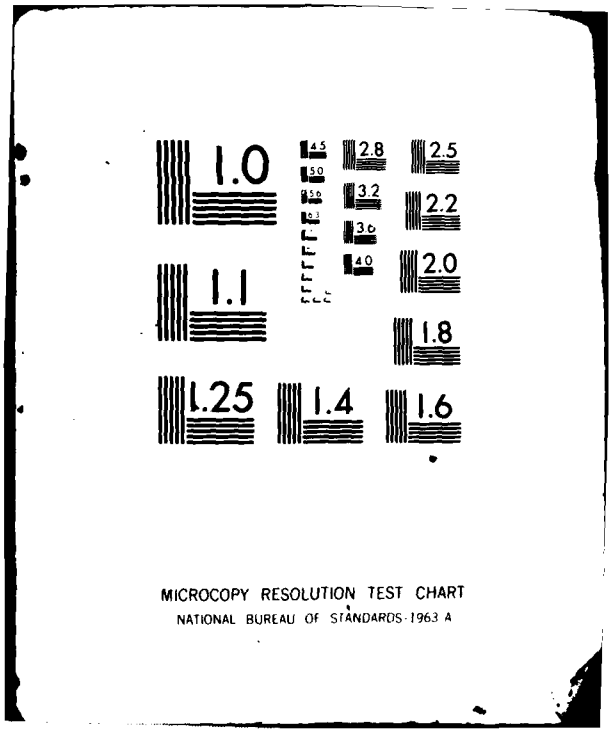
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John T. Fruin, DVM, PhD, LTC (P) VC

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M-258 Kit, Primary Dermal Irritation, Chemical Defense, Chemical Decontamination.

20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*:
The impact of rinsing on the primary dermal irritation caused by the components of the Prototype M-258A-1 Decontamination Kit was assessed by using a modified Draize test. The test called for applying the components as they are intended to be applied under field conditions. Approximately 0.03 to 0.1 g of test substance was applied per dose site. Immediately the sites were rinsed three times with saline. The rinsing reduced the primary dermal irritation caused by the solutions.

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TECHNICAL NOTE NO. 82-27TN

PRIMARY DERMAL IRRITATION POTENTIAL OF COMPONENTS OF THE M-258A-1 DECONTAMINATION KIT (Study 8)

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and
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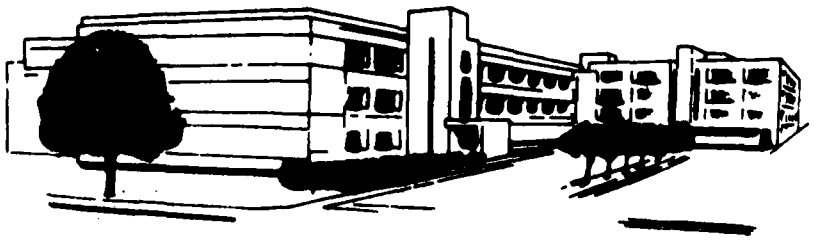
DIVISION OF CUTANEOUS HAZARDS
and
TOXICOLOGY GROUP,
DIVISION OF RESEARCH SUPPORT

NOVEMBER 1981

Toxicology Series 21

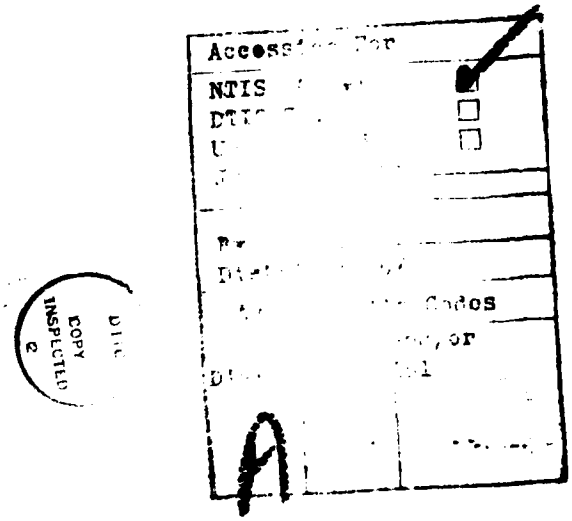


LETTERMAN ARMY INSTITUTE OF RESEARCH PRESIDIO OF SAN FRANCISCO CALIFORNIA 94129

Toxicology Series 21

In conducting the research described in this report, the investigation adhered to the "Guide for the Care and Use of Laboratory Animals," as promulgated by the Committee on Revision of the Guide for Laboratory Animal Facilities and Care, Institute of Laboratory Animal Resources, National Research Council.

20 Nov 81
(Signature and date)



PREFACE

Primary Dermal Irritation GLP Study Report

TESTING FACILITY: Letterman Army Institute of Research
Presidio of San Francisco, CA 94129

SPONSOR: Letterman Army Institute of Research
Presidio of San Francisco, CA 94129

PROJECT: Medical Defense Against Chemical Agents 3S162772.875

GLP STUDY NUMBER: 81026

STUDY DIRECTOR: LTC (P) John T. Fruin, DVM, PhD, VC, Diplomate of American College of Veterinary Preventive Medicine

PRINCIPAL INVESTIGATOR: CPT Warren W. Jederberg, MS, MS

RAW DATA: A copy of the final report, study protocol, raw data, and standard operating procedures will be retained in the LAIR Archives.

TEST SUBSTANCES:

A. Decon I, consisting of a pad pre-wetted with hydroxyethane (ethanol) 72 ± 2% phenol 10 ± 0.5%, sodium hydroxide 5 + 0.5%, ammonium hydroxide 0.2 ± 0.05% and water was used to wipe the back of rabbits for 1 minute.

B. Decon II, consisting of a pad impregnated with a quantity of crystalline chloramine B and an equal quantity of liquid contained in breakable glass ampoules covered with nylon mesh. The liquid containes hydroxyethane (ethanol) 45 ± 2%, zinc chloride 5±0.5% and water. Just prior to dosing, the ampoules were broken and thus the chloramine B impregnated pad was saturated with liquid. Decon II was used to wipe the backs of rabbits for 2-3 min.

C. Decon I and Decon II were used to wipe the same area of the back for 1 and 2-3 minutes, respectively.

D. Control (no treatment)

WORK UNIT: 302 Studies on Potential Dermal Irritation of M-258A-1 Kit

PURPOSE: The purpose of this study was to determine the effects of removing the chemicals used in the M-258A-1 Kits on abraded and intact skin of rabbits with saline damped pads (occluded and non-occluded).

ACKNOWLEDGMENTS

The authors wish to thank SSG Lance White; SP4 Thomas Kellner, BS; PFC Evelyn Zimmerman; Carolyn Lewis, MS; for assistance in performing the research, and for advice in scoring the irritation reactions. The authors also wish to thank M. Mershon, VMD; LTC (P) E. Houston, PhD, MS; LTC R. Howarth, VMD, VC, of the U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Grounds, MD, for providing prototype M-258A-1 Decontamination Kits and background information.

Signatures of Principal Scientists Involved
In The Study

We, the undersigned, believe the study, GLP Study number 81026, described in this report to be scientifically sound and the results and interpretation to be valid. The study was conducted to comply, to the best of our ability, with the Good Laboratory Practice Regulations for Nonclinical Laboratory Studies outlined by the Food and Drug Administration.

WARREN W. JEDERBERG, MS / DATE	JOHN T. FRUIN, DVM, PhD / DATE
CPT, MS	LTC (P), VC
Principal Investigator	Study Director

DEPARTMENT OF THE ARMY
LETTERMAN ARMY INSTITUTE OF RESEARCH
PRESIDIO OF SAN FRANCISCO, CALIFORNIA 94129

REPLY TO
ATTENTION OF:

SGRD-ULZ-QA

18 November 1981

MEMORANDUM FOR RECORD

SUBJECT: Report of GLP Compliance

I hereby certify that in relation to LAIR GLP study 81026 the following inspections were made:

1 Sep 81, 0830 Hrs
1 Sep 81, 0900 Hrs
2 Sep 81
4 Sep 81

Inspection findings were reported to the Study Director on 31 Aug 81. These inspections are also included in the Oct 81 report to management and the Study Director.

JOHN C. JOHNSON
CPT, MS
Quality Assurance Officer

PRIMARY DERMAL IRRITATION POTENTIAL OF COMPONENTS OF THE M-258A-1 DECONTAMINATION KIT (Study 8)

An evaluation of the Prototype M-258A-1 Decontamination Kit for primary dermal irritation potential by using the modified Draize test (1) was recently completed (2). That evaluation using the standard method to apply the test compound produced evidence of severe irritation potential. Further testing was determined to be necessary to determine the kit's irritation potential under conditions of proposed field usage.

Deviation from standards

Rather than applying liquid test substance on gauze, liquid impregnated pads from the M-258A-1 Decontamination Kit were cut into approximately one inch squares. Decon I squares were used to wipe the test area on the backs of rabbits for 1 minute. Decon II squares were used similarly, except the wiping was for 2 minutes. For Decon I plus Decon II the test site was first wiped for 1 minute with Decon I and then for 2 minutes with Decon II.

Immediately after applying the test compounds, the sites were washed with saline. This was done by scrubbing the application site five times with each of three surgical pads soaked in saline.

The test sites on one group of animals were occluded as per SOP-OP-STX-34. The other group was not occluded.

Chemical analyses were not conducted in an effort to conserve resources except for measuring the pH. Our intent was to evaluate the product; the data and reports were not intended for presentation to FDA. The pH of Decon I was 11.7, and Decon II was 6.8. Chemical composition was considered to be that printed on the outer container for the Prototype M-258A-1 Decontamination Kit (Table 1 and 2). The compound was assumed to be stable under conditions of storage and use. Compound purity was unknown.

TABLE 1 (3)

CHEMICAL ANALYSIS OF DECON I
(pH = 10.7 - 10.8)

Component	ETOH	H_2O	Phenol	NaOH	NH_4OH
%	72%±2%	q.s.	10±0.5%	5.0±0.5%	0.2±0.05%
Name	ethanol	water	phenol	sodium hydroxide	ammonium hydroxide
Molecular Structure	C_2H_6O	H_2O	C_6H_6O	NaOH	NH_4OH
Molecular Weight	46.07	18.016	94.12	40.01	35.036

TABLE 2 (3)

CHEMICAL ANALYSIS OF DECON II
(pH = 6.5 - 6.6)

	*LIQUID PORTION			*SOLID PORTION
Component	ETOH	H_2O	$ZnCl_2$	Chloramine B
%	45±2%	50±2.5%	5±0.5%	100%
Name	ethanol	water	zinc chloride	Chloramine B (N-Chlorobenzene-sulfamido-sodium)
Molecular Structure	C_2H_6O	H_2O	$ZnCl_2$	C_6H_5Cl $NNaO_2S$
Molecular Weight	46.07	18.016	136.29	213.64

* Equal quantities of liquid and solid are mixed to form Decon II.

Objective of Study

The objective of this study was to determine the primary dermal irritation, produced by the chemicals in the M-258A-1 Prototype Decontamination Kit, is reduced by immediate rinsing of the abraded and intact skin of rabbits. The study was designed to stimulate field conditions for using the M-258A-1 Decontamination Kit.

METHODS

Historical Listing of Study Events

28 Aug 81	Animals were weighed and sites for exposure were randomized.
28 Aug 81	Animals were close clipped and areas marked.
1 Sep 81	animals were weighed and dosed.
1-15 Sep 81	Animals were observed daily, only significant or abnormal observations were recorded.
2 Sep 81	Bandages removed. 24-hr post exposure score.
4 Sep 81	72-hr post exposure score.
8 Sep 81	7-day post exposure score, weight taken.
15 Sep 81	Animals were scored, (14 day after exposure) and weights taken. Animals were removed from study.

Animal Data

Animal: New Zealand White Rabbits

Sex: Female

Source: Elkhorn Rabbitry

Pre-test conditioning:

a. Some of the animals used were those that had been used previously in other tests and were free from all indications of dermal lesions. All animals had been rested for at least three weeks. The previous test compounds were candidate insect repellents and we do not believe there was any carry over effect.

Dosing Procedures

Method and frequency of administration were dictated by SOP-OP-STX-34. The backs of the animals were close clipped and divided into quardants designated I,II,III,and IV (SOP-OP-STX-34). Areas I and IV were intact on all animals, and areas II and III were abraded by making two perpendicular scratches in the stratum corneum of the skin about 1 1/2 inch long by using an escarifier. The four application sites were about 10 cm apart. A standard latin square table was used to randomize the test sites (SOP-OP-STX-34). The test substance impregnated pads were wiped over the test sites for 1,2 and 3 minutes (see deviation to standards). An Elizabethan collar was placed around each animal's neck to keep animals from self-mutilating the treatment site.

RESULTS

Scoring (SOP-OP-STX-34)

Six animals in each group were exposed to the chemicals. Animals were scored at 24 and 72 hours, 7 and 14 days for edema/erythema (Table 3). Tabular data appear in Appendix A and B. The data in Appendix A were recorded for rabbits on which exposure sites were occluded for 24 hours. No occlusion was made on the rabbits represented by the data in Appendix B. Abraded areas (sites II and III) and intact areas (sites I and IV) were graded separately as well as together. The scores obtained were used as a basis for categorization. Primary irritation potential values were calculated from 24 and 72 hour scores.

TABLE 3

EVALUATION OF SKIN REACTIONS (4)

Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate-to-severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injurious in depth)	4
Possible total erythema score	4*
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (edges raised aproximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Possible total edema score	4*
Possible total score for primary irritation	8

* Any skin reaction more serious than severe erythema, severe edema, vesiculation, ulceration, or necrosis places the chemical in Category IV.

Compounds producing combined averages (intact and abraded scores of 0.51 - 2 are considered mildly irritating (Category II), if the intact score is greater than 0.5, whereas those with indexes from 2 to 5 are moderate irritants (Category III). Category IV irritants are compounds producing moderate to severe primary irritation of intact skin surrounding an abrasion. In addition, these compounds produce necrosis, vesticulation, ulceration, eschars and a combination of these features. (Category assignment and interpretation, A.H. McCreesh, personal communication, 1980.) Tables 4 and 5 demonstrate the primary irritation indexes for the exposed areas.

TABLE 4

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT

AFTER RINSING THREE TIMES AND OCCLUDING FOR 24 HOURS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.17	0.50	0.33	I
Decon II	0.00	0.67	0.33	I
Decon I+II	0.00	0.50	0.25	I
Control	0.00	0.00	0.00	I

TABLE 5

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT

AFTER RINSING THREE TIMES AND NOT OCCLUDING

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.00	1.50	0.75	I
Decon II	0.00	0.50	0.25	I
Decon I+II	0.00	1.00	0.50	I
Control	0.00	0.17	0.08	I

DISCUSSION

In all instances the rinsing seemed adequate to prevent significant irritation.

CONCLUSIONS

Simple rinsing will reduce the primary dermal irritation caused by the components of the M-258A-1 Protype Decontamination Kit.

RECOMMENDATION

Recommendations will be made after the current series of studies is completed.

REFERENCES

1. DRAIZE, J., H.Z. WOODARD, and H.O. CALVERY. Method for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. J Pharmacol Exp Ther. 83:377-390, 1944

2. FRUIN, J.T. and M.A. HANES. The Primary Dermal Irritation Potential of Components of the M-258A-1 Decontamination Kit (Study 1). Institute Report No. 101 San Francisco, CA: Letterman Army Institute of Research, 1981

3. WINDHOLZ, M. (Editor). The Merck Index. Ninth Edition. Rahway, NJ: Merck and Co. 1976

4. McCREESH, A.H. and M. STEINBERG. Chapter 5, Skin Irritation Testing in Animals (In: Advances in Modern Toxicology. Volume 4 Derma-toxicology and Pharmacology. F.N. Marzulli and H.I. Maibach, eds). Washington, D.C.: Hemisphere Publishing Corp., 1977.

Summary of Primary Skin Irritation Test Data (Occluded)

APPENDIX A

APPENDIX A-1

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sept 81	Decon I	N/A	N/A	0.03-0.1 g	A

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites					Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100042	I	1	0	0	0					
F8100043						II	1	0	0	0
F8100051	IV	0	0	0	0					
F8100081						III	1	1	0	0
F8100089	I	0	0	0	0					
F8100094						III	0	0	0	0
Total:		a 1	b 0	a 0	b 0		a 2	b 1	a 0	b 0
		a+b 1		a+b 0			a+b 3		a+b 0	
		C^I + 1					C^A + 3			

Intact Score = C^I / 2xNo. of Sites on test 1/(2x3) = 0.17

Abraded Score = C^A / 2xNo. of Sites on test 3/(2x3) = 0.50

Total Score = $\frac{C^I+C^A}{2 \times \text{No. of Sites on test}}$ 4/(2x6) = 0.33

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-2

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Decon II	N/A	N/A	0.03-0.1 g	B

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100042						II	1	0	0	0
F8100043	I	0	0	0	0					
F8100051						III	1	0	0	0
F8100081	IV	0	0	0	0					
F8100089						II	1	1	0	0
F8100094	I	0	0	0	0					
Total:		a 0	b 0	a 0	b 0		a 3	b 1	a 0	b 0
		a+b 0		a+b 0			a+b 4		a+b 0	
		C^I 0					C^A 4			

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = C^A / 2xNo. of Sites on test 4/(2x3) = 0.67

Total Score = $\frac{C^I + C^A}{2 \times \text{No. of Sites on test}}$ 4/(2x6) = 0.33

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-3

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Decon I + II	N/A	N/A	0.03-0.1 g each I + II	C

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100042						III	1	0	0	0
F8100043	IV	0	0	0	0					
F8100051	I	0	0	0	0					
F8100081						II	1	1	0	0
F8100089						III	0	0	0	0
F8100094	IV	0	0	0	0					
Total:		a 0	b 0	a 0	b 0		a 2	b 1	a 0	b 0
		a+b 0		a+b 0			a+b 3		a+b 0	

C^I + = 0

C^A + = 3

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = C^A / 2xNo. of Sites on test 3/(2x3) = 0.50

Total Score = $\frac{C^I+C^A}{2 \times \text{No. of Sites on test}}$ 3/(2x6) = 0.25

Primary Skin Irritation Index Category I

Remarks: Occluded

APPENDIX A-4

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Control	N/A	N/A	None	D

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites					Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr		Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100042	IV	0	0	0	0						
F8100043							III	0	0	0	0
F8100051							II	0	0	0	0
F8100081	I	0	0	0	0						
F9100089	IV	0	0	0	0						
F8100094							II	0	0	0	0
Total:		a 0	b 0	a 0	b 0			a 0	b 0	a 0	b 0
		a+b 0		a+b 0				a+b 0		a+b 0	
				C^I + 0						C^A + 0	

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = $\frac{C^A}{C^I+C^A}$ / 2xNo. of Sites on test 0/(2x3) = 0.00

Total Score = $\frac{}{2 \times \text{No. of Sites on test}}$ 0/(2x6) = 0.00

Primary Skin Irritation Index Category I

Remarks: Occluded

Summary of Primary Skin Irritation Test Data (Non-occluded)

APPENDIX B

APPENDIX B-1

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026 | Chemical Name | Conc | Solvent | Amt Applied | Route

Date of Application 1 Sep 81 | Decon I | N/A | N/A | 0.03-0.1 g | A

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites					Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr		Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100048							II	1	1	1	1
F8100050	IV	0	0	0	0						
F8100052	I	0	0	0	0						
F8100078							II	1	1	0	0
F8100083							III	1	1	1	0
F8100093	IV	0	0	0	0						
Total:		a 0	b 0	a 0	b 0			a 3	b 3	a 2	b 1
		a+b 0		a+b 0				a+b 6		a+b 3	
				C^I 0	+					C^A 9	+

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = C^A / 2xNo. of Sites on test 9/(2x3) = 1.50

Total Score = $\frac{C^I+C^A}{2} \times$ No. of Sites on test 9/(2x6) = 0.75

Primary Skin Irritation Index Category I

Remarks: Non-Occluded

APPENDIX B-2

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Decon II	N/A	N/A	0.03-0.1 g	B

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites				Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100048	IV	0	0	0	0					
F8100050						III	0	0	0	0
F8100052						II	1	1	1	0
F8100078	I	0	0	0	0					
F8100083	IV	0	0	0	0					
F8100093						III	0	0	0	0
Total:		a 0	b 0	a 0	b 0		a 1	b 1	a 1	b 0
		a+b 0		a+b 0			a+b 2		a+b 1	
				C^I 0	+				C^A 3	+

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = $\frac{C^A}{C^I+C^A}$ / 2xNo. of Sites on test 3/(2x3) = 0.50

Total Score = $\frac{C^I+C^A}{2 \times}$ No. of Sites on test 3/(2x6) = 0.25

Primary Skin Irritation Index Category I

Remarks: Non-Occluded

APPENDIX B-3

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Decon I + II	N/A	N/A	0.03-0.1 g each I + II	C

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites					Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr		Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100048	I	0	0	0	0						
F8100050							II	1	1	0	1
F8100052							III	1	1	1	0
F8100078	IV	0	0	0	0						
F8100083	I	0	0	0	0						
F8100093							II	0	0	0	0
Total:		a 0	b 0	a 0	b 0			a 2	b 2	a 1	b 1
		a+b 0		a+b 0				a+b 4		a+b 2	
				C^I + 0				C^A + 6			

Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = C^A / 2xNo. of Sites on test 6/(2x3) = 1.00

Total Score = $\frac{C^I+C^A}{2 \times \text{No. of Sites on test}}$ 6/(2x6) = 0.50

Primary Skin Irritation Index Category I

Remarks: Non-Occluded

APPENDIX B-4

Summary of Primary Skin Irritation Test Data

GLP Study No. 81026	Chemical Name	Conc	Solvent	Amt Applied	Code
Date of Application 1 Sep 81	Control	N/A	N/A	None	D

Principal Investigator CPT Jederberg

Irritation Scores

		Intact Skin Sites					Abraded Skin Sites				
Rabbit No.	Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr		Site	Erythema 24 hr	Erythema 72 hr	Edema 24 hr	Edema 72 hr
F8100048							III	1	0	0	0
F8100050	I	0	0	0	0						
F8100052	IV	0	0	0	0						
F8100078							III	0	0	0	0
F8100083							II	0	0	0	0
F8100093	I	0	0	0	0						
Total:		a 0	b 0	a 0	b 0			a 1	b 0	a 0	b 0
		a+b 0		a+b 0				a+b 1		a+b 0	
		C^I 0						C^A 1			

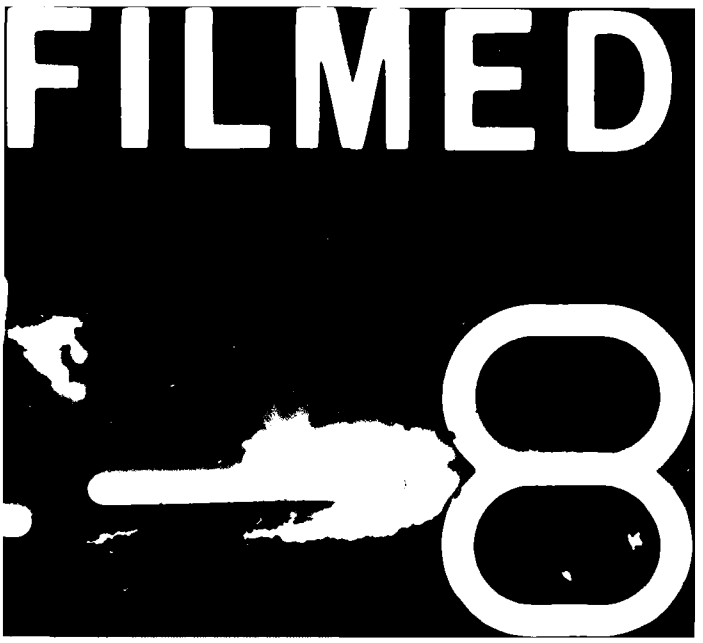
Intact Score = C^I / 2xNo. of Sites on test 0/(2x3) = 0.00

Abraded Score = C^A / 2xNo. of Sites on test 1/(2x3) = 0.17

Total Score = $\frac{C^I + C^A}{2 \times \text{No. of Sites on test}}$ 1/(2x6) = 0.08

Primary Skin Irritation Index Category I

Remarks Non-Occluded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