

Industria' BIO-TEST Laboratories, Inc.
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

4)
HLO 191-73
[REDACTED]

REPORT TO

E. I. du PONT de NEMOURS & COMPANY

SKIN SENSITIZATION TESTS WITH
FOUR SAMPLES
IN ALBINO GUINEA PIGS

[REDACTED]

APRIL 12, 1973

[REDACTED]

[REDACTED]

H-7857
H-7858
H-7859
H-7860

[REDACTED]

RECEIVED

APR 16 1973

HASKELL LAB.

Company Sanitized. Does not contain TSCA CBI

Industrial **BIO-TEST Laboratories, Inc.**

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

April 12, 1973

[REDACTED]
Chief, Oral Toxicology Section
E. I. duPont de Nemours & Company
Haskell Laboratory
Wilmington, Delaware 19898

Re: [REDACTED] - Skin Sensitization Tests with
Four Samples in Albino Guinea Pigs -
[REDACTED]

We are submitting herewith our laboratory report dated
April 12, 1973, prepared in connection with the above study.

Very truly yours,

J. C. Calandra

J. C. Calandra
President

JCC: sjn

Company Sanitized. Does not contain TSCA CB

REPORT TO

E. I. du PONT de NEMOURS & COMPANY

SKIN SENSITIZATION TESTS WITH
FOUR SAMPLES
IN ALBINO GUINEA PIGS

APRIL 12, 1973

I. Introduction

At the request of E. I. du Pont de Nemours & Company, a skin sensitization test was conducted with each of four samples. The samples were identified as:

- 1) [REDACTED] H-7857
- 2) [REDACTED] H-7858
- 3) [REDACTED] H-7859
- 4) [REDACTED] H-7860

Company Sanitized. Does not contain TSCA CBI

II. Summary

The results of the skin sensitization tests in albino guinea pigs are summarized below.

<u>Test Material</u>	<u>Results</u>
 H-7857	Not a Sensitizer
 H-7858	A Sensitizer
 H-7859	Not a Sensitizer
 H-7860	A Sensitizer

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

Beverley Kretchmar
Beverley Kretchmar
Technician
Acute Toxicity

Report approved by:

Carmen Mastri
Carmen Mastri, B.S.
Senior Group Leader
Acute Toxicity

M. L. Keplinger
M. L. Keplinger, Ph.D.
Manager, Toxicology

bc:psh

Company Sanitized. Does not contain TSCA CBI

III. Investigational Procedure

The same procedure was followed with each test material. Ten albino guinea pigs ranging in body weight from 300-400 grams were used as test animals. The test procedure was modeled after that of E. V. Buehler*.

Prior to the test, the irritation threshold was determined for the test material in the appropriate vehicle and the maximum non-irritating concentration was used for testing. The hair was clipped from the backs and flanks of the test animals, and closed patches were applied in the following manner: A Webril pad containing 0.5 ml of the test solution was applied near the midline of the shaved back of each animal. The Webril pad was occluded with a standard size Elastoplast coverlet (1-1/2 inch x 2 inches), and each animal was placed in a guinea pig restrainer for a six-hour exposure period. The animals were insulted in this manner nine times. Twenty-four and 48 hours after the initial insult and 24 hours after the remaining eight insults the application sites were graded for irritation.

* Buehler, E. V., "Delayed Contact Hypersensitivity in the Guinea Pig," Arch. Dermat. 91, February 1965.

Two weeks after the last exposure, all test animals and four control animals from the same population were challenged with duplicate patches. The application sites were scored for irritation 24 and 48 hours after challenge. Any reaction in the test group significantly greater than the maximum reaction produced after the initial insult or that produced in the control group was considered evidence of sensitization.

The scoring criteria for erythema and edema are presented in Table I.

TABLE I

Skin Sensitization Test - Albino Guinea Pigs

Scoring Criteria for Skin Reactions

Reaction	Description	Score
Erythema	Barely perceptible (Edges of area not defined)	1
	Pale red in color and area definable	2
	Definite red in color and area well defined	3
	Beet or crimson red in color	4
Edema	Barely perceptible (Edges of area not defined)	1
	Area definable but not raised more than 1 mm	2
	Area well defined and raised approximately 1 mm	3
	Area raised more than 1 mm	4
Injury in Depth	Escharosis, Necrosis	8
	Maximum Primary Skin Irritation Score =	8

Company Sanitized. Does not contain TSCA CBI

IV. Results

The results of the skin sensitization tests are presented in Tables

II - XIV.

Company Sanitized. Does not contain TSCA CBI

TABLE II

TEST MATERIAL: [REDACTED]; H-7857
 Skin Sensitization Test - Albino Guinea Pigs

Results - Range-Finding Group

Test Material Concentration	Animal Number	Scores Following Application					
		Site 1			Site 2		
		24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours
		Er.	Ed.	Er.	Ed.	Er.	Ed.
0.1% (w/v) Aqueous Solution	1	0	0	0	0	0	0
	2	0	0	0	0	0	0
1.0% (w/v) Aqueous Solution	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
10.0% (w/v) Aqueous Solution	5	0	0	0	0	1	0
	6	0	0	0	0	0	0

Key:

Er. = Erythema
 Ed. = Edema

TABLE III

TEST MATERIAL: 1.0% (w/v) Aqueous Solution of
[REDACTED] H-7857

Skin Sensitization Test - Albino Guinea Pigs

Results - Test Group

Animal Number	Scores Following				Scores Following Challenge Applications							
	Initial Application		Insult Site:		Virgin Site:		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	1	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	1	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0

Key:

Er. = Erythema

Ed. = Edema

TABLE IV

TEST MATERIAL: 1.0% (w/v) Aqueous Solution of
[REDACTED] H-7857

Skin Sensitization Test - Albino Guinea Pigs

Results - Control Group

Animal Number	Scores Following Challenge Application							
	Site 1				Site 2			
	24 Hours		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0

Key:

Er. = Erythema

Ed. = Edema

TABLE V

TEST MATERIAL: [REDACTED] H-7858

Skin Sensitization Test - Albino Guinea Pigs

Results - Range-Finding Group

Test Material Concentration	Animal Number	Scores Following Application					
		Site 1		Site 2			
		24 Hours	48 Hours	24 Hours	48 Hours	Er.	Ed.
0.1% (w/v) Aqueous Solution	1	0	0	0	0	0	0
	2	0	0	0	0	0	0
1.0% (w/v) Aqueous Solution	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
10.0% (w/v) Aqueous Solution	5	0	0	0	0	0	0
	6	0	0	0	0	0	0

Key:

Er. = Erythema
Ed. = Edema

TABLE VI

TEST MATERIAL: 10.0% (w/v) Aqueous Solution of
~~Penicillin~~ H-7858

Skin Sensitization Test - Albino Guinea Pigs

Results - Test Group

Animal Number	Scores Following Initial Application				Scores Following Challenge Applications							
	24 Hours		48 Hours		Insult Site:		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	0	0	0	0	0	0	1	0	0	0	0	0
2	0	0	0	0	0	0	1	0	0	0	0	0
3	0	0	0	0	0	0	1	0	0	0	1	0
4	0	0	0	0	0	0	1	0	0	0	1	0
5	0	0	0	0	0	0	2	0	1	0	1	0
6	0	0	0	0	0	0	1	0	0	0	0	0
7	0	0	0	0	0	0	2	0	0	0	0	0
8	0	0	0	0	0	0	1	0	1	0	1	0
9	0	0	0	0	0	0	1	0	0	0	0	0
10	1	0	0	0	0	0	2	0	1	0	1	0
							2	0	1	0	2	0

Key:

Er. = Erythema
 Ed. = Edema

TABLE VII

TEST MATERIAL: 10.0% (w/v) Aqueous Solution of
~~[REDACTED]~~ H-7858

Skin Sensitization Test - Albino Guinea Pigs

Results - Control Group

Animal Number	Scores Following Challenge Application							
	Site 1				Site 2			
	24 Hours		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0

Key:

Er. = Erythema

Ed. = Edema

Company Sanitized. Does not contain TSCA CBI

TABLE VIII

TEST MATERIAL: [REDACTED] H-7859

Skin Sensitization Test - Albino Guinea Pigs

Results - Range-Finding Group

Test Material Concentration	Animal Number	Scores Following Application					
		Site 1			Site 2		
		24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours
		Er.	Ed.	Er.	Ed.	Er.	Ed.
0.1% (w/v) Aqueous Solution	1	0	0	0	0	0	0
	2	0	0	0	0	0	0
1.0% (w/v) Aqueous Solution	3	0	0	1	0	0	1
	4	0	0	1	0	0	1
10.0% (w/v) Aqueous Solution	5	0	0	0	0	1	0
	6	1	0	1	0	1	1

Key:

Er. = Erythema
Ed. = Edema

Company Sanitized. Does not contain TSCA CBI

TABLE IX

TEST MATERIAL: 0.1% (w/v) Aqueous Solution of
[REDACTED] H-7859

Skin Sensitization Test - Albino Guinea Pigs

Results - Test Group

		Scores Following Insult No.											
		1		2		3		4		5		6	
Animal Number	24 Hours	48 Hours		24 Hours		24 Hours		24 Hours		24 Hours		24 Hours	
		Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	0	0	1	0	2	0	0	1	0	0	0	1	0
2	1	0	1	0	2	1	0	1	0	1	0	2	0
3	0	0	0	0	2	1	0	1	0	1	0	1	0
4	0	0	0	0	-	-	-	-	-	-	-	-	-
5	1	0	1	0	2	0	0	1	0	1	0	1	0
6	0	0	1	0	2	1	0	1	0	1	0	1	0
7	0	0	0	0	2	1	0	1	0	1	0	2	0
8	1	0	1	0	2	0	0	0	0	1	0	2	0
9	0	0	0	0	1	1	0	1	0	1	0	2	0
10	0	0	1	0	1	2	0	0	0	1	0	1	0

Key:

Er. = Erythema

Ed. = Edema

- = Animal died.

Note: Test material concentration was reduced to 0.01% prior to insult No. 4 and the insult site was changed due to increased irritation. The animals were insulted seven times rather than nine in order to minimize skin fatigue.

TABLE X

TEST MATERIAL: 0.01% (w/v) Aqueous Solution of
[REDACTED] H-7859

Skin Sensitization Test - Albino Guinea Pigs

Results - Test Group

Animal Number	Scores Following Challenge Application							
	Insult Site				Virgin Site			
	24 Hours		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	1	0	1	0	1	0	0	0
2	1	0	1	0	0	0	0	0
3	1	0	2	0	0	0	1	0
4	-	-	-	-	-	-	-	-
5	1	0	2	0	1	0	1	0
6	2	0	2	0	1	0	1	0
7	2	0	2	0	1	0	1	0
8	1	0	2	0	1	0	1	0
9	1	0	1	0	1	0	1	0
10	2	0	2	0	2	0	2	0

Key:

Er. = Erythema

Ed. = Edema

- = Animal Died.

TABLE XI

TEST MATERIAL: 0.01% (w/v) Aqueous Solution of
[REDACTED] H-7859

Skin Sensitization Test - Albino Guinea Pigs

Results - Control Group

Animal Number	Scores Following Challenge Application							
	Site 1				Site 2			
	24 Hours		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	1	0	1	0	1	0	1	0
2	2	0	2	0	1	0	1	0
3	1	0	1	0	1	0	1	0
4	1	0	1	0	1	0	0	0

Key:

Er. = Erythema

Ed. = Edema

Company Sanitized. Does not contain TSCA CBI

TABLE XII

TEST MATERIAL: [REDACTED] H-7860

Skin Sensitization Test - Albino Guinea Pigs

Results - Range-Finding Group

Test Material Concentration	Animal Number	Scores Following Application					
		Site 1			Site 2		
		24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours
		Er.	Ed.	Er.	Ed.	Er.	Ed.
0.1% (w/v) Aqueous Solution	1	0	0	0	0	0	0
	2	0	0	0	0	0	0
1.0% (w/v) Aqueous Solution	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
10.0% (w/v) Aqueous Solution	5	0	0	0	0	0	0
	6	0	0	0	0	0	0

Key:

Er. = Erythema

Ed. = Edema

TABLE XIII

TEST MATERIAL: 10.0% (w/v) Aqueous Solution of
~~Penicillin~~ H-7860

Skin Sensitization Test - Albino Guinea Pigs

Results - Test Group

Animal Number	Scores Following Initial Application			Scores Following Challenge Applications					
	24 Hours		48 Hours	Insult Site:		Virgin Site:			
	Er. Ed.		Er. Ed.	24 Hours	48 Hours	24 Hours	48 Hours	48 Hours	48 Hours
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.	Ed.
1	0	0	0	0	0	0	0	0	0
2	0	0	0	1	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0
4	0	0	0	1	0	0	0	0	0
5	0	0	0	1	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0
8	0	0	0	1	0	0	0	1	0
9	0	0	0	1	0	0	0	0	0
10	0	0	1	0	0	0	0	1	0

Key:

Er. = Erythema
 Ed. = Edema

TABLE XIV

TEST MATERIAL: 10.0% (w/v) Aqueous Solution of
[REDACTED] H-7860

Skin Sensitization Test - Albino Guinea Pigs

Results - Control Group

Animal Number	Scores Following Challenge Application							
	Site 1				Site 2			
	24 Hours		48 Hours		24 Hours		48 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0

Key:

Er. = Erythema

Ed. = Edema

Company Sanitized. Does not contain TSCA CBI