

Study Title

100-Person Human Patch Test with
H-20385 (Control Item) and H-20386 (Test Item)

Laboratory Project ID

Haskell Laboratory Report No. 792-93

Study Completed On

25 February 1994

Contracting Laboratory

Biosearch, Incorporated
3408-50 B Street
Philadelphia, Pennsylvania 19134

Author

Armand Affrime

for

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

Study Monitor

John R. Bamberger

Medical Research No.

[REDACTED]

Company Sanitized. Does not contain TSCA CBI

GENERAL INFORMATION

Control Material

Material Tested:

[REDACTED]

Physical Form:

[REDACTED]

Synonyms:

• H-20385
[REDACTED]

Composition:

H-20385 is a [REDACTED]
[REDACTED]

Test Material

Material Tested:

[REDACTED]

Physical Form:

[REDACTED]

Synonyms:

• H-20386
[REDACTED]
[REDACTED]

Composition:

H-20386 is a [REDACTED]
[REDACTED]

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GENERAL INFORMATION (CONT.)

Stability:

In the absence of visible evidence to the contrary, the test materials were assumed to be stable under the conditions of administration.

Sponsor:

DuPont Fibers
E. I. du Pont de Nemours and Company
Wilmington, Delaware

Study Initiated - Completed:

10 January 1994 - 25 February 1994

In-Life Phase
Initiated - Completed:

10 January 1994 - 17 February 1994

DuPont HLO 792-93

DUPONT CENTRAL RESEARCH AND DEVELOPMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

25 February 1994

Joyce M. Materniak
DuPont Fibers
Chambers Works

100-Person Human Patch Test with
H-20385 (Control Item) and H-20386 (Test Item)

Attached is a report from Biosearch, Inc. (Project No. 93-7949H). Included in the report are patch test methods, results, and conclusions.

The purpose of this study was to determine the potential of H-20385 (Control Item) and H-20386 (Test Item) to cause delayed contact hypersensitivity in humans. During the induction and challenge phases of this study, H-20385 (Control Item) and H-20386 (Test Item) produced no adverse skin responses in 100% and 100%, respectively, of those subjects who were active participants.

Based upon the effects observed with the test materials placed repeatedly on the skin during both the induction and challenge phases, neither H-20385 (Control Item) nor H-20386 (Test Item) are considered sensitizing agents under the conditions that prevailed in this study.

John R. Bamberger
John R. Bamberger, B.S.
Toxicologist

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BIOSEARCH INCORPORATED

P.O. Box 8598, Philadelphia, Pennsylvania 19101

Telephone: (215) 739-4499

Fax: (215) 423-9210

Project Number: 93-7949H

Testing Facility: Biosearch Incorporated
3408-50 "B" Street
Philadelphia, PA 19134

Sponsor: E.I. Du Pont De Nemours & Company
P.O. Box 50, Elkton Road
Newark, DE 19714

Test Article: H-20385

Test Article Description: [REDACTED]

Test Article Received: 12/14/93

Study Initiated: 01/10/94 **Study Completed:** 02/17/94

Date of Report: 02/25/94

Test: Modified Draize Repeated Insult Patch Test Study in Human Volunteers.

Object of Test: To determine the irritating, fatiguing and sensitizing properties of the test article.

Reference: The method employed in carrying out this test was similar to that described in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" by J.H. Draize and published by the Association of Food and Drug Officials of the United States.

Method of Test: **Test Panel:** The test involved the application of the test article to the upper arms of a group of 120 volunteer panelists. The panelists involved in this study ranged from 18 to 55 years of age. One hundred and ten panelists completed the study (see Panelist List, Appendix I). These panelists were all determined to be in good general health and free of any visible skin disease or anomaly in the area to be patched. Each panelist was required to read, understand and sign an informed consent statement.

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E.I. Du Pont De Nemours & Company - H-20385

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:
(continued)

Patch Preparation: The test article was tested as supplied. A portion of test article, approximately one inch square, was applied to the appropriate skin site and covered with 2" Dermicel® hypoallergenic cloth tape (Johnson & Johnson, New Brunswick, NJ 08903).

Induction Phase: The patch was applied to its designated contact site on the upper arm, and remained in place for 24 hours. At the end of this period, the patch was removed and the site was examined for any dermal response. The panelists were then rested for a 24-hour period after which the skin site was again examined. A patch was then applied to the same site as previously used. The second application was identical to the first and remained in place 24 hours. This procedure was repeated on Mondays, Wednesdays and Fridays until a series of nine applications had been made. Patch applications made on Friday were removed by the panelist on Saturday. The panelists examined the site for any dermal response and reported their observations prior to the next application. The same site continued to be used throughout the study. In the event when one induction patch application was missed, the panelist was allowed to make it up at the end of the induction patch period. This was done on the Monday following the last scheduled induction patch application.

Severe ice and snow storms in January made travel to the laboratory impossible for some of the panelists on several test days. Adjustments in the test schedule for individual panelists are shown in Table 1.

Challenge Phase: After the 9th application, a rest period of approximately 2 weeks elapsed after which a challenge application was applied in the same manner and to the same site as described above. A duplicate challenge application was also applied in the same manner to a virgin site (previously untreated) on the other arm. The challenge application was removed after 24 hours and the sites were examined and graded for signs of irritation or sensitization. A follow-up examination was conducted at 48 hours after the challenge application.

Grading Scale: The grading scale used throughout both the induction and challenge phases is shown in Appendix II.

Results: Individual panelist data are presented in Table 1. A summary of the data is presented in Table 2.

Conclusion: From the results obtained with this test panel, the test article is most likely not a primary skin irritant. The test article is most likely not a fatiguing agent. The test article is most likely not a sensitizing agent.

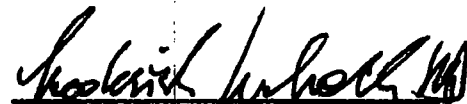
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Project Number: 93-7949H

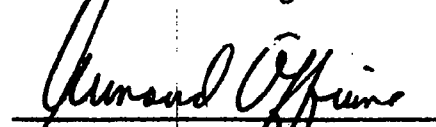
E.I. Du Pont de Nemours & Company - H-20385

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

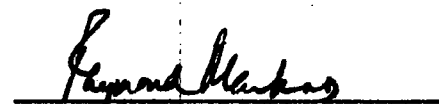
Signatures: Submitted by Biosearch, Incorporated:


Frederick Urbach, M.D.
Consultant Dermatologist

2/25/94
Date

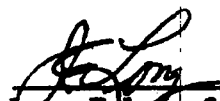

Armand Affrime, M.D.
Study Director

2/25/94
Date

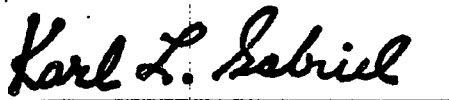

Raymond Mark, M.D.
Medical Director

2/25/94
Date

Approved by:


James E. Long, Sc.D.
Vice President, Laboratory Operations
& Regulatory Affairs

2/25/94
Date


Karl L. Gabriel, V.M.D., Ph.D.
President

2-25-94
Date

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Subject Number	Induction Phase										Challenge	
	1	2	3(m)	4(m)	5	6	7	8	9	Original Site 24-48	Virgin Site 24-48	
1	0	0	0	0	-	0	0	0	0	0	0	
2	0	0	0	0	-	0	0	0	0	0	0	
3	0	0	0	0	D	D	D	D	D	D	D	
4	0	0	0	0	0	0	0	0	0	0	0	
5	0	0	0	0	0	0	0	0	0	0	0	
6	0	0	0	0	0	0	0	0	0	0	0	
7	0	0	0	0	0	0	0	0	0	0	0	
8	0	0	0	0	0	0	0	0	0	0	0	
9	0	0	0 (a)	0	0	0	0	0	0	0	0	
10	0	0	0	0	0	0	0	0	0	0	0	
11	0	0	0	0	0	0	0	0	0	0	0	
12	0	0	0	0	0	0	0	0	0	0	0	
13	0	0	0 (a)	0	0	0	0	0	0	0	0	
14	0	0	0	0	0	0	0	0	0	0	0	
15	0	0	0	0	0	0	0	0	0	0	0	
16	0	0	0	0	0	0	0	0	0	0	0	
17	0	0	0	0	0	0	0	0	0	0	0	
18	0	0	0	0	0	0	0	0	0	0	0	
19	0	0	0	0	0	0	0	0	0	0	0	
20	0	0	0	0	D	D	D	D	D	D	D	
21	0	0	0	0	-	0	0	0	0	0	0	
22	0	0	0	0	-	0	0	0	0	0	0	
23	0	0	0	0	0	0	0	0	0	0	0	
24	0	0	0	0	0	0	0	0	0	0	0	
25	0	0	0 (a)	0	0	0	0	0	0	0	0	

(a) - Day of severe ice and snow storms.

24 - Reading 24 hours after application.

48 - Reading 48 hours after previous application but just before next application.

- Missed reading.

(a) - Patch applied 1 day late.

D - Discontinued for personal reasons.

Project Number: 93-7949H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(s)	4(a)	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
26	0	0	0	0	0	0	0	0	0		0	0
27	0	0	0	0	0	0	0	0	0		0	0
28	0	0	0	0	0	0	0	0	0		0	0
29	0	0	0	0	0	0	0	0	0		0	0
30	0	0	0	0	0	0	0	0	0		0	0
31	0	0	0	0	0	0	0	0	0		0	0
32	0	0	0	0	0	0	0	0	0		0	0
33	0	0	0	0	0	0	0	0	0		0	0
34	0	0	0	0	0	0	0	0	0		0	0
35	0	0	0	0	0	0	0	0	0		0	0
36	0	0	0	0	0	0	0	0	0		0	0
37	0	0	0	0	0	0	0	0	0		0	0
38	0	0	0	0	0	0	0	0	0		0	0
39	0	0	0	0	0	0	0	0	0		0	0
40	0	0	0	0	0	0	0	0	0		0	0
41	0	0	0	0	0	0	0	0	0		0	0
42	0	0	0	0	0	0	0	0	0		0	0
43	0	0	0	0	0	0	0	0	0		0	0
44	0	0	0	0	0	0	0	0	0		0	0
45	0	0	0	0	0	0	0	0	0		0	0
46	0	0	0	0	0	0	0	0	0		0	0
47	0	0	0	0	0	0	0	0	0		0	0
48	0	0	0	0	0	0	0	0	0		0	0
49	0	0	0	0	0	0	0	0	0		0	0
50	0	0	0	0	0	0	0	0	0		0	0

(s) - Day of severe ice and snow storms.

24 - Reading 24 hours after application.

48 - Reading 48 hours after previous application but just before next application.

- - Missed reading. # - Read at 72 hours.

- - Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the

next scheduled application day, and the patch series extended until 9 induction applications were applied.

** - Make-up patch application. (a) - Patch applied 1 day late.

D - Discontinued for personal reasons.

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenges	
	1	2	3(a)	4(a)	5	6	7	8	9	10**	Original Site	Virgin Site
	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0(a)	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0(a)	0	0	0	0	0	0	0
57	0	0	0	0	0(a)	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0(a)	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0(a)	0	0	0	0	0	0	0	0
69	0	0	0	0(a)	0	0	0	0	0	0(b)	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0(a)	0	0	0	0	0	0	0	0

(s) = Day of severe ice and snow storms.

24 = Reading 24 hours after application.

48 = Reading 48 hours after previous application but just before next application.

* = Missed reading.

+ = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

(a) = Patch applied 1 day late.

D = Discontinued for personal reasons.

(b) = Panelist received 1 make-up; technical error.

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Project Number: 93-7949H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(a)	4(a)	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
76	0 0	0 0	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
77	0 0	0 0	0 0(a)	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
78	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
79	0 0	0 0	0 0	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0
80	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
81	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
82	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
83	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
84	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
85	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
86	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
87	0 0	0 0	0 0(a)	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
88	0 0	0 0	0 0(a)	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
89	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
90	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
91	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
92	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
93	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
94	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
95	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
96	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
97	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
98	0 0	0 -*	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
99	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
100	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

(a) - Day of severe ice and snow storms.

24 - Reading 24 hours after application.

48 - Reading 48 hours after previous application but just before next application.

- Missed reading.

- Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

++ - Make-up patch application.

D - Discontinued for personal reasons.

(a) - Patch applied 1 day late.

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Project Number: 93-7949H

E.I. Du Pont de Nemours & Company - H-20385, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(s)	4(s)	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
101	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
102	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
103	0 0	0 0	0 0	0 0	- 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
104	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
105	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
106	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
107	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
108	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
109	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
110	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
111	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
112	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
113	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
114	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
115	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
116	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
117	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
118	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
119	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
120	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

(s) = Day of severe ice and snow storms.

24 = Reading 24 hours after application.

48 = Reading 48 hours after previous application but just before next application.

- = Missed reading.

+ = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

++ = Make-up patch application.

(a) = Patch applied 1 day late.

D = Discontinued for personal reasons.

Project Number: 93-7949H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

	Induction Phase										Challenge										
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site									
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48									
Total	120	120	120	120	120	120	120	120	120	120	120	120									
Subjects:	120	120	120	120	120	120	120	120	120	120	120	120									
Grade	0	116	117	115	116	116	114	94	104	91	101	101	101	110	109	17	17	107	105	107	105
±	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1+	0	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0
3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	2	0	2	1	1	0	20	8	20	10	10	0	3	0	1	0	0	1	0	0	2
D	2	3	3	3	3	6	6	8	9	9	9	10	10	10	10	10	10	10	10	13	13

24 - Reading 24 hours after application.
 48 - Reading 48 hours after previous application but just before next application.
 - - Missed reading.
 D - Discontinued for personal reasons.

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BIOSEARCH INCORPORATED

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Telephone: (215) 739-4499

Fax: (215) 423-9210

Project Number: 93-7949H

Testing Facility: Biosearch Incorporated
3408-50 "B" Street
Philadelphia, PA 19134

Sponsor: E.I. Du Pont De Nemours & Company
P.O. Box 50, Elkton Road
Newark, DE 19714

Test Article: H-20386

Test Article Description: [REDACTED]

Test Article Received: 12/14/93

Study Initiated: 01/10/94 **Study Completed:** 02/17/94

Date of Report: 02/25/94

Test: Modified Draize Repeated Insult Patch Test Study in Human Volunteers.

Object of Test: To determine the irritating, fatiguing and sensitizing properties of the test article.

Reference: The method employed in carrying out this test was similar to that described in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" by J.H. Draize and published by the Association of Food and Drug Officials of the United States.

Method of Test: **Test Panel:** The test involved the application of the test article to the upper arms of a group of 120 volunteer panelists. The panelists involved in this study ranged from 18 to 55 years of age. One hundred and ten panelists completed the study (see Panelist List, Appendix I). These panelists were all determined to be in good general health and free of any visible skin disease or anomaly in the area to be patched. Each panelist was required to read, understand and sign an informed consent statement.

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:
(continued)

Patch Preparation: The test article was tested as supplied. A portion of test article, approximately one inch square, was applied to the appropriate skin site and covered with 2" Dermicel® hypoallergenic cloth tape (Johnson & Johnson, New Brunswick, NJ 08903).

Induction Phase: The patch was applied to its designated contact site on the upper arm, and remained in place for 24 hours. At the end of this period, the patch was removed and the site was examined for any dermal response. The panelists were then rested for a 24-hour period after which the skin site was again examined. A patch was then applied to the same site as previously used. The second application was identical to the first and remained in place 24 hours. This procedure was repeated on Mondays, Wednesdays and Fridays until a series of nine applications had been made. Patch applications made on Friday were removed by the panelist on Saturday. The panelists examined the site for any dermal response and reported their observations prior to the next application. The same site continued to be used throughout the study. In the event when one induction patch application was missed, the panelist was allowed to make it up at the end of the induction patch period. This was done on the Monday following the last scheduled induction patch application.

Severe ice and snow storms in January made travel to the laboratory impossible for some of the panelists on several test days. Adjustments in the test schedule for individual panelists are shown in Table 1.

Challenge Phase: After the 9th application, a rest period of approximately 2 weeks elapsed after which a challenge application was applied in the same manner and to the same site as described above. A duplicate challenge application was also applied in the same manner to a virgin site (previously untreated) on the other arm. The challenge application was removed after 24 hours and the sites were examined and graded for signs of irritation or sensitization. A follow-up examination was conducted at 48 hours after the challenge application.

Grading Scale: The grading scale used throughout both the induction and challenge phases is shown in Appendix II.

Results: Individual panelist data are presented in Table 1. A summary of the data is presented in Table 2.

Conclusion: From the results obtained with this test panel, the test article is most likely not a primary skin irritant. The test article is most likely not a fatiguing agent. The test article is most likely not a sensitizing agent.

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Project Number: 93-7949H

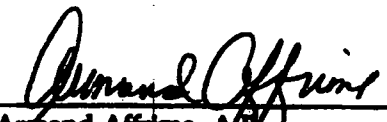
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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

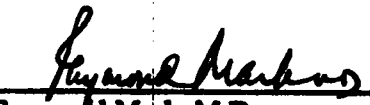
Signatures: Submitted by Biosearch, Incorporated:


Frederick Urbach, M.D.
Consultant Dermatologist

2/25/94
Date

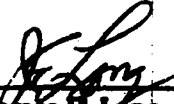

Armand Affrime, A.B.
Study Director

2/25/94
Date


Raymond Mark, M.D.
Medical Director

2/25/94
Date

Approved by:


James El Long, Sc.D.
Vice President, Laboratory Operations
& Regulatory Affairs

2/25/94
Date


Karl L. Gabriel, V.M.D., Ph.D.
President

2-25-94
Date

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Subject Number	Induction Phase										Challenge	
	1	2	3(s)	4(s)	5	6	7	8	9		Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48		24 48	24 48
1	0 0	0 0	0 0	0 0	-	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	0 0	0 0		0 0	0 0
3	0 0	0 0	0 0	0 0	D D	D D	D D	D D	D D		D D	D D
4	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0		0 0	0 0
6	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
7	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0		0 0	0 0
9	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0		0 0	0 0
11	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
12	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
13	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
14	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
15	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
16	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
17	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
18	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
19	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
20	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
21	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
22	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
23	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
24	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
25	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0

(s) - Day of severe ice and snow storms.

24 - Reading 24 hours after application.

48 - Reading 48 hours after previous application but just before next application.

- Missed reading.

(a) - Patch applied 1 day late.

D - Discontinued for personal reasons.

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(s)	4(a)	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
26	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0

(s) = Day of severe ice and snow storms.

24 = Reading 24 hours after application.

48 = Reading 48 hours after previous application but just before next application.

* = Missed reading. # = Read at 72 hours.

Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the

next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application. (a) = Patch applied 1 day late.

D = Discontinued for personal reasons.

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(a)	4(a)	5	6	7	8	9	10+	Original Site	Virgin Site
	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0

(a) = Day of severe ice and snow storms.

24 = Reading 24 hours after application.

48 = Reading 48 hours after previous application but just before next application.

- = Missed reading.

* = Make-up patch application.

Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

(a) = Patch applied 1 day late.

(b) = Panelist received 1 make-up; technical error.

D = Discontinued for personal reasons.

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(a)	4(a)	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
76	0 0	0 0	0 0	0 -*	- 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
77	0 0	0 0	0 0(a)	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
78	0 0	0 0	0 0	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0
79	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
80	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
81	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
82	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
83	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
84	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
85	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
86	0 0	0 0	0 0	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
87	0 0	0 0	0 0(a)	0 0	0 -*	0 0	0 0	0 0	0 0	0 0	0 0	0 0
88	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
89	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
90	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
91	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
92	0 0	0 0	0 0	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
93	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
94	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
95	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
96	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
97	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
98	0 0	0 -*	0 0(a)	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
99	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
100	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

(a) - Day of severe ice and snow storms.

24 - Reading 24 hours after application.

48 - Reading 48 hours after previous application but just before next application.

- - Missed reading.

+ - Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

++ - Make-up patch application.

(a) - Patch applied 1 day late.

D - Discontinued for personal reasons.

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Project Number: 93-7949H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Subject Number	Induction Phase										Challenge	
	1	2	3(s)	4(s)	5	6	7	8	9	10**	Original Site	Virgin Site
	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48	24-48
101	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0
105	-	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0
109	D	D	D	D	D	D	D	D	D	D	D	D
110	D	D	D	D	D	D	D	D	D	D	D	D
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	0	0	0
113	0	0	0	0	0	0	0	0	0	0	0	0
114	0	0	0	0	0	0	0	0	0	0	0	0
115	0	0	0	0	0	0	0	0	0	0	0	0
116	0	0	0	0	0	0	0	0	0	0	0	0
117	0	0	0	0	0	0	0	0	0	0	0	0
118	0	0	0	0	0	0	0	0	0	0	0	0
119	0	0	0	0	0	0	0	0	0	0	0	0
120	0	0	0	0	0	0	0	0	0	0	0	0

(s) = Day of severe ice and snow storms.

24 = Reading 24 hours after application.

48 = Reading 48 hours after previous application but just before next application.

- = Missed reading.

* = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

(a) = Patch applied 1 day late.

D = Discontinued for personal reasons.

Project Number: 93-7949H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48	24 48
Total	120	120	120	120	120	120	120	120	120	120	120	120
Subjects:	120	120	120	120	120	120	120	120	120	120	120	120
Grade												
0	116	117	115	116	116	114	94	104	91	101	101	101
±	0	0	0	0	0	0	0	0	0	0	0	0
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	0	0	0	0	0	0	0	0	0	0
4+	0	0	0	0	0	0	0	0	0	0	0	0
-	2	0	2	1	1	0	20	8	20	10	10	0
D	2	3	3	3	3	6	6	8	9	9	10	10

- 24 = Reading 24 hours after application.
- 48 = Reading 48 hours after previous application but just before next application.
- = Missed reading.
- D = Discontinued for personal reasons.

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Project Number: 93-7949H

DuPont HLO 792-93
Appendix I

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

Panelist Number	Initials	Age	Occupation	Allergies
1	W.L.B.	39	Unemployed	Hayfever
2	E.P.	29	Unemployed	-
3	L.P.	30	Homemaker	-
4	D.Z.	52	Homemaker	Tomatoes
5	J.B.	39	Homemaker	Asthma, Penicillin, Animal Hair, Seasonal
6	R.G.	30	Homemaker	Hayfever
7	J.R.	27	Dish Washer	Poison Ivy, Seasonal
8	N.R.	41	Homemaker	Hayfever
9	J.P.	35	Unemployed	Hayfever
10	B.T.	25	Homemaker	-
11	J.S.	45	Homemaker	Darvon, Penicillin
12	P.M.	31	Homemaker	Cats
13	P.H.	34	Nurse	-
14	D.L.	33	Homemaker	-
15	V.M.	32	Painter	Shellfish
16	C.D.	44	Homemaker	-
17	N.C.	39	Homemaker	Dust
18	P.C.	36	Brick Pointer	Penicillin
19	D.S.	29	Homemaker	Penicillin, Seasonal, Hayfever
20	M.F.	27	Homemaker	-
21	K.G.	52	Homemaker	Cats
22	D.M.	27	Homemaker	Penicillin, Aspirin
23	K.B.	22	Cashier	-
24	S.L.	49	School Aide	Tomatoes
25	E.R.	29	Homemaker	Seasonal
26	J.R.	37	Stock Person	Penicillin
27	J.R.	19	Student	-
28	R.D.B.	47	Unemployed	Sinus
29	C.M.	29	Homemaker	Penicillin
30	R.S.	24	Homemaker	Seasonal, Hayfever
31	D.O.	34	Homemaker	Hayfever, Seasonal
32	O.M.	30	Homemaker	-
33	B.T.	28	Homemaker	Penicillin
34	N.S.	29	Homemaker	Sinus
35	H.F.	46	Homemaker	Dogs, Hayfever, Ragweed, Sulfa
36	L.C.	24	Homemaker	Asthma
37	E.W.	19	Clerk	Pollen
38	E.C.	40	Homemaker	Sinus
39	S.A.	33	Homemaker	Cats
40	H.W.	38	Homemaker	Hayfever
41	S.R.	42	Homemaker	Dust
42	S.B.	39	Check Cashier	Dust Occasionally
43	M.C.	21	Cashier	-
44	B.C.	43	Crossing Guard	-
45	D.H.	38	Secretary	Animal Hair
46	J.H.	46	Machine Operato	-
47	R.S.	26	Driver	Hayfever
48	J.I.	29	Homemaker	Hayfever
49	W.W.	21	Student	Dust, Asthma
50	L.W.	38	Factory work	Sinus
51	M.H.	41	Homemaker	Penicillin
52	G.S.	53	Homemaker	-
53	C.S.	44	Cashier	Tetanus
54	D.B.	20	Student	Cat Hair
55	E.F.	45	Homemaker	-
56	L.S.	44	Homemaker	-
57	J.H.	34	Homemaker	-
58	T.D.	35	Unemployed	Hayfever
59	D.C.	44	Bus Attendant	-
60	A.L.	19	Makes Lampshade	-

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Appendix I

E.I. Du Pont De Nemours & Company

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST (continued)

Panelists Number	Initials	Age	Occupation	Allergies
61	K.H.	41	Bus Driver	-
62	C.S.	37	Teacher's Aide	-
63	J.K.	25	Unemployed	-
64	T.S.	38	Unemployed	-
65	S.S.	38	Homemaker	-
66	A.W.N.	46	Processor	-
67	H.H.	54	Disabled	-
68	C.G.	46	Homemaker	-
69	V.G.	21	Homemaker	-
70	P.J.	37	Homemaker	Sinus
71	M.F.	42	Homemaker	-
72	J.F.	46	Homemaker	-
73	A.V.	20	Babysitter	-
74	W.V.	41	Tire Surgeon	-
75	R.R.	29	Unemployed	-
76	J.W.	24	Homemaker	-
77	K.G.	42	Homemaker	-
78	M.V.	34	Homemaker	-
79	E.H.	40	Supervisor	-
80	M.G.	55	Homemaker	-
81	K.H.	46	Homemaker	-
82	J.M.k.	27	Homemaker	-
83	D.R.	28	Cosmetologist	-
84	M.G.	19	Student	-
85	M.K.	48	Construction	-
86	C.S.	39	Homemaker	-
87	S.S.	35	Homemaker	-
88	C.M.	24	Presser	-
89	A.T.	18	Student	-
90	P.W.	42	Homemaker	-
91	M.R.	53	Homemaker	-
92	C.R.	37	Homemaker	-
93	A.P.	41	Avon Lady	Penicillin
94	J.G.	35	Unemployed	-
95	J.P.	43	Unemployed	-
96	I.D.	31	Homemaker	-
97	M.C.	50	Homemaker	-
98	R.F.	18	Student	Dust
99	M.E.F.	48	Cook	-
100	D.L.	27	Homemaker	-
101	M.S.	19	Student	-
102	C.G.	18	Student	-
103	M.J.	36	Homemaker	-
104	R.B.	35	Homemaker	-
105	S.M.	32	Nurse's Aide	-
106	M.L.	26	Burger King	-
107	I.G.	51	Homemaker	-
108	C.U.	49	Homemaker	-
109	J.N.	19	Student	Pollen
110	J.J.	22	Metal Worker	Ragweed
111	I.W.	52	Homemaker	-
112	M.P.	19	Student	-
113	R.B.	24	Homemaker	-
114	A.B.	26	Roofers	-
115	A.E.	41	Homemaker	-
116	D.B.	37	Maintenance	-
117	S.S.	41	Unemployed	-
118	C.A.D.	55	Homemaker	-
119	S.B.	38	Homemaker	-
120	M.A.	18	Student	-

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Appendix II

E.I. Du Pont De Nemours & Company - H-20386

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

GRADING SCALE

Human Patch Test Studies

Reading	Interpretation
0	negative
±	suspicious
1+	slight erythema
2+	well defined erythema
3+	erythema with induration
4+	erythema with ulceration

DEFINITIONS*

Sensitization is a phenomenon which manifests itself by local effects on either skin or mucous membranes. It differs from primary irritation in that it may also involve tissues remote from the site of application. These reactions represent an allergy to a chemical which is not obtained on first contact, but requires a number of prior exposures for development.

Repeated patch applications of substances to both man and animals reveal that certain substances which, at a given concentration, do not produce primary irritation may elicit severe skin reactions after a number of exposures. Nevertheless, these reactions may not be considered incidents of sensitization since after 10-14 days of rest the skin recovers its original resistance to injury by the substance. For the lack of a better term such reactions have been called "skin fatigue". This latter term is a misnomer in that it does not imply a condition in which the skin has lost significant normal physiological function. This phenomenon consists of a subtle change in which the skin no longer exhibits its original refractoriness or resistance to the continued or repeated action of an agent.

* Draize, J.H. 1959. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. In DERMAL TOXICITY, p.46-53. Topeka, Kansas: Association of Food and Drug Officials of the United States.

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