

Study Title

100-Person Human Patch Test with
H-21275 (Control Item), H-21273 (Test Item 1),
and H-21274 (Test Item 2)

Laboratory Project ID

Haskell Laboratory Report No. 447-95

Study Completed On

August 24, 1995

Contracting Laboratory

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

Author

James E. Long

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

Gregory S. Ladics

Medical Research No.

[REDACTED]

GENERAL INFORMATION

Control Material

Material Tested:

Physical Form:

Synonyms:

Other Codes:

[REDACTED]
[REDACTED]
[REDACTED]
o H-21273

Control item

Test Material

Material Tested:

Physical Form:

Synonyms:

Other Codes:

[REDACTED]
[REDACTED]
[REDACTED]
o H-21273

Test item 1

Material Tested:

Physical Form:

Synonyms:

Other Codes:

Stability:

Sponsor:

Study Initiated - Completed:

In-Life Phase
Initiated - Completed:

[REDACTED]
[REDACTED]
[REDACTED]
o H-21274

Test item 2

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

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

6/21/95 - 8/24/95

6/21/95 - 7/28/95

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

August 28, 1995

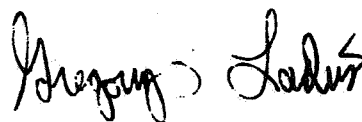
J. M. Materniak
DuPont Specialty Chemicals
Jackson Lab

100-Person Human Patch Test with
H-21275 (Control Item), H-21273 (Test Item 1),
and H-21274 (Test Item 2)

Attached is a report from Biosearch, Inc. (Project No. 95-8267H). Included in the report are patch test methods, results, and conclusions.

The purpose of this study was to determine the potential of H-21275 (Control Item), H-21273 (Test Item 1), and H-21274 (Test Item 2) to cause irritation or delayed contact hypersensitivity in humans. During the induction and challenge phases of this study, H-21275 (Control Item), H-21273 (Test Item 1), and H-21274 (Test Item 2) 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-21275 (Control Item), H-21273 (Test Item 1), nor H-21274 (Test Item 2) are considered skin irritants nor sensitizing agents under the conditions that prevailed in this study.



Gregory S. Ladics, Ph.D.
Research Toxicologist

BIOSEARCH INCORPORATED

P.O. Box 8598, Philadelphia, Pennsylvania 19101

Telephone: (215) 739-4499

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Project Number: 95-8267H

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-21273/H-21274

Control Article: H-21275

Test Article
Description:

[REDACTED]

Control Article
Description:

[REDACTED]

Test Articles
Received:

06/16/95

Control Article
Received:

06/16/95

Study Initiated:

06/21/95

Study Completed: 07/28/95

Date of Report:

08/22/95

Test:

Modified Draize Repeated Insult Patch Test Study in
Human Volunteers

Object of Test:

To determine the 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 122 volunteer panelists. The panelists ranged from 18 to 67 years of age. One hundred and nine panelists completed the study (see Panelist List, Appendix III). Prior to the initiation of the study, all panelists were 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.

E.I. du Pont de Nemours & Company - H-21273/H-21274/H-21275

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:
(continued)

Patch Preparation: The control article (H-21275) and the test articles (H-21273 and H-21274) were tested as supplied. A portion of each, approximately one inch square, was placed onto a strip of 2" Dermicel® hypo-allergenic cloth tape (Johnson & Johnson, New Brunswick, NJ 08903). Before applying this strip, each portion of test material was flattened with a gloved finger to insure proper application. This tape strip was then pressed into place on the upper left arm of each panelist at the appropriate test site.

Induction Phase: These patches were applied to their designated contact site and remained in place for 24 hours. At the end of this period, the patches were removed and the sites were examined for any dermal response. The panelists were then rested for a 24-hour period after which the skin sites were again examined. New patches were then applied to the same sites as previously used. The second applications were 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 panelists on Saturday. The panelists examined the sites (obtained assistance if necessary) for any dermal response at the time of removal and again at 48 hours and reported their observations prior to the next application. The same sites were used throughout the study.

During the third week of the Induction Phase with periods of extremely high temperature and humidity, the test articles patch strips either fell off or were moved out of place in the case of several panelists. When this occurred, additional tape (Micropore® 3M, 3M Health Care, St. Paul, MN 55144-1000), was used for the next application. This addition plus using a new Lot# of Dermicel appeared to solve the problem. These few occurrences did not appear to interfere with obtaining valid results from the study.

In the event when one induction application was missed, the panelist was allowed to make it up at the end of the induction patch period. These patches were applied on Friday following the last scheduled (ninth) induction patch application on Wednesday.

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 sites 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 applications were 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 applications (24 hours after patch removal).

Project Number: 95-8267H

DuPont HLO 447-95

E.I. du Pont de Nemours & Company - H-21273/H-21274/H-21275

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:
(continued)

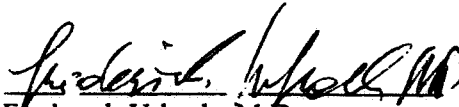
Grading Scale: The grading scale used throughout both the induction and challenge phases is shown in Appendix IV.

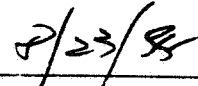
Results: Results obtained with the control article (H-21275) are presented in Appendix I. Individual panelist data for the control article are presented in Table 1. A summary of the data for the control article is presented in Table 2. Results obtained with the test articles (H-21273 and H-21274) are presented in Appendix II. Individual panelist data for the test articles are presented in Tables 1 and 3. Summaries of the data for each of the test articles are presented in Tables 2 and 4.

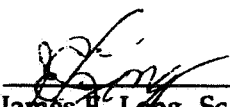
Conclusion: From the results obtained with this test panel, the test and control articles do not appear to be primary skin irritants. The test and control articles do not appear to be fatiguing agents. The test and control articles do not appear to be sensitizing agents under the study conditions utilized.

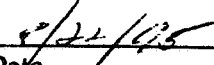
Signatures:

Submitted by Biosearch, Incorporated:

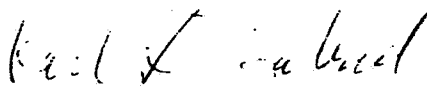

Frederick Urbach, M.D.
Consultant Dermatologist

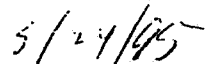

Date 5/23/95


James H. Long, Sc.D.
Study Director/Vice President, Laboratory
Operations & Regulatory Affairs


Date 5/24/95

Approved by:


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


Date 5/24/95

Project Number: 95-8267H

DuPont HLO 447-95

APPENDIX I
RESULTS FOR CONTROL ARTICLE

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 72	24 48	24 48
1	0	0	0	0	0	0	0	0	0		0	0
2	0	0	0	0	0	0	0	0	0		0	0
3	0	0	0	0	0	0	0	0	0		0	0
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	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
11	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
13	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
15	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
17	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
19	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
21	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
23	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
25	0	0	0	0	0	0	0	0	0	0	0	0
24	D	D	D	D	D	D	D	D	D	D	D	D
48												
72												
120												
*												
**												
D												

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 * = Missed reading. (a) Challenge patches applied one day late due to an emergency.
 * = 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 from the study for personal reasons.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	Original Site	Virgin Site	
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	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	

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.

- = Missed reading.

D = Discontinued from the study for personal reasons.

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	Original Site	Virgin Site	
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 48	24 48	
51	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
53	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
55	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
57	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
59	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
61	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
63	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
65	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
67	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
69	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
71	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
73	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	
75	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.

- = Missed reading.

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge											
	1		2		3		4		5		6		7		8		9		Original Site		Virgin Site	
	24 48	24 48	24 72	24 72	24 48	24 48	24 120	24 48	24 48	24 48	24 48	24 72	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	
77	0	0	0	0	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	
79	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	
81	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	
83	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	
85	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	
87	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
88	0	0	-	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
90	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0	
92	0	0	0	0	0	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	
94	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	
96	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	
98	0	0	0	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	
100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.

- = 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.

D = Discontinued from the study for personal reasons.

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	10** 24 72	Original Site 24 48	Virgin Site 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
102	0 0	0 0	0 0	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
104	0 0	0 0	0 0	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
106	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	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
109	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
111	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
113	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
115	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
117	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	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
120	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
121	0 0	0 0	0 0	0 0	0 -*	-	0 0	0 0	0 0	0 0	0 0	0 0
122	0 0	0 0	0 0	0 0	0 -*	-	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = 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 from the study for personal reasons.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21275, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

	<u>Induction Phase</u>										<u>Challenge</u>	
											Original Site	Virgin Site
	1	2	3	4	5	6	7	8	9	10**	24 48	24 48
<u>Total</u>	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 72	4	4
<u>Panelists:</u>	122 122	122 122	122 122	122 122	122 122	122 122	122 122	122 122	122 122	122 122	122 122	122 122
<u>Grade</u>												
0	118 116	116 118	116 116	115 116	116 114	110 115	115 113	110 110	108 108	4	3	109 109
±	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
1+	0 0	0 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 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 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 0	0 0
-	0 2	2 0	2 1	2 0	0 2	6 0	0 0	2 1	3 3	0 0	1 1	1 1
D	4 4	4 4	4 5	5 6	6 6	6 7	7 9	10 11	11 11	0 1	12 12	12 12

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = Missed reading.
 ** = Make-up patch application.
 D = Discontinued from the study for personal reasons.

DuPont HLO 447-95

Company Sanitized. Does not contain TSCA CBI

APPENDIX II
RESULTS FOR TEST ARTICLES

Project Number: 95 B26711

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site 24 48	Virgin Site 24 48
1	0 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 0
3	0 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 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 D	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	D D	D D	D D	D D	D D	D D	D D	D D	D D		D D	D D

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application.
 * = Missed reading. (a) Challenge patches applied one day late due to an emergency.
 * = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day.
 ** = Make-up patch application.
 D = Discontinued from the study for personal reasons.

DuPont HLO 447-95

Company Sanitized. Does not contain TSCA CRJ

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data (continued)

Panelist Number	Induction Phase									Challenge	
	1	2	3	4	5	6	7	8	9	Original Site	Virgin Site
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 48	24 48
26	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
28	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
30	0 0	0 0	0 1+	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
32	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
34	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
36	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
38	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
40	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
42	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
44	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
46	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
48	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
50	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.
48 = Reading 48 hours after previous application but just before next application.
72 = Reading 72 hours after previous application but just before next application.
120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
- = Missed reading.
D = Discontinued from the study for personal reasons.

DuPont HLO 447-95

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase								Challenge		
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	Original Site 24 48	Virgin Site 24 48
51	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
53	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
55	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
57	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
59	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
61	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
63	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
65	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
67	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
69	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
71	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
73	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
75	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.

- = Missed reading.

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1		2		3		4		5		Original Site	Virgin Site
	24 48	24 72	24 48	24 72	24 48	24 72	24 48	24 72	24 48	24 72	24 48	24 48
76	0	0	0	0	0	0	0	0	0	0	0	0
77	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
79	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
81	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
83	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
85	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
87	0	0	0	0	0	0	0	0	0	0	0	0
88	0	-*	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	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
94	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
96	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
98	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
100	0	0	0	0	0	0	0	0	0	0	0	0

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 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.

D = Discontinued from the study for personal reasons.

Project Number: 95 8267H

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO 447-95

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										10** 24 72	Challenge	
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	Original Site 24 48		Virgin Site 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	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	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	
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	
121	0	0	0	0	0	0	0	0	0	0	0	0	
122	0	0	0	0	0	0	0	0	0	0	0	0	

24 = Reading 24 hours after application.
48 = Reading 48 hours after previous application but just before next application.
72 = Reading 72 hours after previous application but just before next application.
120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
- = 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 from the study for personal reasons.

Company Sanitized. Does not contain TSCA CBI

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21273, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

Induction Phase

Challenge
Original Site 24 48
Virgin Site 24 48

	1	2	3	4	5	6	7	8	9	10**	
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 72	
Total	122	122	122	122	122	122	122	122	122	122	122
Panelists:	122	122	122	122	122	122	122	122	122	122	122
Grade											
0	118	116	116	115	116	115	115	113	110	110	108 108
±	0	0	0	0	0	0	0	0	0	0	0
1+	0	0	0	0	0	0	0	0	0	0	0
2+	0	0	0	0	0	0	0	0	0	0	0
3+	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	2	0	2	1	2	0	0	0	0
D	4	4	4	4	5	5	6	6	7	9	10 11 11 11

24 = Reading 24 hours after application.
48 = Reading 48 hours after previous application but just before next application.
72 = Reading 72 hours after previous application but just before next application.
120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
- = Missed reading.
** = Make-up patch application.
D = Discontinued from the study for personal reasons.

DuPont HLO 447-95

Company Sanitized. Does not contain TSCA CB#

Project Number: 95-8267H

E.I. du Pont de Nemours & Company H. 11274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site 24 48	Virgin Site 24 48
1	0 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 0
3	0 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 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 D	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	D D	D D	D D	D D	D D	D D	D D	D D	D D		D D	D D

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = Missed reading. (a) Challenge patches applied one day late due to an emergency.
 * = 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 from the study for personal reasons.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H 21274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data (continued)

Panelist Number	Induction Phase									Challenge	
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	Original Site 24 48	Virgin Site 24 48
26	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
28	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
30	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
32	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
34	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
36	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
38	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
40	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
41	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D
42	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
44	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
46	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
48	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
50	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = Missed reading.
 D = Discontinued from the study for personal reasons.

DuPont HLO 447-95

Company Sanitized. Does not contain TSCA CBI

Project Number: 95 H267H

E.I. du Pont de Nemours & Company - H-21274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase									Challenge	
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	Original Site 24 48	Virgin Site 24 48
51	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
53	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
55	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
57	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
59	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
61	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
63	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
65	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
67	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
69	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
71	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
73	0 0	0 0	0 0	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0
75	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.

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

72 = Reading 72 hours after previous application but just before next application.

120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.

- = Missed reading.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 Individual Panelist Data

Panelist Number	Induction Phase									Challenge	
	1 24 48	2 24 72	3 24 48	4 24 48	5 24 120	6 24 48	7 24 72	8 24 48	9 24 48	Original Site 24 48	Virgin Site 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	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
79	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
81	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
83	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
85	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
87	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
88	0 - *	0 0	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	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
90	0 0	0 0	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	0 0	0 0	0 0	0 0	0 0	0 0	0 0
92	0 0	0 0	0 0	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
94	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
96	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
98	0 0	0 0	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
100	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = 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.
 D = Discontinued from the study for personal reasons.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company H 21274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site 24 48	Virgin Site 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
102	0 0	0 0	0 0	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
104	0 0	0 0	0 0	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
106	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	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
109	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
111	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
113	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
115	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
117	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	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
120	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
121	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0		0 0	0 0
122	0 0	0 0	0 0	0 0	0 -*	0 -*	0 0	0 0	0 0	0 0	0 0	0 0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = 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 from the study for personal reasons.

Project Number: 95-8267H

E.I. du Pont de Nemours & Company - H-21274, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 4 - Summary of Data

	Induction Phase										Challenge	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
	24 48	24 72	24 48	24 48	24 120	24 48	24 72	24 48	24 48	24 72	24 48	24 48
Total	122	122	122	122	122	122	122	122	122	4	122	122
Panelists:	122	122	122	122	122	122	122	122	122	4	122	122
Grade												
0	118	116	116	115	116	110	115	110	110	4	109	109
±	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
-	0	2	2	0	0	2	0	0	0	0	1	1
D	4	4	4	4	5	6	6	7	9	10	11	12

24 = Reading 24 hours after application.
 48 = Reading 48 hours after previous application but just before next application.
 72 = Reading 72 hours after previous application but just before next application.
 120 = Reading 120 hours after previous application but just before next application due to the 4th of July holidays.
 - = Missed reading.
 ** = Make-up patch application.
 D = Discontinued from the study for personal reasons.

APPENDIX III
PANELIST LIST

E.I. Du Pont De Nemours & Company

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

Panelist Number	Initials	Age	Occupation	Allergies
1	C.C.	49	Homemaker	-
2	G.F.	34	Homemaker	-
3	D.L.	28	Homemaker	-
4	J.M.	37	Homemaker	Hayfever, Pollen
5	S.E.A.	29	Homemaker	-
6	T.S.	39	Homemaker	-
7	P.H.	58	Homemaker	-
8	A.W.N.	47	Processor	-
9	M.S.	37	Homemaker	-
10	M.C.	48	Homemaker	-
11	M.M.	48	Driver	Hay fever, Tomatoes
12	F.P.M.	53	Unemployed	-
13	R.A.R.	54	Pastor/Minister	-
14	A.L.	19	Student	-
15	K.C.	46	Teacher's Aide	Dust
16	S.S.	58	Homemaker	-
17	L.S.	58	Retired	-
18	K.G.	43	Homemaker	Penicillin
19	M.S.	29	Unemployed	-
20	M.S.	50	Homemaker	-
21	L.O.	39	Homemaker	Cats
22	E.W.	64	Stock Girl	-
23	J.C.C.	24	Student	-
24	P.M.	32	Homemaker	-
25	K.S.B.	19	Student	-
26	P.J.	48	Homemaker	-
27	B.V.	26	Homemaker	-
28	T.P.	39	Clerk	-
29	M.W.	39	Homemaker	-
30	J.K.	62	Handyman	-
31	E.A.H.	47	Homemaker	-
32	A.R.	42	Unemployed	-
33	J.S.	59	Retired	-
34	P.P.	31	Homemaker	-
35	M.C.	32	Unemployed	-
36	J.J.H.	62	Ambul. Driver	-
37	S.B.	57	Homemaker	-
38	J.N.	18	Student	Penicillin
39	B.M.	67	Retired	-
40	C.M.	29	Homemaker	-
41	J.M.	42	Homemaker	Penicillin
42	B.G.	43	Homemaker	-
43	L.D.	40	Homemaker	-
44	R.B.	18	Student	-
45	E.S.	34	Homemaker	-
46	H.V.	58	Homemaker	-
47	V.P.	34	Homemaker	-
48	L.T.	35	Homemaker	-
49	P.A.	34	Unemployed	-
50	M.W.	66	Homemaker	-
51	P.M.	55	Food Service	-
52	G.I.	38	Unemployed	-
53	B.H.	40	Homemaker	-
54	J.R.	22	Unemployed	Hayfever

E.I. Du Pont De Nemours & Company

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

Panelist Number	Initials	Age	Occupation	Allergies
55	M.H.	40	Homemaker	Hayfever, Grass
56	T.W.	45	Forklift Driver	-
57	M.S.	55	Homemaker	-
58	G.E.S.	29	Unemployed	Ragweed, Pollen
59	C.S.	45	Pretzel Twister	-
60	M.S.	20	Homemaker	-
61	P.J.	38	Homemaker	-
62	K.P.	55	Retired/Homemak	-
63	L.O.	35	Homemaker	-
64	K.M.D.	54	Homemaker	-
65	S.R.	31	Homemaker	-
66	L.L.D.	47	Acme (Clerk)	Penicillin
67	A.L.L.	51	Homemaker	-
68	D.E.	39	Homemaker	-
69	C.C.	22	Student	-
70	M.C.	52	Homemaker	-
71	T.M.	67	Retired	-
72	M.M.	53	Homemaker	Codeine
73	H.R.	23	Homemaker	-
74	B.E.	47	Crossing Guard	-
75	M.C.	29	Homemaker	-
76	L.V.	52	Homemaker	-
77	M.A.	44	Homemaker	-
78	C.G.	43	Homemaker	-
79	K.G.	40	Homemaker	-
80	L.C.	31	Homemaker	Hayfever, Dust, Fish, Nickel
81	J.S.	48	Unemployed	-
82	D.C.	16	Bus Attendent	-
83	H.C.R.	61	Unemployed	Hayfever, Dust, Dog Hair
84	N.V.	27	Homemaker	-
85	C.S.	41	Homemaker	-
86	E.W.	36	Homemaker	-
87	B.S.	68	Homemaker	-
88	J.F.	41	Unemployed	-
89	M.A.	67	Homemaker	-
90	L.D.	28	Crossing Guard	-
91	E.R.	27	Homemaker	-
92	M.D.	23	Student	Shell fish
93	M.F.	43	Data Entry	-
94	M.D.	26	Homemaker	-
95	M.C.T.	47	Unemployed	-
96	R.J.	63	Homemaker	-
97	K.W.	34	Homemaker	-
98	R.C.G.	52	Homemaker	Bluefish
99	J.H.	48	Machine Oper.	-
100	K.D.	23	Homemaker	-
101	B.S.	32	Homemaker	-
102	J.W.	44	Painter	-
103	D.N.	34	Homemaker	Penicillin
104	M.E.O.	37	Homemaker	-
105	R.A.S.	18	Student	-
106	R.S.	41	Homemaker	-
107	E.S.	22	Homemaker	-
108	D.B.	22	Factory	Cat Hair

Project Number: 95-8267H

Appendix III

E.I. Du Pont De Nemours & Company

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

Panelist Number	Initials	Age	Occupation	Allergies
109	M.F.	25	Homemaker	-
110	S.F.	23	Student	-
111	C.L.S.	24	Homemaker	-
112	M.S.	19	Student	-
113	A.G.	63	Homemaker	-
114	B.B.	37	Homemaker	-
115	E.P.	37	Factory Worker	-
116	M.F.	43	Homemaker	-
117	L.V.	33	Homemaker	-
118	L.B.	49	Homemaker	-
119	M.T.	39	Homemaker	-
120	P.W.	44	Homemaker	-
121	D.R.	48	Secretary	-
122	L.B.	27	Homemaker	-

Project Number: 95-8267H

DuPont HLO 447-95

APPENDIX IV
GRADING SCALE

E.I. du Pont de Nemours & Company - H-21273/H-21274/H-21275

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

GRADING SCALE

Human Patch Test Studies

<u>Reading</u>	<u>Interpretation</u>
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.