

TRADE SECRET

Study Title

**100-PERSON HUMAN REPEATED INSULT PATCH TEST
WITH H-23046 (CONTROL), H-23004 (TEST), AND H-23045 (TEST)**

LABORATORY PROJECT ID: HLO-1998-01285

DATA REQUIREMENTS:

AUTHOR: David Gabriel

STUDY COMPLETED ON: April 17, 1998

PERFORMING LABORATORY: ConTox Ltd.

For

E. I. Du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P.O. Box 50
Newark, Delaware 19714-0050

**MEDICAL RESEARCH NO. OR WORK
REQUEST NO.:** [REDACTED]

GENERAL INFORMATION

Control Material

Material Tested:

[REDACTED]

Haskell Sample No.

23046

Synonyms/Codes:

[REDACTED]

Physical Form:

[REDACTED]

Test Material

Material Tested:

[REDACTED]

Haskell Sample No.:

23004

Synonyms/Codes:

[REDACTED]

Physical Form:

[REDACTED]

Test Material

Material Tested:

[REDACTED]

Haskell Sample No.:

23045

Synonyms/Codes:

[REDACTED]

Physical Form:

[REDACTED]

Sponsor:

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

Study Initiated - Completed:

January 5, 1998 – See cover page

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

May 5, 1998

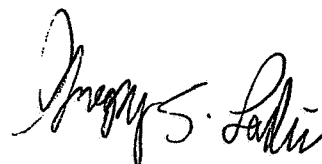
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CHAMBERS WORKS

100-Person Human Patch Test with
H-23046 (CONTROL), H-23004 (TEST), AND H-23045 (TEST)

Attached is a report from ConTox Limited (Project No. 98-8412H). Included in the report are patch test methods, results, and conclusions.

The purpose of this study was to determine the potential of H-23046 (Control Item), H-23004 (Test Item), and H-23045 (Test Item) to cause irritation or delayed contact hypersensitivity in humans. During the induction and challenge phases of this study, H-23046 (Control Item), H-23004 (Test Item) and H-23045 (Test Item) produced no adverse skin responses in 100%, 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-23046 (Control Item), H-23004 (Test Item) or H-23045 (Test Item) are considered skin irritants nor sensitizing agents under the conditions that prevailed in this study.



Gregory S. Ladics, Ph.D.
Research Toxicologist

ConTox Limited

P.O. Box 368, Fort Washington, Pennsylvania 19034-0368

Telephone: (215) 288-4882

Fax: (610) 834-7221

Project Number: 98-8412H

Testing Facility: ConTox Limited
1358 East Lycoming Street
Philadelphia, PA 19124

Sponsor: E. I. du Pont de Nemours and Company
Wilmington, Delaware

Test Articles: H-23004 and H-23045

Control Article: H-23046

Test Articles
Description:

[REDACTED]

Control Article
Description:

[REDACTED]

Test Articles
Received:

1/2/98

Control Article
Received:

1/2/98

Study Initiated: 1/5/98

Study Completed: 2/11/98

Date of Report: 4/17/98

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

Object of Test: To determine the sensitizing properties of the test articles.

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.

E.I. du Pont de Nemours & Company - H-23004, H-23045 and H-23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test: Test Panel: The test involved the application of the test article to the upper arms of a group of 111 volunteer panelists. The panelists ranged from 18 to 69 years of age (see Panelist List, Appendix III). One hundred and six panelists completed the study. 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.

Patch Preparation: The control fabric (H-23046) and the test fabric (H-23045) were tested as supplied. The test and control fabrics were cut into approximately one inch square portions. A second test article (H-23004) was prepared as a 4:1 dilution in deionized water (20% w/w). An approximate 0.1 ml portion of test article was placed onto a 3/4" diameter Lintine® disk (Filter Fabrics, Inc. Goshen, In. 46526), and all the test articles were placed onto a strip of 2" Dermicel® hypoallergenic cloth tape (Johnson & Johnson, New Brunswick, NJ 08903). Before applying this strip, each portion of test material was secured in place 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 its designated test site.

Induction Phase: These patches were applied to their designated contact sites 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 (with 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.

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 Monday following the last scheduled (ninth) induction application on Friday.

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.

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E.I. du Pont de Nemours & Company - H-23004, H-23045 and H-23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:

(continued)

A follow-up examination was conducted at 48 hours after the challenge applications (24 hours after patch removal). The grading scale used throughout both the induction and challenge phases is shown in Appendix IV.

Results:

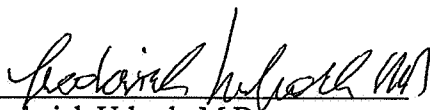
Results obtained with the control article (H-23046) are presented in Appendix I. Individual panelist data for the control article are presented in Table 1. A summary of the data for the control article is presented in Table 2. Results obtained with the test articles (H-23004, H-23045) are presented in Appendix II. Individual panelist data for the test articles are presented in Tables 1 and 3. A summary of the data for the test articles is presented in Tables 2 and 4.

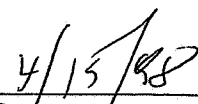
Conclusion:

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.

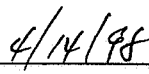
Signatures:

Submitted by ConTox Limited:

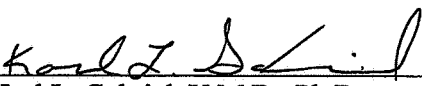

Frederick Urbach, M.D.
Consultant Dermatologist

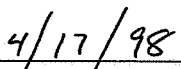

Date 4/15/98


Raymond Mark, M.D.
Study Director/Consultant


Date 4/14/98

Approved by:


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


Date 4/17/98

APPENDIX I
RESULTS FOR CONTROL ARTICLE

Appendix I

Project Number: 98-8412H

Control Article: 23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

[illegible]

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch

day, and the patch series extended un-

== Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

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.**

Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

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Appendix I

Appendix I

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	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
26	0	0	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	0	0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after application.
 72 = Reading 72 hours after 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.
 ** = Make-up patch application.

- = Missed reading.
 D = Discontinued from the study for personal reasons.
 (a) = Not graded. Next patch applied.

Project Number: 98-8412H

Control Article: 23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Appendix I

Project Number: 98-8412H
E.I. du Pont de Nemours & Company - H-23046
Modified Draize Repeated Insult Patch Test Study in Human Volunteers

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Appendix I

Table I - Individual Panelist Data

Panelist Number	Induction Phase									Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	
51	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	0
52	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	0
53	72 0	72 0	72 0	72 0	72 0	72 0	72 0	72 0	72 0	72 0	72 0	72 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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	0 0	0

24 = Reading 24 hours after application.

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72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

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(a) = Not graded. Next patch applied.

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

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Appendix I

Project Number: 98-8412H
 Control Article: 23046
 Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table I - Individual Panelist Data

Panelist Number	Induction Phase																		Challenge Phase					
	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
76	0	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	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	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	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	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	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	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	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	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	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	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	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

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24 = Reading 24 hours after application.
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 72 = Reading 72 hours after application.
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 - = Missed reading.
 D = Discontinued from the study for personal reasons.
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Appendix I

Project Number: 98-8412H
 Control Article: 23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
101	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0	24 0
102	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 0	48 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 0
104	0 0	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	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	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
108	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D
109	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D	D D
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

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Appendix I

Appendix I

Project Number: 98-8412H

Control Article: 23046

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

Table 2 - Summary of Data												
	Induction Phase										Challenge Phase	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
Total	24	48	24	48	24	48	24	48	24	48	24	48
Panelists:	111	111	111	111	111	111	111	111	111	111	111	111
Grade	0	108	109	109	108	108	108	107	107	108	106	106
±	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
-	1	0	0	1	5	0	0	0	1	1	5	0
*	0	0	0	0	1	0	0	0	0	0	0	0
(a)	0	0	0	0	1	0	0	0	0	0	0	0
D	2	2	2	2	3	3	3	3	3	3	5	5

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

* = 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.

APPENDIX II
RESULTS FOR TEST ARTICLES

Appendix II

Project Number: 98-8412H
Test Article: 23004
Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	24	48	Virgin Site
1	24	48	24	48	24	48	24	48	24	72	24	48	24	48
2	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
4	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
6	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
8	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
10	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
12	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
14	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
16	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
18	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
20	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
22	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
24	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

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24 = Reading 24 hours after application.
48 = Reading 48 hours after application.
72 = Reading 72 hours after 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.
** = Make-up patch application.

- = Missed reading.
D = Discontinued from the study for personal reasons.
(a) = Not graded. Next patch applied.

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Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Table 1 - Individual Panelist Data

Table 1 - Individual Panelist Data																								
Panelist Number	Induction Phase												Challenge Phase											
	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
26	0	0	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	0	0

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase			
	1		2		3		4		5		6		7	
	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	0	0
52	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
54	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
56	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
58	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
60	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
62	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
64	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
66	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
68	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
70	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
72	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
74	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

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- 24 = Reading 24 hours after application.
 48 = Reading 48 hours after application.
 72 = Reading 72 hours after 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.
 ** = Make-up patch application.

- = Missed reading.
 D = Discontinued from the study for personal reasons.
 (a) = Not graded. Next patch applied.

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Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Project Number: 98-8412H

Test Article: 23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	24	48
76	24	48	24	48	24	48	24	48	24	48	24	48	24	48
77	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
79	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
81	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
83	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
85	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
87	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
89	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
91	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
93	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
95	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
97	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
99	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

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

* = 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.

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Project Number: 98-8412H

Test Article: 23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Appendix II

Project Number: 98-8412H
E.I. du Pont de Nemours & Company - H-23004
Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285
Appendix II

Table 1 - Individual Panelist Data

Panelist Number		Induction Phase																		Challenge Phase					
		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
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	0
102	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
103	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
104	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
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	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	0
107	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
108	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
109	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
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	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	0

24 = Reading 24 hours after application.
48 = Reading 48 hours after application.
72 = Reading 72 hours after 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.
** = Make-up patch application.

- = Missed reading.
D = Discontinued from the study for personal reasons.
(a) = Not graded. Next patch applied.

Project Number: 98-8412H
Test Article: 23004

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Appendix II

Project Number: 98-8412H
E.I. du Pont de Nemours & Company - H-23004
Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285
Appendix II

Table 2 - Summary of Data

	Induction Phase										Challenge Phase	
	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	111 111	111 111	111 111	111 111	111 111	111 111	111 111	111 111	111 111	2 2	111 111	111 111
Panelists:	111 111	111 111	111 111	111 111	111 111	111 111	111 111	111 111	111 111	2 2	111 111	111 111
Grade	0	108 109	109 109	108 108	108 108	108 108	107 107	107 107	108 108	2 2	106 106	106 106
	±	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
	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
	- 21 -	1 0	0 0	1 5	0 0	0 0	1 1	5 0	0 0	0 0	0 0	0 0
	*	0 0	0 0	1 0	0 0	0 0	0 0	1 0	0 0	0 0	0 0	0 0
	(a)	0 0	0 0	0 0	1 0	0 0	0 0	0 0	1 0	0 0	0 0	0 0
	D	2 2	2 2	2 3	3 3	3 3	3 3	3 3	3 3	0 0	5 5	5 5

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24 = Reading 24 hours after application.
48 = Reading 48 hours after application.
72 = Reading 72 hours after 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.
** = Make-up patch application.

- = Missed reading.
D = Discontinued from the study for personal reasons.
(a) = Not graded. Next patch applied.

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Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Project Number: 98-8412H

Test Article: 23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase			
	1		2		3		4		5		6		7	
	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
2	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
4	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
6	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
8	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
10	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
12	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
14	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
16	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
18	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
20	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
22	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
24	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

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24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

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Appendix II

Project Number: 98-8412H

Test Article: 23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

[illegible]

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 == Reading 72 hours after application.

* = Panelist missed the scheduled patch

day, and the patch series extended un-

== Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

(c) Not graded. Next patch applied.
personal reasons. Panelist was patched on the next scheduled application

applications were applied.

Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Project Number: 98-8412H

Test Article: 23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase																		Challenge Phase	
	1		2		3		4		5		6		7		8		9		10**	Virgin Site
	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	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
53	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
55	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
57	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
59	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
61	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
63	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
65	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
67	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
69	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
71	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
73	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
75	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch was applied.

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Project Number: 98-8412H

E.I. du Pont de Nemours & Company - H-23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Project Number: 98-8412H

Test Article: 23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase			
	1		2		3		4		5		6		7	
	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
77	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
79	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
81	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
83	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
85	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
87	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
89	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
91	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
93	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
95	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
97	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
99	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

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

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Project Number: 98-8412H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO-1998-01285

Appendix II

Appendix II

Project Number: 98-8412H

Test Article: 23045

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 3 - Individual Panelist Data

Panelist Number	Induction Phase										Challenge Phase	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site
101	24	24	24	24	24	24	24	24	24	24	24	24
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	D	D	D	D	D	D	D	D	D	D	D	D
109	D	D	D	D	D	D	D	D	D	D	D	D
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

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

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Project Number: 98-8412H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 4 - Summary of Data

	Induction Phase										Challenge Phase	
	1		2		3		4		5		Original Site	
	24	48	24	48	24	48	24	48	24	48	24	48
Total	111	111	111	111	111	111	111	111	111	111	111	111
Panelists:	111	111	111	111	111	111	111	111	111	111	111	111
Grade	0	108	109	109	109	108	102	107	108	108	106	106
±	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
27	1	0	0	0	1	5	0	0	0	0	0	0
*	0	0	0	0	0	1	0	0	0	0	0	0
(a)	0	0	0	0	0	1	0	0	0	0	0	0
D	2	2	2	2	2	3	3	3	3	3	5	5

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= Reading 24 hours after application.

= Reading 48 hours after application.

= Reading 72 hours after 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.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

(a) = Not graded. Next patch applied.

= 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.

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APPENDIX III

PANELIST LIST

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Panelist List

<u>Panelist #</u>	<u>Initials</u>	<u>Age</u>	<u>Occupation</u>	<u>Allergies</u>
1	R.H.	45	Homemaker	
2	S.D.	30	Waitress	Penicillin
3	W.C.	47	Laborer	
4	J.M.	48	Meat Wrapper	
5	M.R.	36	Homemaker	Penicillin
6	E.K.	38	Homemaker	
7	K.K.	27	Cement Worker	
8	T.R.	54	Bartender	
9	J.L.	41	Secretary	
10	W.M.	31	Waitress	
11	L.S.	51	Printer	
12	E.S.	49	Laborer	
13	B.R.	32	Secretary	
14	D.P.	26	Hairdresser	Animal Dander, Hayfever
15	E.T.	42	Dental Assistant	
16	J.H.	38	Homemaker	
17	V.F.	50	Welder	
18	B.C.	29	Laborer	
19	A.M.	35	Unemployed	
20	I.M.	31	Homecare Nurse	
21	B.M.	24	Homemaker	
22	A.S.	32	Baker	Penicillin
23	M.T.	34	Meatpacker	
24	L.H.	50	Waitress	Hayfever
25	C.W.	29	Hostess	
26	C.W.	42	Homemaker	
27	S.A.	37	Homemaker	
28	B.B.	42	Homemaker	
29	N.B.	46	Homemaker	
30	J.B.	29	Insurance Adjuster	
31	C.O.	45	Homemaker	
32	L.W.	34	Homemaker	Hayfever
33	L.M.	31	Homecare Nurse	
34	J.S.	31	Homemaker	Hayfever
35	T.T.	33	Homemaker	Hayfever
36	S.D.	35	Homemaker	
37	J.W.	47	Painter	
38	M.G.	50	Homemaker	
39	M.S.	41	Homemaker	Hayfever
40	R.S.	49	Laborer	Hayfever
41	C.L.	57	Homemaker	
42	M.B.	33	Homemaker	
43	M.B.	57	Homemaker	
44	L.D.	34	Homemaker	
45	P.A.	36	Laborer	

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Panelist List

<u>Panelist #</u>	<u>Initials</u>	<u>Age</u>	<u>Occupation</u>	<u>Allergies</u>
46	M.A.	69	School Aide	
47	C.A.	37	Homemaker	
48	V.P.	37	Homemaker	
49	J.B.	27	Homemaker	
50	P.P.	33	Office Worker	
51	R.W.	43	Laborer	
52	S.B.	59	Homemaker	
53	M.W.	42	Homemaker	
54	J.K.	64	Laborer	
55	J.P.	42	Clerk	
56	D.R.	51	Homemaker	
57	A.E.	45	Homemaker	
58	J.G.	52	Factory Worker	Penicillin
59	K.W.	36	Homemaker	
60	M.B.	61	Retired	
61	L.P.	37	Daycare Worker	Hayfever
62	M.D.	35	Homemaker	
63	L.P.	28	Homemaker	
64	T.H.	29	Salesman	
65	H.J.	45	Homemaker	Penicillin
66	P.M.	58	Homemaker	Hayfever
67	L.M.	63	Retired	
68	P.L.	59	Security Guard	
69	D.D.	60	Crossing Guard	
70	L.B.	58	Homemaker	
71	T.W.	44	Shipper	
72	J.G.	18	Unemployed	
73	D.R.	20	Factory Worker	
74	L.M.	40	Homemaker	
75	D.R.	35	Homemaker	
76	S.L.	40	Store Clerk	
77	E.L.	49	Daycare Teacher	
78	L.B.	29	Homemaker	
79	M.C.	51	Daycare Teacher	Penicillin
80	M.W.	51	Daycare Teacher	Penicillin
81	J.C.	63	Retired	
82	P.C.	47	Homemaker	
83	K.K.	35	Homemaker	
84	M.W.	44	Homemaker	Hayfever
85	K.B.	33	Homemaker	
86	T.S.	45	Security Guard	
87	T.S.	43	Retired	
88	M.G.	59	Homemaker	
89	D.G.	32	Homemaker	
90	S.M.	57	Homemaker	Penicillin

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Panelist List

<u>Panelist #</u>	<u>Initials</u>	<u>Age</u>	<u>Occupation</u>	<u>Allergies</u>
91	B.M.	69	Retired	
92	E.K.	44	Homemaker	
93	C.J.	41	Homemaker	
94	S.L.	41	Homemaker	
95	S.S.	61	Homemaker	
96	L.S.	60	Retired	
97	M.A.	68	Homemaker	
98	K.D.	26	Childcare Worker	
99	M.C.	37	Homemaker	
100	P.H.	57	Homemaker	
101	J.H.	40	Homemaker	
102	M.B.	41	Homemaker	
103	P.C.	51	Teacher	
104	S.M.	28	Hairdresser	
105	Y.H.	42	Homemaker	
106	H.R.	40	Laborer	
107	C.T.	35	Homemaker	
108	V.M.	33	Nursing Aide	Hayfever
109	N.S.	38	Homemaker	
110	M.F.	27	Homemaker	
111	H.S.	40	Childcare	

APPENDIX IV
GRADING SCALE

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 require 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 but 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.