



**Clinical
Research
Laboratories, Inc.**

Final Report

Repeated Insult Patch Test

CLIENT: React, Inc.
3765 Kettle Court East
Delafield, WI 53018

ATTENTION: Bruce Tavares

TEST MATERIAL: EnviroPure 301

CRL STUDY NUMBER: CRL18802-1

AUTHORIZED SIGNATURES:

Bruce E. Kanengiser, M.D.
President/Medical Director

Marilee Candino, R.N.
Director/Clinical Services

George J. Neumaier, M.D.
Diplomate American Board
of Dermatology

Michael J. Muscatiello, Ph.D.
Executive Vice President/C.O.O.

REPORT DATE: April 18, 2002



**Clinical
Research
Laboratories, Inc.**

**Good Clinical Practice
Final Report Review Statement**

Clinical Study Number: CRL18802-1

Start Date: February 20, 2002

Completion Date: April 5, 2002

This clinical study report has been reviewed to assure that it correctly describes the method of testing and that the reported results accurately reflect the data obtained during the study.

Reviewer

Date



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FINAL REPORT

REPEATED INSULT PATCH TEST

PURPOSE

The purpose of this study was to determine the dermal irritation and sensitization potential of a test material.

INVESTIGATIVE SITE

Clinical Research Laboratories, Inc.
371 Hoes Lane
Piscataway, New Jersey 08854

TEST MATERIAL

The following test material was provided by React, Inc. and was received by Clinical Research Laboratories, Inc. on February 14, 2002:

EnviroPure 301

The test material was coded with the following CRL identification number:

CRL18802-1

The test material was tested as received.

STUDY DATES

This study was initiated on February 20, 2002 and was completed on April 5, 2002.



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PANEL SELECTION

Each subject was assigned a permanent CRL identification number. All subjects signed an Informed Consent Form in compliance with 21 CFR Part 50: "Protection of Human Subjects." All subjects completed a Subject Profile/Medical History Form provided by Clinical Research Laboratories, Inc. prior to the study (Subject Demographics - Appendix I).

No individuals were impaneled if they exhibited or had a history of acute or chronic dermatologic, medical, or physical conditions that could interfere with dermal scoring. No subject was using sympathomimetics, antihistamines, non-steroidal anti-inflammatory agents, or corticosteroids during the study period. No known pregnant or lactating women were impaneled in the study.

TEST METHOD

Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. The test material, which was prepared as described in the Test Material section of the report, was applied under a semi-occlusive patch* to the upper back (between the scapulae) and was allowed to remain in direct skin contact for a period of 24 hours.

Patches were applied to the same site on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. This schedule may have been modified to allow for missed visits or holidays. If a subject was unable to report on an assigned test date, the test material was applied on 2 consecutive days during the Induction Phase and/or a makeup day was added at the end of the Induction Phase.

The sites were graded by a CRL technician for dermal irritation and sensitization 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, unless the patching schedule was altered as described above.

* Semi-occlusive Strip (TruMed Technologies Inc., Burnsville, Minnesota)



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TEST METHOD (Continued)

The sites were graded according to the following scoring system:

Dermal Scores

- 0 No visible skin reaction
- ± Barely perceptible erythema (minimal)
- 1+ Mild erythema (diffuse)
- 2+ Well defined erythema
- 3+ Erythema and edema
- 4+ Erythema and edema with vesiculation

If a "2+" reaction or greater occurred, the test material was applied to an adjacent virgin site. If a "2+" reaction or greater occurred on the new site, the subject was not patched again during the Induction Phase but was challenged on the appropriate day of the study. At the discretion of the Study Director, patch sites with scores less than a "2+" may have been changed.

Following approximately a 2 week rest period, the challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96 hour reading.



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RESULTS

This study was initiated with 56 subjects. Three subjects discontinued study participation for reasons unrelated to the test material. A total of 53 subjects completed the study.

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I.

CONCLUSION

Based on the test population of 53 subjects and under the conditions of this study, the sample identified as EnviroPure 301 did not demonstrate a potential for eliciting dermal irritation or sensitization.

RETENTION

All of the original documents relating to this study will be retained by Clinical Research Laboratories, Inc. for a time period of at least 5 years or as otherwise required by law.

Test materials shall be archived by Clinical Research Laboratories, Inc. for a period no less than 6 months, unless otherwise instructed by Sponsor.



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Appendix I

Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex
1	MD	11617	41	F
2	DR	13607	52	F
3	ES	09428	54	F
4	GA	15147	48	F
5	GL	14892	58	F
6	WL	07361	37	F
7	JA	14538	54	M
8	KB	14078	23	M
9	LM	14399	51	F
10	ZM	09802	60	F
11	JH	10120	43	F
12	DP	08438	45	F
13	ET	09473	63	F
14	LC	09990	38	F
15	AA	14568	57	F
16	HF	00706	67	F
17	NR	02271	50	F
18	HR	15518	52	F
19	FD	13964	32	F
20	IS	13035	46	F
21	KP	03825	41	F
22	JM	10420	32	F
23	AM	08690	65	F
24	NK	12925	62	F
25	KS	15142	46	F
26	RS	09280	44	M
27	RH	05925	41	M
28	LS	15746	37	F

Subject Number	Subject Initials	CRL ID #	Age	Sex
29	MM	08786	63	F
30	SG	14821	43	F
31	HP	07754	68	F
32	DS	06408	39	F
33	VB	14072	66	F
34	RF	10436	69	F
35	TP	14507	42	F
36	KC	09476	54	F
37	DG	01828	44	F
38	BC	01703	69	F
39	AP	03541	52	F
40	AG	15019	23	M
41	MV	15003	50	F
42	LH	13156	42	M
43	MT	15911	49	F
44	SR	15278	37	F
45	MM	08660	58	F
46	BM	00087	58	F
47	JS	03048	37	F
48	JC	13903	45	F
49	AM	13657	20	M
50	ES	14911	48	F
51	MP	12044	57	F
52	GV	15704	33	M
53	LN	14920	45	F
54	PS	03839	46	F
55	MF	15890	42	F
56	VP	15507	23	F



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TABLE I

Tabulation of Individual Scores

Test Material: EnviroPure 301 (CRL18802-1)

PATCH TEST CONDITION: Test as received **PATCH TYPE:** Semi-occlusive

Subject Number	Subject Initials	CRL ID #	Induction Scores									Challenge Scores			
			1	2	3	4	5	6	7	8	9	24 Hr	48 Hr	72 Hr	
1	MD	11617	0	0	0	0	0	0	0	0	0	0	0	0	0
2	DR	13607	0	0	0	0	0	0	0	0	0	0	0	0	0
3	ES	09428	0	0	0	0	0	0	0	0	0	0	0	0	0
4	GA	15147	0	0	0	0	0	0	0	0	0	0	0	0	0
5	GL	14892	0	0	0	0	0	0	0	0	0	0	0	0	0
6	WL	07361	0	0	0	0	0	0	0	0	0	0	0	0	0
7	JA	14538	0	0	0	0	0	0	0	0	0	0	0	0	0
8	KB	14078	0	Discontinued Study											
9	LM	14399	0	0	0	0	0	0	0	0	0	0	0	0	0
10	ZM	09802	0	0	0	0	0	0	0	0	0	0	0	0	0
11	JH	10120	0	0	0	0	0	0	0	0	0	0	0	0	0
12	DP	08438	0	0	0	0	0	0	0	0	0	0	0	0	0
13	ET	09473	0	0	0	0	0	0	0	0	0	0	0	0	0
14	LC	09990	0	0	0	0	0	0	0	0	0	0	0	0	X
15	AA	14568	0	0	0	0	0	0	0	0	0	0	0	0	0
16	HF	00706	0	0	0	0	0	0	0	0	0	0	0	0	0
17	NR	02271	0	0	0	0	0	0	0	0	0	0	0	0	0
18	HR	15518	0	0	0	0	0	0	0	0	0	0	0	0	0
19	FD	13964	0	0	0	0	0	0	0	0	0	0	0	0	0
20	IS	13035	0	0	0	0	0	0	0	0	0	0	0	0	0
21	KP	03825	0	0	0	0	0	0	0	0	0	0	0	0	0
22	JM	10420	0	0	0	0	0	0	0	0	0	0	0	0	0
23	AM	08690	0	0	0	0	0	0	0	0	0	0	0	0	0
24	NK	12925	0	0	0	0	0	0	0	0	0	0	0	0	0
25	KS	15142	0	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent



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**TABLE I
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Tabulation of Individual Scores

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			1	2	3	4	5	6	7	8	9	24 Hr	48 Hr	72 Hr
26	RS	09280	0	0	0	0	0	0	0	0	0	0	0	0
27	RH	05925	0	0	0	0	0	0	0	0	0	0	0	0
28	LS	15746	0	0	0	0	0	0	0	0	0	0	0	0
29	MM	08786	0	0	0	0	0	0	0	0	0	0	0	0
30	SG	14821	0	0	0	0	0	0	0	0	0	0	0	0
31	HP	07754	0	0	0	0	0	0	0	0	0	0	0	0
32	DS	06408	0	0	0	0	0	0	0	0	0	0	0	0
33	VB	14072	0	0	0	0	0	0	0	0	0	0	0	0
34	RF	10436	0	0	0	0	0	0	0	0	0	0	0	0
35	TP	14507	0	0	0	0	0	0	0	0	0	0	0	0
36	KC	09476	0	0	0	0	0	0	0	0	0	0	0	0
37	DG	01828	0	0	0	0	0	0	0	0	0	0	0	0
38	BC	01703	0	0	0	0	0	0	0	0	0	0	0	0
39	AP	03541	0	0	0	0	0	0	0	0	0	0	0	0
40	AG	15019	0	0	0	0	0	0	0	0	0	0	0	0
41	MV	15003	0	0	0	0	0	0	0	0	0	0	0	0
42	LH	13156	0	0	0	0	0	0	0	0	0	0	0	0
43	MT	15911	0	0	0	0	0	0	0	0	0	0	0	0
44	SR	15278	0	0	0	0	0	0	0	0	0	0	0	0
45	MM	08660	0	0	0	0	0	0	0	0	0	0	0	0
46	BM	00087	0	0	0	0	0	0	0	0	0	0	0	0
47	JS	03048	0	0	0	0	0	0	0	0	0	0	0	0
48	JC	13903	0	0	0	0	0	0	0	0	0	0	0	0
49	AM	13657	0	0	0	0	0	0	0	0	0	0	0	0
50	ES	14911	0	0	0	0	0	0	0	0	0	X	0	0

X = Subject Absent



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(Continued)**

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			1	2	3	4	5	6	7	8	9	24 Hr	48 Hr	72 Hr	
51	MP	12044	0	0	0	0	0	0	0	0	0	0	0	0	0
52	GV	15704	0	0	0	0	0	0	0	Discontinued Study					
53	LN	14920	0	0	0	0	0	0	0	0	0	0	0	0	0
54	PS	03839	0	0	0	0	0	0	0	0	0	0	0	0	0
55	MF	15890	0	0	0	0	0	0	0	0	0	0	0	0	0
56	VP	15507	0	0	Discontinued Study										