



**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:** Enviro Pure 310 Batch No. 10902

**CRL STUDY NUMBER:** CRL111002

**AUTHORIZED SIGNATURES:**

Handwritten signature of Bruce E. Kanengiser in black ink, written over a horizontal line.

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

Handwritten signature of George J. Neumaier in black ink, written over a horizontal line.

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

Handwritten signature of Marilee Candino in black ink, written over a horizontal line.

**Marilee Candino, R.N.**  
Director/Clinical Services

Handwritten signature of Michael J. Muscatiello in black ink, written over a horizontal line.

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

**REPORT DATE:** November 21, 2002



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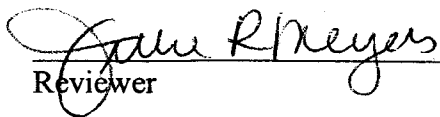
**Good Clinical Practice  
Final Report Review Statement**

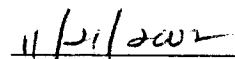
**Clinical Study Number:** CRL111002

**Start Date:** September 30, 2002

**Completion Date:** November 8, 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 September 25, 2002:

Enviro Pure 310 Batch No. 10902

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

CRL111002

The test material was tested as received.

#### STUDY DATES

This study was initiated on September 30, 2002 and was completed on November 8, 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. Seven subjects discontinued study participation for reasons unrelated to the test material. A total of 49 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 49 subjects and under the conditions of this study, the sample identified as Enviro Pure 310 Batch No. 10902 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
57	DJ	15823	23	F
58	MJ	11599	39	M
59	LN	14920	45	F
60	JL	06319	34	F
61	TS	17093	22	F
62	JV	17101	42	F
63	KA	16701	50	F
64	CK	02313	42	F
65	DG	01828	44	F
66	HP	07754	69	F
67	MK	11951	48	F
68	TR	15196	55	F
69	DM	15195	59	F
70	BK	14848	59	F
71	MM	15711	45	F
72	KB	17080	35	M
73	MC	13430	43	M
74	BY	17038	47	F
75	LL	17103	19	F
76	AP	16236	26	F
77	MC	16497	56	F
78	RB	10492	35	F
79	JH	15412	35	F
80	LK	09568	30	F
81	AD	15642	65	M
82	JB	05171	51	F
83	ME	01693	47	F
84	AH	07601	36	F

Subject Number	Subject Initials	CRL ID #	Age	Sex
85	MJ	01875	42	F
86	AA	08730	43	F
87	JM	07179	42	F
88	DC	12376	47	F
89	JM	12757	35	F
90	JW	16392	36	F
91	LF	00771	46	F
92	BM	00087	58	F
93	DB	14756	34	F
94	LJ	13038	55	F
95	JR	15859	28	F
96	NQ	10096	55	F
97	HM	15712	43	M
98	VM	00863	34	F
99	JG	17106	32	F
100	TS	17107	40	F
101	AJ	05488	56	F
102	LA	14506	31	F
103	CE	12823	41	F
104	DP	08438	46	F
105	CW	16399	42	F
106	RV	03808	51	F
107	CM	04021	68	F
108	TB	16546	53	F
109	PL	15956	39	F
110	LW	12613	22	F
111	MS	15256	49	F
112	BR	15502	45	F





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**TABLE I  
 (Continued)**

**Tabulation of Individual Scores**

**Test Material:** Enviro Pure 310 Batch No. 10902 (CRL111002)

**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		
82	JB	05171	0	0	0	0	0	0	0	0	0	0	0	0		
83	ME	01693	0	0	0	0	0	0	0	0	0	0	0	0		
84	AH	07601	0	0	Discontinued Study											
85	MJ	01875	Discontinued Study													
86	AA	08730	0	0	0	0	0	0	0	0	0	0	0	0		
87	JM	07179	0	0	0	0	0	0	0	0	0	0	0	0		
88	DC	12376	0	0	0	0	0	0	0	0	0	0	0	0		
89	JM	12757	0	0	0	0	0	0	0	0	0	0	0	0		
90	JW	16392	0	0	0	0	0	0	0	0	0	0	0	0		
91	LF	00771	0	0	0	0	0	0	0	0	0	0	0	0		
92	BM	00087	0	0	0	0	0	0	0	0	0	0	0	0		
93	DB	14756	0	0	0	0	0	Discontinued Study								
94	LJ	13038	0	0	0	0	0	0	0	0	0	0	0	0		
95	JR	15859	0	0	0	0	0	0	0	0	0	0	0	0		
96	NQ	10096	0	0	0	0	0	0	0	0	0	0	0	0		
97	HM	15712	0	0	0	0	0	0	0	0	0	0	0	0		
98	VM	00863	0	0	0	0	0	0	0	0	0	0	0	0		
99	JG	17106	0	0	0	0	0	0	0	0	0	0	0	0		
100	TS	17107	0	0	0	0	0	0	0	0	0	0	0	0		
101	AJ	05488	0	0	0	0	0	0	0	0	0	0	0	0		
102	LA	14506	0	0	0	0	0	0	0	0	0	X	0	0		
103	CE	12823	0	0	0	0	0	0	0	0	0	0	0	0		
104	DP	08438	0	0	0	0	0	0	0	0	0	0	0	0		
105	CW	16399	0	0	0	0	0	0	0	0	0	0	0	0		
106	RV	03808	0	0	0	0	0	0	0	0	0	0	0	0		

X = Subject Absent



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**TABLE I  
(Continued)**

**Tabulation of Individual Scores**

**Test Material:** Enviro Pure 310 Batch No. 10902

(CRL111002)

**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	
107	CM	04021	0	0	0	0	0	0	0	0	0	0	0	0	0
108	TB	16546	0	0	0	0	0	0	0	0	0	0	0	X	0
109	PL	15956	Discontinued Study												
110	LW	12613	Discontinued Study												
111	MS	15256	0	0	0	0	0	0	0	0	0	0	0	0	0
112	BR	15502	0	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent