



**Clinical  
Research  
Laboratories, Inc.**

**Final Report**

**Repeated Insult Patch Test**


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


**ATTENTION:** Bruce Tavares

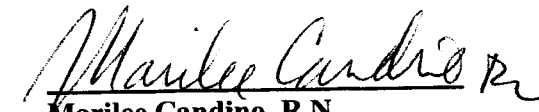
**TEST MATERIAL:** Enviro Pure 306 Batch No. 7162

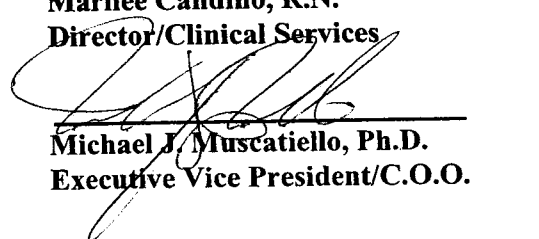
**CRL STUDY NUMBER:** CRL96402-4

**AUTHORIZED SIGNATURES:**

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

  
George J. Neumaier, M.D.  
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Director/Clinical Services

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

**REPORT DATE:** October 17, 2002



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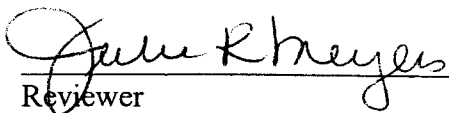
**Good Clinical Practice  
Final Report Review Statement**

**Clinical Study Number:** CRL96402-4

**Start Date:** August 26, 2002

**Completion Date:** October 4, 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

10/17/2002  
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 August 16, 2002:

Enviro Pure 306 Batch No. 7162

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

CRL96402-4

The test material was tested as received.

#### STUDY DATES

This study was initiated on August 26, 2002 and was completed on October 4, 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. Nine subjects discontinued study participation for reasons unrelated to the test material. A total of 47 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 47 subjects and under the conditions of this study, the sample identified as Enviro Pure 306 Batch No. 7162 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	DF	16692	44	F
2	DR	13607	53	F
3	NP	16915	39	M
4	DL	16927	40	F
5	JP	15332	28	F
6	AR	13392	62	F
7	CS	03643	50	F
8	MK	11942	30	F
9	RN	14458	30	F
10	LM	13745	58	F
11	RK	15853	58	M
12	DM	15498	56	F
13	SF	16570	37	F
14	JL	16904	20	F
15	KT	06277	47	F
16	BW	01644	62	F
17	BA	00164	43	F
18	JH	14416	70	F
19	VS	04571	34	F
20	RF	10436	69	F
21	GB	16920	62	F
22	NB	16907	50	M
23	FJ	06137	57	F
24	KM	16945	18	M
25	AL	13686	24	F
26	NG	15376	48	F
27	KB	16908	33	F
28	AG	15019	23	M

Subject Number	Subject Initials	CRL ID #	Age	Sex
29	JM	16167	45	F
30	AM	03950	43	F
31	AJ	06417	23	M
32	SR	15278	37	F
33	TW	16946	26	F
34	CL	14050	37	F
35	PL	16070	50	M
36	HV	16925	33	F
37	BT	16924	33	F
38	TS	16923	33	F
39	TD	16941	26	F
40	RM	16898	39	M
41	SV	14673	42	F
42	EW	00641	47	F
43	MM	15443	41	F
44	CC	16466	37	F
45	JB	07118	56	F
46	MD	05390	42	F
47	EA	16434	52	M
48	ME	01155	40	F
49	JB	16948	19	F
50	JB	16949	22	F
51	CP	16909	40	F
52	BG	16881	18	F
53	EM	15780	43	F
54	IC	16936	23	F
55	DD	16939	44	F
56	KL	16938	45	F





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**TABLE I**  
**(Continued)**

**Tabulation of Individual Scores**

**Test Material:** Enviro Pure 306 Batch No. 7162

(CRL96402-4)

**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
26	NG	15376	0	0	0	0	0	0	0	0	0	0	0	0
27	KB	16908	0	0	0	0	0	0	0	0	0	0	0	0
28	AG	15019	0	0	0	0	0	0	0	0	0	0	0	0
29	JM	16167	0	0	0	0	0	0	0	0	0	0	0	0
30	AM	03950	0	0	0	0	0	0	0	0	0	0	0	0
31	AJ	06417	0	0	0	0	0	0	0	0	0	0	0	0
32	SR	15278	0	0	0	0	0	0	0	0	0	0	0	0
33	TW	16946	Discontinued Study											
34	CL	14050	0	0	0	0	0	0	0	0	0	0	0	0
35	PL	16070	0	0	0	0	0	0	0	0	0	0	0	0
36	HV	16925	0	0	0	0	0	0	0	0	0	0	0	0
37	BT	16924	0	0	0	0	0	0	0	0	0	0	0	0
38	TS	16923	0	0	0	0	0	0	0	0	0	0	0	0
39	TD	16941	0	0	0	0	0	0	0	0	0	0	0	0
40	RM	16898	0	Discontinued Study										
41	SV	14673	0	0	0	0	0	0	0	0	0	0	0	0
42	EW	00641	0	0	0	0	0	0	0	0	0	0	0	0
43	MM	15443	0	0	0	0	0	0	0	0	0	0	0	0
44	CC	16466	0	0	0	0	0	0	0	0	0	0	0	0
45	JB	07118	0	0	0	0	0	0	0	0	0	0	0	0
46	MD	05390	0	Discontinued Study										
47	EA	16434	Discontinued Study											
48	ME	01155	0	0	0	0	0	0	0	0	0	0	0	0
49	JB	16948	0	0	0	0	Discontinued Study							
50	JB	16949	0	0	0	0	Discontinued Study							

