



**Clinical  
Research  
Laboratories, Inc.**

**Final Report**

**Safety Evaluation of  
a Nail Polish Remover**


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

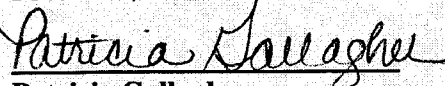
**ATTENTION:** Bruce Tavares


**TEST MATERIALS:** Nature Solv-Liquid


**CRL STUDY NUMBER:** CRL136702

**AUTHORIZED SIGNATURES:**

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

  
Patricia Gallagher  
Licensed Cosmetologist

  
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Director/Clinical Services

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

**REPORT DATE:** February 25, 2003



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**Good Clinical Practice  
Final Report Review Statement**

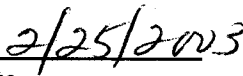
**Clinical Study Number:** CRL136702

**Start Date:** January 7, 2003

**Completion Date:** February 4, 2003

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

### Safety and Efficacy Evaluation of a Nail Polish Remover

#### PURPOSE

The purpose of this study was to evaluate the safety of a nail polish remover under exaggerated use conditions.

#### STUDY 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 December 17, 2002:

Nature Solv-Liquid

Brucci nail enamel and cotton pads were supplied by Clinical Research Laboratories, Inc.

All test materials were stored at room temperature and humidity. The jars of nail polish remover were coded with the CRL identification numbers listed below:

CRL136702-1 through CRL136702-27

#### STUDY DATES

This study was initiated on January 7, 2003 and was completed on February 4, 2003.



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## **PANELIST SELECTION**

Twenty-seven female panelists between the ages of 28 and 63 years were selected for the study (Panelist Demographics - Appendix I). All subjects had healthy nails and cuticles and were frequent users of nail products. No panelists participated in this study if they had repaired nails, recently removed tips, wraps or acrylics or were nail biters. No subject had a history of sensitivity to nail enamels or nail enamel removers. No pregnant or lactating women were included in the study. Subjects taking systemic or topical corticosteroids, anti-inflammatories or antihistamines were excluded from study participation. All panelists signed and completed a Panelist Profile/Medical History Form provided by Clinical Research Laboratories, Inc. prior to the study. All panelists signed an Informed Consent in compliance with 21 CFR Part 50: "Protection of Human Subjects".

## **TEST METHOD**

Upon arrival, a CRL technician examined the hands, nails, and cuticles of each subject to determine eligibility. An evaluation of the cuticles for signs of irritation was conducted and recorded (Table I).

Qualified subjects were given a supply of the test nail polish remover, nail enamel and cotton pads, along with instructions for use and a diary. Subjects were instructed to remove their nail enamel using the test product provided, 3 times per week for 4 weeks for a total of 12 uses. Subjects were instructed to use their usual brand of hand care products and not to introduce the use of any new hand care or nail products for the duration of the study.

Subjects returned after 4 weeks of use for a final evaluation of the cuticles for signs of irritation. The last use of the test product was within 24 hours of the final visit. Subjects returned the Diary and any unused product at the final visit.

## **TEST RESULTS**

All 27 subjects completed the study.

### **I. Dermatologic Evaluation**

A summary of dermal evaluations appear in Table I.

Four subjects exhibited slight to moderate dryness of the cuticles at the baseline examination, which diminished completely at the final examination. Four subjects, who exhibited no baseline irritation, exhibited mild dryness of one or more cuticles at the final examination. Nineteen subjects exhibited no erythema, edema or dryness at the baseline or final examination.



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## II. Daily Diary Summary

A review of daily diaries indicated that there were no adverse experiences reported during the study period.

## CONCLUSION

Based on the test population of 27 subjects and under the conditions of this study, the test material identified as Nature Solv-Liquid demonstrated no clinically significant potential for eliciting dermal irritation.

## RETENTION

All of the original score sheets of 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.

All test materials remaining at the conclusion of the study will be returned to the Sponsor.



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## Appendix I

### Safety and Efficacy Evaluation of a Nail Polish Remover

#### Panelist Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex
1	SB	16902	44	F
2	JM	07179	42	F
3	CD	16834	28	F
4	KM	00302	49	F
5	WW	16548	33	F
6	AR	17119	32	F
7	SV	14673	43	F
8	RG	17331	59	F
9	JS	13183	36	F
10	MR	17214	59	F
11	JD	02378	52	F
12	GP	17371	63	F
13	LR	15814	37	F
14	MM	15079	51	F
15	JT	16092	53	F
16	FM	12729	40	F
17	AT	14383	46	F
18	TB	17085	54	F
19	MD	01269	60	F
20	TP	14507	42	F
21	SW	17068	45	F
22	DM	16596	40	F
23	LJ	13038	55	F
24	KL	16938	46	F
25	DD	16939	44	F
26	CS	16293	38	F
27	SO	06837	38	F



# Clinical Research Laboratories, Inc.

Table I

Safety and Efficacy Evaluation of a Nail Polish Remover

**Dermatologic Evaluation**

Subject No.	Baseline Examination										Final Examination										
	Right Hand - Cuticles					Left Hand - Cuticles					Right Hand - Cuticles					Left Hand - Cuticles					
	S	R	M	I	T	S	R	M	I	T	S	R	M	I	T	S	R	M	I	T	
1	0	0	0	0	0	0	0	0	0	0	0	0	1D	0	1D	0	0	0	0	0	
2	0	0	0	0	0	0	0	0	0	0	0	0	1D	1D	1D	1D	1D	1D	1D	0	0
3	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
5	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
7	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
9	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
11	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
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	1D	1D	1D	0	0	0	0	0	1D	0	0	0	0	0	0	0	0	0	0
15	0	1D	1D	0	2D	0	0	0	1D	1D	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	1D	1D	1D	0	0	0	0	0	1D
17	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
19	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
21	0	0	0	0	0	1D	1D	1D	1D	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
23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	1D	0	1D	0	0	0	1D	1D	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	1D	0	0	0	0	0	0	0
26	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

Dermal Scoring Scale:

- 0 = None
- 1 = Slight
- 2 = Moderate
- 3 = Severe

- E = Erythema
- ed = Edema
- D = Dryness

Finger Code:

- S = Small Finger
- R = Ring Finger
- M = Middle Finger
- I = Index Finger
- T = Thumb