



**FINAL REPORT**


**CLIENT:** Cezanne Professional Products, LLC  
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Delray Beach, FL 33444  
US


**ATTENTION:** Lita Kaufman

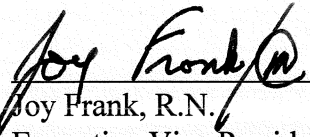
**TEST:** Repeated Insult Patch Test  
Protocol No.: CP-01.01S

**TEST MATERIAL:** Cezanne Perfect Finish Keratin Smoothing Treatment 16oz

**EXPERIMENT  
REFERENCE NUMBER:** C13-4918.01

Reviewed by:   
Richard R. Eisenberg, M.D.  
Medical Director  
Board Certified Dermatologist

Approved by:  23 Apr 2014  
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Approved by:  23 Apr 2014  
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Revision Date: April 23, 2014

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**QUALITY ASSURANCE UNIT STATEMENT**

**Study Number:** C13-4918.01

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Quality Assurance Representative

April 24, 2014

Date

**Objective:** To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

**Participants:** Fifty-seven (57) qualified subjects, male and female, ranging in age from 21 to 79 years, were selected for this evaluation. Fifty-five (55) subjects completed this study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

**Inclusion Criteria:**

- a. Male and female subjects, age 16<sup>a</sup> and over.
- b. Absence of any visible skin disease which might be confused with a skin reaction from the test material.
- c. Prohibition of use of topical or systemic steroids and/or antihistamines for at least seven days prior to study initiation.
- d. Completion of a Medical History form and the understanding and signing of an Informed Consent form.
- e. Considered reliable and capable of following directions.

**Exclusion Criteria:**

- a. Ill health.
- b. Under a doctor's care or taking medication(s) which could influence the outcome of the study.
- c. Females who are pregnant or nursing.
- d. A history of adverse reactions to cosmetics or other personal care products.

**Test Material:** Cezanne Perfect Finish Keratin Smoothing Treatment 16oz

<b>Study Schedule:</b>	<u>Panel #</u>	<u>Initiation Date</u>	<u>Completion Date</u>
	20130413	November 11, 2013	December 19, 2013

**Methodology:** Prior to the initiation of this study, the test material was prepared as a 10% dilution, using distilled water.

<sup>a</sup>With parental or guardian consent

**Methodology  
(continued):**

The upper back between the scapulae served as the treatment area. Approximately 0.2 ml of the test material, or an amount sufficient to cover the contact surface, was applied to the 1" x 1" absorbent pad portion of a clear adhesive dressing. This was then applied to the appropriate treatment site to form a semi-occlusive patch.

**Induction Phase:**

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home, twenty-four hours after application. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications were discontinued for the remainder of this test phase, if a moderate (2-level) reaction was observed on this new test site. Applications would also be discontinued if marked (3-level) or severe (4-level) reactivity was noted.

Rest periods consisted of twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours following each Saturday removal.

**Challenge Phase:**

Approximately two (2) weeks after the final Induction patch application, a Challenge patch was applied to a virgin test site adjacent to the original Induction patch site, following the same procedure described for Induction. The patch was removed and the site scored at the clinic twenty-four and seventy-two hours post-application.

**Methodology  
(continued):****Evaluation Criteria (Erythema and additional Dermal Sequelae):**

<b>0</b>	<b>=</b>	<b>No visible skin reaction</b>	<b>E</b>	<b>=</b>	<b>Edema</b>
<b>0.5</b>	<b>=</b>	<b>Barely perceptible</b>	<b>D</b>	<b>=</b>	<b>Dryness</b>
<b>1</b>	<b>=</b>	<b>Mild</b>	<b>S</b>	<b>=</b>	<b>Staining</b>
<b>2</b>	<b>=</b>	<b>Moderate</b>	<b>P</b>	<b>=</b>	<b>Papules</b>
<b>3</b>	<b>=</b>	<b>Marked</b>	<b>V</b>	<b>=</b>	<b>Vesicles</b>
<b>4</b>	<b>=</b>	<b>Severe</b>	<b>B</b>	<b>=</b>	<b>Bullae</b>
			<b>U</b>	<b>=</b>	<b>Ulceration</b>
			<b>Sp</b>	<b>=</b>	<b>Spreading</b>

Erythema was scored numerically according to this key. If present, additional Dermal Sequelae were indicated by the appropriate letter code and a numerical value for severity.

**Adverse Events:** There were no adverse events.

**Amendments:** There were no amendments.

**Deviations:** There were no deviations.

**Revision:** Client requested to have test material name changed.

**Results:** The results of each participant are appended (Table 1).  
Observations remained negative throughout the test interval.  
Subject demographics are presented in Table 2.

**Summary:** Under the conditions of this study, test material, Cezanne Perfect Finish Keratin Smoothing Treatment 16oz, did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1  
 Panel #20130413

Individual Results

Cezanne Perfect Finish Keratin Smoothing Treatment 16oz

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
1	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
3	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
5	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
7	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
9	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
11	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
13	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
15	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
17	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
19	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
21	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
23	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
25	0	0	0	0	0	0	0	0	0	0	0	0	0
26	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
28	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

24\* = Supervised removal of 1<sup>st</sup> Induction and Challenge Patch

Table 1  
 (continued)  
 Panel #20130413

Individual Results

Cezanne Perfect Finish Keratin Smoothing Treatment 16oz

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
30	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
32	0	0	0	0	0	0	0	0	0	0	0	0	0
33	-----DID NOT COMPLETE STUDY-----												
34	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
36	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
38	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
40	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
42	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
44	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
46	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
48	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
50	0	0	0	0	0	0	0	0	0	0	0	0	0
51	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
53	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
55	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
57	-----DID NOT COMPLETE STUDY-----												

24\* = Supervised removal of 1<sup>st</sup> Induction and Challenge Patch

Table 2  
Panel #20130413

Subject Demographics

Subject Number	Initials	Age	Sex
1	J-M	68	F
2	C-W	54	F
3	GVW	43	F
4	Y-F	36	F
5	LOF	62	M
6	KDL	50	F
7	AMQ	66	F
8	JPQ	61	F
9	K-T	38	F
10	CTJ	38	F
11	LCP	78	M
12	GCL	63	F
13	F-G	79	M
14	L-G	78	F
15	RAC	53	M
16	E-B	74	F
17	M-B	68	F
18	GCG	49	M
19	JJR	24	F
20	CES	43	F
21	IEF	69	F
22	JEF	75	F
23	JDG	63	F
24	EMG	62	F
25	SLW	43	F
26	RLM	65	F
27	SKS	60	F
28	B-L	74	F
29	T-S	62	M



Table 2  
(continued)  
Panel #20130413

Subject Demographics

Subject Number	Initials	Age	Sex
30	D-M	62	F
31	DHM	46	M
32	D-Z	52	F
33	EJK	52	M
34	R-M	57	F
35	LSG	39	F
36	OKB	21	F
37	RLB	49	M
38	M-H	74	F
39	D-P	28	F
40	A-S	61	F
41	E-Q	51	M
42	SCS	61	F
43	MAH	73	F
44	FAR	73	M
45	JCR	73	F
46	WHR	59	M
47	A-C	77	M
48	M-M	22	M
49	JMM	67	F
50	CMD	22	F
51	KJD	59	M
52	M-D	70	F
53	GJD	73	M
54	HLC	45	M
55	J-V	36	M
56	B-C	72	F
57	OOB	50	M