CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FINAL REPORT

CLIENT: [redacted]

ATTENTION: Ivana Veljkovic

TEST: Repeated Insult Patch Test
Protocol No.: CP-01.01S
Protocol Date: 06/29/20

TEST MATERIAL: Stellar Cleanser, Lot#: [redacted]

STUDY NUMBER: C21-7666.02

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

Approved by: Joy Frank, R.N.
Executive Vice President, Clinical Evaluations

QUALITY ASSURANCE UNIT STATEMENT

Study Number: C21-7666.02

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 with no further notice in a manner that renders them useless.

Quality Assurance Representative

4-21-22
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.

Subjects: Fifty-nine (59) qualified subjects, male and female, ranging in age from 21 to 75 years, were selected for this evaluation. Fifty (50) subjects completed this clinical trial. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

Inclusion Criteria:

1. Subjects must have read, signed, and dated an Informed Consent Form that included a HIPAA statement;
2. Subjects who were male or female, aged 16-79 years, inclusive;
3. Subjects who were considered reliable and capable of understanding and following directions; and
4. Subjects aged 16 or 17 years must have read, signed, and dated an Adolescent Assent Form after their parent or legal guardian had read, signed, and dated an Informed Consent Form.

Exclusion Criteria:

1. Subjects who were in ill health, as determined by the Principal Investigator;
2. Subjects who were taking medication, other than birth control, that, in the opinion of the Investigator, could have influenced the purpose, integrity, or outcome of the trial;
3. Subjects who had used any prescribed or OTC anti-inflammatory, antihistamine, corticosteroid, immunosuppressant, or antibiotic drug within 7 days prior to initiation of the trial or during their participation on this trial;
4. Female subjects who were pregnant, planning to become pregnant, or lactating during the trial;
5. Subjects with any visible disease, sunburn, scars, excessive tattoos, etc., that might have been confused with a skin reaction to the test material or, as determined by the Principal Investigator, might have interfered with the evaluation;
6. Subjects who had a history of adverse reactions to cosmetics, adhesive tapes, OTC drugs, or other personal care products; or
7. Subjects who introduced the use of any new cosmetic, toiletry, or personal care products during the trial.

Test Material: Stellar Cleanser, Lot#: [redacted]

Trial Schedule:

Panel #	Initiation Date	Completion Date
20220015	February 9, 2022	April 14, 2022

Methodology:

The informed consent process fully apprised each potential subject of the risks and benefits associated with the research clinical trial and of the confidentiality requirements relating to the subject's clinical trial records. If the potential subject agreed to participate in the research clinical trial, then the potential subject executed the Informed Consent Form (ICF) after which the potential subject entered the clinical trial as a subject. Staff who conducted the informed consent process also executed the form. Each subject received a signed copy of the fully executed ICF. If at any time during the clinical trial the subject had questions, the ICF directed the subject to a Subject Rights Advocate, whose contact information was in the ICF. Subjects completed a Medical History Form to determine initial qualification.

Prior to the initiation of this clinical trial, the test material was prepared as a 10% dilution, using distilled water.

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 in^2 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, one day 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 one day following each Tuesday and Thursday removal, and two days following each Saturday removal.

Methodology (continued):

Challenge Phase:

At least 10 days following the final Induction Phase patch removal, 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 Day 1 and Day 3 post-application.

Evaluation Criteria (Erythema and additional Dermal Sequelae):

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

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.

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 clinical trial, test material, Stellar Cleanser, Lot#: [redacted] indicated no potential for dermal irritation or allergic contact sensitization.

Table 1
Panel #20220015

Individual Results

Stellar Cleanser, Lot#: [redacted]

Subject Number	Induction Phase										Virgin Challenge Site	
	Day1*	1	2	3	4	5	6	7	8	9	Day 1*	Day 3
1	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
3	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
5	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
7	0	0	0	0	0	0	WITHDREW CONSENT					
8	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
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	WITHDREW CONSENT							
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0[m]	0	0	0	0	0	0
14	WITHDREW CONSENT											
15	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
17	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
19	0	WITHDREW CONSENT										
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	WITHDREW CONSENT								
22	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
24	0	WITHDREW CONSENT										
25	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
27	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
29	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal
m = Additional makeup day granted at the discretion of the clinic supervisor

Table 1
(continued)
Panel #20220015

Individual Results

Stellar Cleanser, Lot#: [redacted]

Subject Number	Day1*	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site Day 1*	Day 3
30	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
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	----------WITHDREW CONSENT----------										
36	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
38	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
40	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
42	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
44	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
46	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
48	0	0	0	0	0	0	0	---------WITHDREW CONSENT--------				
49	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
51	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
53	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
55	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	----WC---	
57	0	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal
WC = Withdrew consent

Table 2
Panel #20220015

Subject Demographics

Subject Number	ID#	Age	Gender
1	91777	61	F
2	38796	53	F
3	27864	61	F
4	16599	72	F
5	48073	48	F
6	91755	45	F
7	91776	58	M
8	64599	69	F
9	91786	37	M
10	85801	51	F
11	91811	56	F
12	91761	30	M
13	91821	61	F
14	91783	21	F
15	76666	66	F
16	91815	40	M
17	91796	54	M
18	91828	57	M
19	91831	69	F
20	85513	61	F
21	91833	42	F
22	91820	53	F
23	91853	35	M
24	91840	65	F
25	59484	37	F
26	91854	40	F
27	91839	32	F
28	91856	53	F
29	91858	44	F

Table 2
(continued)
Panel #20220015

Subject Demographics

Subject Number	ID#	Age	Gender
30	65310	55	F
31	85752	72	M
32	91863	46	F
33	91838	53	M
34	91837	23	F
35	77553	27	F
36	91859	34	M
37	87071	59	F
38	9225	61	F
39	54357	55	F
40	91874	62	F
41	55452	67	F
42	84430	57	F
43	91795	44	M
44	5822	60	F
45	91646	64	M
46	91826	62	F
47	85935	49	M
48	83442	55	F
49	86028	51	F
50	83441	22	F
51	91869	43	F
52	90737	72	F
53	66198	75	F
54	48843	51	F
55	48845	53	M
56	2773	51	F
57	6222	59	F
58	73659	69	F
59	76927	37	F