

FINAL REPORT

CLIENT:	Olaplex, LLC

1482 East Valley Road #701 Santa Barbara, CA 93108

ATTENTION:

TEST: Repeated Insult Patch Test

Protocol No.: CP-01.01S Protocol Date: 09/28/14

TEST MATERIAL: Olaplex No. 7 Bonding Oil Lot: 59-27

STUDY NUMBER: C18-7629.01

Reviewed by:

Approved by:

Approved by:

Revision Date: February 13, 2019





FDA Registration# 1000151293 DEA Registration# RC0199744 Schedule I-V US EPA/NJ DEP Registration# NJD982726648 ISO/IEC 17025:2005 Accredited



QUALITY ASSURANCE UNIT STATEMENT

Study Number: C18-7629.01

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



2-14-19 Date

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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:

One hundred twelve (112) qualified subjects, male and female, ranging in age from 16 to 76 years, were selected for this evaluation. One hundred six (106) 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^a to 79 years.
- 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:

Olaplex No. 7 Bonding Oil Lot: 59-27

Study Schedule: Panel # Initiation Date Completion Date

20180541 December 10, 2018 January 25, 2019

^aWith parental or guardian consent

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Methodology:

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 one day following each Tuesday and Thursday removal, and two days 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 Day 1 and Day 3 post-application.

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Methodology (continued):

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	\mathbf{V}	=	Vesicles
4	-	Severe	В	=	Bullae
			\mathbf{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:

Subject #93 was unable to report on Day 1 post challenge application. He kept his patches in place until the following testing day. He was, therefore, evaluated on Day 2 and Day 3 post challenge application. The Principal Investigator deemed that this would not affect test results.

Revision:

Report revised to update sample name due to typographical error on client sample submission form.

Results:

The results of each participant are appended (Table 1).

Observations remained within normal limits throughout the test interval.

Subject demographics are presented in Table 2.

Summary:

Under the conditions of this study, test material, Olaplex No. 7 Bonding Oil Lot: 59-27, indicated no potential for dermal irritation or allergic contact sensitization.

Revised: 2/13/19

Table 1 Panel #20180541

Individual Results

Olaplex No. 7 Bonding Oil Lot: 59-27

Subject					Indu	ction Ph	ase				Virgin Ch Site	
Number	Day1*	11	2	3	4	5	6	7	8	9	Day1*	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	0	0	0	0	0	0
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	O	0	0	0
11	0	0	0	0	0	0	0	0	O	0	0	0
12	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
14	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
16	0	0	0	0	0	0	0	0	O	0	0	0
17	0	0	0	0	0	0^{m}	0	0	0	0	0	0
18	0	0	1 ^{E1}	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	O	0	0	0
21	0	0	0	0	0	0	0	0	O	0	0	0
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	0	0	0	0	0	0	0	0	0	0	0
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

E = Edema

Table 1 (continued) Panel #20180541

Individual Results

Olaplex No. 7 Bonding Oil Lot: 59-27

					2 31	50 101500			5006 Pc 15 11		Virgin Cl	
Subject											Site	
Number	Day1*	1	2	3	4	5	6	7	8	9	Day1*	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				D	ID NOT	COMP	LETE S	TUDY-			
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	0	0	0	0	0	0	0	0	0	0	0
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	O	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	O	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	O	0	0	0	0
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				I	OID NO	T COM	PLETE S	STUDY			
53	0	0	O	0	0	0	0	O	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	0	0
57	0	0	0	0	0	0	0	O	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal

Table 1 (continued) Panel #20180541

Individual Results

Olaplex No. 7 Bonding Oil Lot: 59-27

Subject					Indu	ction Ph	ase				Virgin Cl Site	
Number	Day1*	1	2	3	4	5	6	7	8	9	Day1*	
59	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0
61	0				D	ID NOT	COMP	LETE S	TUDY-			
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0
76	0	0	0	0	0	0	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	O	0	0	0	0
84	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal

Revised: 2/13/19

Table 1 (continued) Panel #20180541

Individual Results

Olaplex No. 7 Bonding Oil Lot: 59-27

Subject					Indu	ction Ph	ase		o ne en ee ne ne ee ne ee ne ee		Virgin Cl Site	
Number	Day1*	1	2	3	4	5	6	7	8	9	Day1*	Day 3
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0					DID N	OT CC	MPLET	E STUI)YY		
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	O	0	0	0
93	0	0	0	0	0	0	0	0	O	0	0**	0
94	0	0	0	0	0	0	0	0	0	0	DN	C
95	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0
101	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	O	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	$0_{\mathbf{m}}$	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	D	ID NOT	COMPL	ETE STUDY	
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal

** = Observation recorded on Day 2, per deviation

DNC = Did not complete study

m = Additional makeup day granted at the discretion of the clinic supervisor

Table 2 Panel #20180541

Subject			
Number	Initials	Age	Gender
1	KRG	57	F
2	A-L	65	F
3	SAR	63	F
	GYM	53	F
4		58	F
5	LPF	53	F
6	DMO		
7	LCS	65	M F
8	HFH	66	
9	E-T	55	M
10	S-A	50	F
11	LSG	69	F
12	DTN	40	M
13	SKF	50	F
14	PDF	54	F
15	F-S	25	M
16	J-D	30	F
17	A-C	46	F
18	WIP	60	F
19	MYL	37	F
20	EMH	29	F
21	C-H	47	F
22	GAC	68	F
23	DCG	65	F
24	LDP	71	F
25	JKG	17	F
26	TLV	57	F
27	YDC	49	F
28	CJP	72	F
29	KLB	32	F

Table 2 (continued) Panel #20180541

Subject			
Number	Initials	Age	Gender
20	MUC	65	F
30	MVC		r F
31	S-P	61	
32	RRE	48	M
33	LMB	58	F
34	GCL	72	F
35	R-G	76	F
36	J-L	40	F
37	LDC	61	F
38	KJC	52	M
39	CMP	50	F
40	JGP	16	M
41	NAC	21	F
42	QAT	39	M
43	SAM	54	F
44	JAE	50	F
45	SPP	29	F
46	EPS	16	F
47	WAM	50	F
48	JPM	23	M
49	RAG	32	M
50	TAS	44	F
51	G-G	46	F
52	LYH	29	F
53	A-R	67	F
54	MJF	37	F
55	N-D	27	F
56	DNB	66	F
57	D-M	39	F
58	E-B	32	M

Table 2 (continued) Panel #20180541

Subject			
Number	Initials	Age	Gender
	***	•	_
59	JMP	20	F
60	MAD	48	F
61	M-G	27	F
62	DMD	44	F
63	MCJ	35	F
64	LJB	54	F
65	J-D	32	F
66	NPF	51	F
67	CMB	51	F
68	A-R	54	F
69	KRM	56	F
70	G-S	50	F
71	RET	56	M
72	DCA	73	F
73	AMD	70	F
74	JCD	70	F
75	RJD	62	M
76	ACT	64	F
77	JST	65	M
78	LSZ	48	F
79	EAZ	16	M
80	TAZ	16	M
81	J-S	39	F
82	BAG	60	F
83	N-T	56	F
84	LML	35	F
85	AEC	26	F
86	IRE	30	F
87	MIO	50	F

Table 2 (continued) Panel #20180541

Subject			
Number	Initials	Age	Gender
88	AFC	26	M
89	TAW	51	F
	DMP	23	F
90	AJV	28	M
91	YNR	50	F
92		35	M
93	RAM	33	F
94	CZA		г М
95	MLH	60 53	
96	PME	53	F F
97	KDG	58	
98	GLE	54	M
99	MFH	58	M
100	EMS	64	F
101	BAM	59	F
102	W-B	73	F
103	MJR	68	F
104	MSM	43	M
105	V-K	29	F
106	SKH	36	M
107	D-P	63	F
108	LMF	76	F
109	MRH	47	F
110	R-M	61	M
111	WSK	57	F
112	J-H	59	M