

FINAL REPORT

CLIENT: Cosway Company, Inc. 20633 Fordyce Ave

Carson, CA 90810

US

ATTENTION:

TEST: Repeated Insult Patch Test

Protocol No.: CP-01.01S

TEST MATERIAL: OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17,

Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

EXPERIMENT

REFERENCE NUMBER: C17-4001.02

Reviewed by:

Approved by:

Approved by:

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.



QUALITY ASSURANCE UNIT STATEMENT

Study Number: C17-4001.02

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 in a manner that renders them useless.



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 thirteen (113) qualified subjects, male and female, ranging in age from 18 to 69 years, were selected for this evaluation. One hundred seven (107) 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.
- A history of adverse reactions to cosmetics or other personal care products.

Test Material:

OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

Study Schedule: Panel # Initiation Date Completion Date

20170311 August 23, 2017 September 28, 2017

^aWith parental or guardian consent

Methodology:

Prior to the initiation of this study, 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" 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.

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:

During the rest phase of RIPT, Subject #90 went to the emergency room at Mountainside Hospital, Montclair, N.J. for treatment of a generalized rash over most of her body. She was given an injection of hydrocortisone and Benadryl and provided with an Epi pen. She did report that she had changed her brand of soap that she had been using. The Principal Investigator judged the severity of this response as severe, but unlikely related to the test material. She was removed from this clinical trial.

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 study, test material, OLAPLEX NO. 5

MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050, indicated no potential for dermal irritation or

allergic contact sensitization.

Table 1 Panel #20170311

OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

											Virgin C	
Subject Number		Induction Phase									Site	
	Day1*	1	2	3	4	5	6	7	8	9	Day1*	Day 3
1	0	0	0	0	0	0	0		-DID N	от сом	PLETE STU	DY
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	0	0	0	0
11	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
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	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	0	0	0	0	0	0	0	0	0	0	0
20	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
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

Table 1 (continued) Panel #20170311

OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

Subject	etInduction Phase							Virgin Cl Site				
Number	Day1*	1	2	3	4	5	6	7	8	9	Day1*	
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	0	0	0	0			-DID NO	OT COM	IPLETE:	STUDY	
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	0	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	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	0	0
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

Table 1 (continued) Panel #20170311

OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

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	0	0	0	0	0	0	0	0	0	0	0
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						-DID NO	OT COM	IPLETE	STUD	Y		
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		-DID N	OT COM	PLETE STUD)Y
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	0	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

Table 1 (continued) Panel #20170311

OLAPLEX NO. 5 MOISTURE BOND CONDITONER 07/31/17, Fno. FC-393-56, Bno. SM-394-54, Part no. 545-7050

C-1-14					T., J.,	-4: DI-					Virgin Cl Site	
Subject Number	D1*	1	2	3	Inau 4	ction Pn	ase	7	8	9	Site Day1*	
Number	Day1*	1			4		0		8	9	Dayı	Day 3
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	DNC	C
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0
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	0	0	0	0
104	0	0	0	0	0	0	0	0	-DII	NOT CO	OMPLETE ST	UDY-
105	0	0	0	0	0	0	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	0	0	0	0	0
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
113	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal
DNC = Did not complete study

Table 2 Panel #20170311

Subject			520 500
Number	Initials	Age	Gender
1	R-S	50	M
2	DJD	69	M
3	MLH	59	M
4	MLH	64	F
5	GLE	53	M
6	MFH	57	M
7	GLM	29	F
8	EMS	67	M
9	BFF	57	F
10	PAD	57	F
11	J-C	57	M
12	XLO	55	F
13	KMB	55	F
14	PAS	66	F
15	MAM	36	M
16	S-S	44	F
17	SAM	54	F
18	CJA	61	F
19	J-D	69	M
20	CJB	45	F
21	GCD	68	F
22	E-R	33	F
23	MEG	49	M
24	C-P	46	F
25	JJS	65	F
26	R-M	59	M
27	LRR	38	M
28	J-H	58	M
29	PME	52	F

Table 2 (continued) Panel #20170311

Subject			
Number	Initials	Age	Gender
30	ALS	35	M
31	PCC	69	F
32	RGS	43	F
33	K-S	64	M
34	EMS	62	F
35	EAC	50	M
36	MHB	65	F
37	R-V	63	F
38	RTE	64	M
39	JED	35	F
40	FCR	49	F
41	GCP	65	F
42	MKP	43	F
43	D-T	68	F
44	HRH	37	F
45	TMH	64	M
46	MBK	62	M
47	J-V	39	M
48	HLG	42	M
49	HLC	49	M
50	TSS	50	F
51	MEO	46	F
52	MDA	55	M
53	G-D	64	M
54	J-D	59	F
55	SMW	65	F
56	ANG	60	F
57	VLL	39	· F
58	MRH	46	F

Table 2 (continued) Panel #20170311

Subject			
Number	Initials	Age	Gender
50	D D	64	M
59	D-D	29	M
60	G-H		
61	PAB	66	F
62	LMP	47	F
63	G-M	49	F
64	FMC	55	F
65	VMA	58	M
66	RFP	66	M
67	FTF	59	M
68	CWF	59	F
69	JEZ	67	F
70	AVM	52	M
71	TSB	32	F
72	G-M	36	F
73	SKF	28	F
74	JAA	40	F
75	RMP	26	F
76	DMO	51	F
77	MAS	47	M
78	KAD	59	F
79	SAB	56	F
80	LAK	52	F
81	C-C	40	F
82	L-S	44	F
83	MML	41	F
84	FTC	57	M
85	M-B	46	F
86	JHW	60	F
87	TLV	56	F

Table 2 (continued) Panel #20170311

Subject			
Number	Initials	Age	Gender
00	MEH	56	F
88	CNH	21	F
89			
90	KGM	35	F
91	N-M	46	F
92	MAO	63	F
93	LAM	54	M
94	ALM	54	M
95	ERD	24	M
96	RMG	62	F
97	TSS	37	F
98	M-S	48	F
99	M-D	35	F
100	P-M	28	M
101	KAP	54	F
102	NGM	56	F
103	CTH	37	M
104	JMR	43	M
105	JMB	29	M
106	A-R	18	F
107	ENR	48	F
108	C-S	59	F
109	BKB	65	F
110	C-B	38	F
111	S-Y	31	M
112	A-Y	59	F
113	Y-W	46	F