

FINAL REPORT

CLIENT:	
ATTENTION:	Ivana Veljkovic
TEST:	Repeated Insult Patch Test Protocol No.: CP-01.01S Protocol Date: 05/17/22
TEST MATERIAL:	HA Pep Lot Number: Formula Number:
STUDY NUMBER:	C22-6760.01

Reviewed by: Richard R. Eisenberg, M.D.

Medical Director

Board Certified Dermatologist

Approved by: Joy Frank, R.N.

Executive Vice President, Clinical Evaluations



FDA Registration# 1000151293 DEA Registration# RC0199744 Schedule I-V US EPA/NJ DEP Registration# NJD982726648 ISO/IEC 17025:2017 Accredited

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QUALITY ASSURANCE UNIT STATEMENT

Study Number: C22-6760.01

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 five (5) years. At any time prior to the completion of the fifth 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

234-33 Date

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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-six (56) qualified subjects, male and female, ranging in age from 21 to 78 years, were selected for this evaluation. Fifty-three (53) 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:	HA	Pep	Lot	Number:	Formula	Number:	

Page 4 of 10

Trial Schedule: Panel # Initiation Date Completion Date

20220271 January 4, 2023 February 17, 2023

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.

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 in² 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	\mathbf{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

There were no adverse events.

Amendments:

There were no amendments.

Deviations:

There were no deviations.



Page 6 of 10

Results: The results of each participant are append	ded	(Table	1)).
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Observations remained negative throughout the test interval.

Subject demographics are presented in Table 2.

Summary:

Under the conditions of this clinical trial, test material, HA Pep Lot Number: Formula Number: , indicated no

potential for dermal irritation or allergic contact sensitization.

Page 7 of 10

Table 1 Panel #20220271

Individual Results

HA Pep Lot Number Formula Number:

Subject					Ind	uction P	hase				Virgin S	Challenge ite
Number	Day1*	1	2	3	4	5	6	7	8	9		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	0	0	0	0	0	0
8					WIT	HDREV	W CONS	SENT				
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

Page 8 of 10

Table 1 (continued) Panel #20220271

Individual Results

HA Pep Lot Number: Formula Number:

Subject	17				Ind	uction P	hase				S	Challeng ite
Number	Day1*	11	2	3	4	5	6	7	8	9	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	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0			WI7	HDRE	W CON	SENT		
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	W	/ITHDRE	W CONSE	VT
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	$O_{\rm m}$	0	0	0	0	0
49				SU	BJECT	NUMBE	ER NOT	ASSIGN	VED			
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	O	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0^{m}	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

Day 1* = Supervised removal

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

Table 2 Panel #20220271

Subject Demographics

Subject		705	
Number	ID#	Age	Gender
1	9328	71	F
2	93041	32	M
3	93040	28	F
4	84162	77	F
5	2587	72	F
6	36860	78	F
7	50139	71	F
8	83152	71	F
9	92740	66	M
10	71085	64	M
11	91609	42	F
12	67526	28	F
13	46058	40	F
14	4058	68	F
15	63820	63	F
16	92347	56	F
17	88259	57	F
18	63469	33	F
19	63294	36	M
20	8162	52	M
21	92081	21	M
22	57910	56	F
23	57911	57	M
24	80470	54	M
25	54458	77	F
26	35746	41	F
27	3851	65	F
28	84695	42	F
29	86384	64	M

Table 2 (continued) Panel #20220271

Subject Demographics

Subject			~ .
Number	ID#	Age	Gender
30	43449	45	M
31	76480	30	M
32	90641	31	F
33	38376	50	F
34	69287	52	F
35	55568	35	F
36	86989	50	M
37	90343	53	F
38	86031	33	F
39	77282	68	F
40	80978	23	M
41	88163	37	F
42	203	73	F
43	93219	67	F
44	47011	43	F
45	33067	67	M
46	55761	57	F
47	34027	57	M
48	82461	45	F
49	-	-	-
50	49630	59	F
51	92022	55	M
52	92095	60	F
53	80104	67	F
54	148	67	F
55	85456	31	M
56	92616	61	M
57	43174	37	F

^{- =} Subject number not assigned