Consumer Product Testing Co.
EST. 1973

FINAL REPORT

CLIENT:

Creative Strategy, Inc.
High Park Nihonbashi Bldg. 4F
2-45-4 Nihonbashi-Hamacho
Chuo-ku, Tokyo 103-0007, Japan

SPONSOR:

IST Corporation
3-3 Kanda Kaji-cho
Chiyoda-ku, Tokyo
101-0045, Japan

TEST:

48 Hour Patch Test
Protocol No.: CP-01.02

TEST MATERIAL:

Cathode circulation system Electrolyzed water ph 12.7

EXPERIMENT REFERENCE NUMBER:

C13-4785.02

Reviewed by:

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

Approved by:

Michael Caswell, Ph.D., CCRA, CCRC
Vice President, Clinical Evaluations

Approved by:

Joy Frank, R.N.
Executive Vice President, Clinical Evaluations

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QUALITY ASSURANCE UNIT STATEMENT

Trial Number: C13-4785.02

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.

Quality Assurance Representative

11/20/13
Date

Objective: To determine by epidermal contact the primary irritation potential of a test material.

Participants: Fifty-two (52) subjects, male and female, ranging in age from 16 to 78 years, who qualified were selected for this evaluation. Fifty-one (51) subjects completed this study. The remaining subject discontinued his participation for personal reasons unrelated to the use of the test material.

Inclusion Criteria:

a. Male and female subjects, age 16[a] 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: Cathode circulation system Electrolyzed water ph 12.7

Study Schedule:

Panel #	Initiation Date	Completion Date
20130404	November 5, 2013	November 8, 2013

[a]With parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. An amount sufficient to cover the contact surface was applied to the 3/4" x 3/4" absorbent pad portion of an adhesive dressing. When secured to the appropriate treatment site, this dressing formed an occlusive patch.

The test material remained in contact with the skin for a total of forty-eight hours. This site was then evaluated for gross changes. Absence of any visible skin change was assigned a zero value. The test site was re-evaluated at seventy-two hours.

As instructed, the test material was not exposed to the air, when not in use.

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 within normal limits throughout the test interval.

Subject demographics are presented in Table 2.

Summary:

Under the conditions of this study, test material, Cathode circulation system Electrolyzed water ph 12.7, did not indicate a clinically significant potential for dermal irritation.

Table 1
Panel #20130404

Individual Results

Cathode circulation system Electrolyzed water ph 12.7

Subject Number	Observations 48 Hours	72 Hours
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	**1**[E1]
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0
21	0	0
22	0	0
23	0	0
24	0	0
25	0	0
26	0	0
27	0	0

E = Edema

Table 1
(continued)
Panel #20130404

Individual Results

Cathode circulation system Electrolyzed water ph 12.7

Subject Number	Observations 48 Hours	72 Hours
28	0	0
29	0	0
30	0	0
31	0	0
32	0	0
33	0	0
34	0	0
35	0	0
36	0	0
37	0	0
38	0	0
39	0	0
40	0	0
41	0	0
42	0	0
43	0	0
44	0	0
45	0	0
46	0	0
47	0	0
48	0	DNC
49	0	0
50	0	0
51	0	0
52	0	0

DNC = Did not complete study

Table 2
Panel #20130404

Subject Demographics

Subject Number	Initials	Age	Sex
1	SET	74	F
2	PLB	67	F
3	GSG	71	F
4	VKB	68	F
5	DLC	66	M
6	KAD	67	F
7	REM	76	F
8	SLD	66	F
9	PAF	66	F
10	AAS	67	F
11	CAB	66	F
12	MIH	72	F
13	JCC	77	F
14	M-P	48	F
15	JDC	26	M
16	REC	32	F
17	ALW	24	F
18	SAR	46	F
19	DLM	52	F
20	D-L	46	F
21	LMV	50	F
22	ATD	53	F
23	DAB	56	F
24	RSS	24	F
25	B-N	78	M
26	L-N	63	F
27	FAB	37	F

Table 2
(continued)
Panel #20130404

Subject Demographics

Subject Number	Initials	Age	Sex
28	AMC	26	F
29	NEH	18	F
30	MEL	55	F
31	VMR	50	F
32	KTJ	18	M
33	AEA	51	F
34	L-A	36	M
35	D-L	53	F
36	EMF	61	F
37	LJD	43	F
38	CAC	24	F
39	KWH	45	M
40	MGV	63	F
41	G-D	48	M
42	LVB	30	F
43	BRK	53	F
44	DAF	57	F
45	AMM	29	F
46	L-H	36	F
47	LNG	29	F
48	J-K	48	M
49	XMN	16	F
50	GJB	27	M
51	LJA	36	F
52	BLB	25	M