Consumer Product Testing Co.

EST. 1975

FINAL REPORT

CLIENT:	Mizue Aikawa ARGO, Inc. 4-7-37-B203 Minamitanaka Nerima-ku, Tokyo 177-0035, Japan
SPONSOR:	Kikuboshi Co., Ltd. No. 8 Kikuboshi Tower Bldg 3-20-18 Asakusabashi, Taito-ku Tokyo 111-0053, Japan
TEST:	Repeated Insult Patch Test Protocol No.: 1.01
TEST MATERIAL:	Moissage Hand Treatment
EXPERIMENT REFERENCE NUMBER:	C09-0211.01

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

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

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QUALITY ASSURANCE UNIT STATEMENT

Study No.: C09-0211.01

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. These studies have been performed with adherence to the applicable ICH Guideline E6 for Good Clinical Practice and requirements provided for in 21 CFR parts 50 and 56 and in accordance to standard operating procedures and applicable protocols. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study. All data pertinent to this study will be stored in the Consumer Product Testing Company archive, unless specified otherwise, in writing by the Sponsor.

Quality Assurance personnel involved:

Quality Assurance — Date: 3/11/09

The representative signature of the Quality Assurance Unit signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols.

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: Fifty-seven (57) qualified subjects, male and female, ranging in age from 16 to 75 years, were selected for this evaluation. Fifty-five (55) 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] 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: Moissage Hand Treatment

Study Schedule:

Panel #	Initiation Date	Completion Date
20090015	January 19, 2009	February 26, 2009

[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 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. It was noted that due to inclement weather, numerous subjects were unable to report as scheduled. Those subjects who also required a makeup day may have experienced a delay between applications.

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 twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours 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 twenty-four and seventy-two hours 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.

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, Moissage Hand Treatment, did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1
Panel #20090015

Individual Results

Moissage Hand Treatment

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	72 hr
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	----------DID NOT COMPLETE STUDY----------											
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	----------DID NOT COMPLETE STUDY----------								
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^W	0	0	0	0	0	0	0
17	0	0	0	0	0^W	0	0	0	0	0	0	0
18	0	0	0	0	0^W	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^W	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^W	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^W	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
0^W = Inclement weather. Subject unable to report as scheduled.

Table 1
(continued)
Panel #20090015

Individual Results

Moissage Hand Treatment

Subject Number	24*hr	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site 24*hr	72 hr
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	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^{W}	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

24* = Supervised removal of 1st Induction and Challenge Patch
0^{W} = Inclement weather. Subject unable to report as scheduled.

Table 2
Panel #20090015

Subject Data

Subject Number	Initials	Age	Sex
1	PP	54	F
2	TP	58	F
3	CO	38	F
4	KC	60	F
5	JB	66	M
6	CD	46	F
7	LJ	44	F
8	CS	71	M
9	RS	69	F
10	RF	59	M
11	WM	48	M
12	RC	43	M
13	LG	59	F
14	JL	67	F
15	ML	41	F
16	AD	56	F
17	JD	25	M
18	JD	60	M
19	EG	44	M
20	SC	27	F
21	CR	47	F
22	GJ	39	F
23	MK	67	F
24	DA	65	M
25	JF	29	F
26	CA	37	M
27	MH	38	F
28	HC	40	M
29	FK	46	F

Table 2
(continued)
Panel #20090015

Subject Data

Subject Number	Initials	Age	Sex
30	CA	32	F
31	IR	49	F
32	BE	34	F
33	AE	17	F
34	MR	54	F
35	CC	71	M
36	CC	55	F
37	BM	17	F
38	CM	16	F
39	KM	45	F
40	DS	33	F
41	EJ	66	F
42	AS	23	M
43	RE	21	F
44	CM	68	F
45	RA	30	M
46	IO	56	F
47	FY	29	F
48	OY	49	F
49	JD	68	F
50	DM	53	F
51	BT	45	F
52	JT	17	F
53	LH	46	F
54	YD	48	F
55	LC	75	F
56	GC	52	F
57	MY	43	M