



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

CLIENT: Folex Imaging
6 Daniel Road East
Fairfield, NJ 07004

ATTENTION: David Robinson

TEST: Repeated Insult Patch Test
Protocol No.: 1.01

TEST MATERIAL: INKJET TATTOO MATERIAL

**EXPERIMENT
REFERENCE NUMBER:** C01-0093.01

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QUALITY ASSURANCE UNIT STATEMENT

Study No.: C01-0093.01

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected at time intervals to assure the integrity of the study. The findings of such inspections are reported to management and the Study Director. All materials and data pertinent to this study will be stored or disposed of in accordance with current Standard Operating Procedures.

Date(s) of inspection: March 8, 2001
 March 21, 2001
 March 23, 2001
 March 27, 2001

Senior personnel involved:

OnChi Cheung, B.S. - Quality Assurance Supervisor
Carol Ann Higgins, B.S. - Quality Assurance Associate


Kathleen Alworth, B.A.
Director of Quality Assurance

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-nine (59) qualified subjects, male and female, ranging in age from 18 to 77 years, were selected for this evaluation. Fifty-seven (57) 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: INKJET TATTOO MATERIAL

Study Schedule:	<u>Panel #</u>	<u>Initiation Date</u>	<u>Completion Date</u>
	20010069	February 5, 2001	March 15, 2001

^aWith parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. The release paper was removed and the tattoo was applied to the appropriate treatment site. This sample was positioned to ensure that the adhesive side maintained direct skin contact.

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 are 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. It was noted that due to a holiday weekend and/or inclement weather which occurred during the Induction Phase, subjects who required a makeup day experienced a delay between applications.

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 Key:

- 0 = No visible skin reaction
- + = Barely perceptible or spotty erythema
- 1 = Mild erythema covering most of the test site
- 2 = Moderate erythema, possible presence of mild edema
- 3 = Marked erythema, possible edema
- 4 = Severe erythema, possible edema, vesiculation, bullae and/or ulceration

Results:

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

Observations remained within normal limits throughout the test interval.

Summary:

Under the conditions of this study, test material, INKJET TATTOO MATERIAL, did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1
 Panel #20010069

Individual Results

INKJET TATTOO MATERIAL

Subject Number	24*hr	Induction Phase									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
1	0	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	0
3	0	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	0
5	0	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	0
7	0	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	0
9	0	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	0
11	0	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	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	0
15	0	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	0
17	0	0	1	0	0	0	0	0	0	0	0	0	0
18	0	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	0
20	0	0	0	0	0	0	0	0	0	0 ^w	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	0
23	0	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	0
25	0	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	0
27	0	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	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 - = Subject not present for supervised removal
 W = Inclement weather, subject unable to report as scheduled

Table 1
 (continued)
 Panel #20010069

Individual Results

INKJET TATTOO MATERIAL

Subject Number	24*hr	Induction Phase									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
30	0	0	0	0	0	0	0	0	0	0	--DNC--		
31	0	0	0	0	0	-----DID NOT COMPLETE STUDY-----							
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 ^w	0	0
35	0	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	0
37	0	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	0
39	0	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	0
41	0	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	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0 ^w	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0 ^w	0	0
47	0	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	0
49	0	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	0
51	0	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	0
53	0	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	0
55	0	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	0
57	0	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	0
59	-	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 - = Subject not present for supervised removal
 W = Inclement weather, subject unable to report as scheduled

DNC = Did not complete study

Table 2
Panel #20010069

Subject Data

Subject Number	Initials	Age	Sex
1	AG	61	F
2	EM	38	F
3	DS	27	M
4	FC	62	F
5	LJ	40	F
6	DB	69	F
7	RM	51	F
8	RS	36	F
9	JP	43	F
10	WS	43	F
11	ML	19	F
12	CP	41	F
13	CH	40	F
14	IC	47	F
15	RC	45	F
16	GP	50	F
17	LQ	40	F
18	JB	36	M
19	SP	44	M
20	DR	61	F
21	BM	41	F
22	JG	56	F
23	DG	59	F
24	JR	65	M
25	DP	46	F
26	TP	37	M
27	MF	57	F
28	RC	18	F
29	JZ	36	F

Table 2
(continued)
Panel #20010069

Subject Data

Subject Number	Initials	Age	Sex
30	EL	47	F
31	AR	20	F
32	RS	29	F
33	AM	59	F
34	PM	53	F
35	LP	42	M
36	JZ	41	F
37	JP	53	M
38	LC	51	M
39	AG	45	F
40	AC	65	M
41	JM	32	F
42	LC	49	F
43	HD	55	M
44	TS	42	F
45	NS	49	F
46	AR	33	F
47	RL	48	F
48	CP	50	F
49	SF	66	F
50	RF	45	F
51	PR	77	F
52	DT	53	F
53	JM	31	F
54	GF	37	F
55	JF	40	M
56	HK	33	F
57	CF	46	F
58	GC	30	F
59	VE	20	F