Phenyl-Substituted Methicones

data5_PhenylSubMethicones_092022.pdf

EXPERT PANEL MEETING
September 26-27, 2022

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: April 21, 2022

SUBJECT: Trimethylsiloxyphenyl Dimethicone, Diphenylsiloxy Phenyl Trimeticone, Phenyl Trimethicone and Diphenyl Dimethicone

Anonymous. 2005. Human patch test (shine gloss containing 5.0% Trimethylsiloxyphenyl Dimethicone).

Anonymous. 2012. Determination of the irritating propensities of serum (containing 2.0% Trimethylsiloxyphenyl Dimethicone) on human skin.

Anonymous. 2009. Repeated insult patch test (cream containing 3.0% Trimethylsiloxyphenyl Dimethicone).

Anonymous. 2012. Determination of the photo-allergic potential of serum (containing 2.0% Trimethylsiloxyphenyl Dimethicone): In humans.

Anonymous. 2019. Human patch test (late night ampoules containing 0.5% Diphenylsiloxy Phenyl Trimethicone).

Anonymous. 2019. Repeated insult patch test (product containing 0.5% Diphenylsiloxy Phenyl Trimethicone).

Anonymous. 2009. Human patch test (eye primer containing 10.0% Phenyl Trimethicone).

Anonymous. 2010. A 14-day cumulative irritation assay (SPF cream containing 3.2363% Phenyl Trimethicone).

Anonymous. 2014. An evaluation of the contact sensitization potential of topically-coded products in human skin by means of the human maximization assay (concealer containing 26.18% Phenyl Trimethicone).

Anonymous. 2012. An assessment of the photosensitization potential of three topical coded test products using a human photocontact allergenicity assay (lotion 2 contains 7.5% Phenyl Trimethicone).

Anonymous. 2008. Human patch test (lip color containing 9.06% Diphenyl Dimethicone).

[redacted]

RESEARCH AND DEVELOPMENT
[redacted] DEPARTMENT

[redacted] **REPORT: HUMAN PATCH TEST**

This test follows the procedure described in SOP, HPT.1 **TO:** [redacted]

PRODUCT PROFILE NO: [redacted] DATE: May 16, 2005 LAB REF.: [redacted]05

1. TEST MATERIAL: [redacted] Shine Gloss F#[redacted]. contains 5% Trimethylsiloxyphenyl Dimethicone
2. CONTROL MATERIAL: [redacted] Frizz Relief Shine Spray Lot#33370 F[redacted]
3. TEST PROCEDURE:

Single-Insult (24hr.)__X__ Occlusive (Blenderm) Patch__X__Semi-Occlusive Patch_____.

4. CONCENTRATION:

Full-Strength_X_ Aqueous ____ Solution _____ Dispersion_____ Aqueous Paste_____.
Other:_____.

__X__Volatiles were allowed to evaporate on the patch ~30 minutes prior to occlusion. Patch was hydrated just prior to application to skin _____.

5. TEST RESULTS:

TEST MATERIAL	*SUBJECTS*	*IRRITATION SCORE**									
		0	±	1	1+	2	2+	3	3+	4	PII
[redacted]s Shine Gloss F#[redacted]	18	18	0	0	0	0	0	0	0	0	0.00
[redacted]s Frizz Relief Shine Spray F#[redacted]	18	18	0	0	0	0	0	0	0	0	0.00

___ Skin staining noted. Erythematous response were read "through" the Stain.

6. CONCLUSIONS:

A. There were no significant differences in irritancy observed between the Test Material (s) and the Reference Control (s)._X_.

B. _____.

Study Conducted By: [redacted] Approved By: [redacted]

* SCORE
0 = No evidence of any effect.
± (Barely Perceptible) = minimal faint uniform or spotty erythema
1 (Mild) = Pink uniform erythema covering most of the contact site.
2 (Moderate) = Pink-red erythema visibly uniform in entire contact area.
3 (Marked) = Bright red erythema with accompanying edema petechiae or papules.
4 (Severe) = Deep red erythema with vesiculation or weeping with or without edema.

+, 1+, 2+ and 3+ = Intermediate scores contributing 0.5, 1.5, 2.5 and 3.5 respectively, to the P.I.I.
P.I.I. - Primary Irritation Index - a value depicting the average skin response of the test panel as a whole. It is calculated by choosing the higher of the two Irritation Scores per panelist, adding them all together and dividing by the total number of test subjects.

CC: [redacted]

[redacted]

[redacted]

REPORT: [redacted]

serum contains 2.0%
Trimethylsiloxyphenyl Dimethicone

DETERMINATION OF THE IRRITATING PROPENSITIES OF SERUM; CODE [redacted] ON HUMAN SKIN

Prepared for

[redacted]

30 January 2012

TABLE OF CONTENTS

SITE OF STUDY

[redacted]

STAFF

[redacted] BA	President
[redacted] MDCM	Medical Director
[redacted] MD	Dermatologist
[redacted]	Director, Dermatological Studies
[redacted]	Senior Technician
[redacted]	Senior Technician
[redacted]	Director, Quality Assurance

STATEMENT OF COMPLIANCE WITH GOOD CLINICAL PRACTICES

This study was conducted in conformance with the standards of Good Clinical Practices that are applicable to the protection of subjects undergoing procedures such as those conducted in this study.

2/1/12
Date

[redacted]
Director, Dermatological Studies

6 February 2012
Date

[redacted] MDCM
Medical Director

1 FEB 12
Date

[redacted] MD
Dermatologist

STATEMENT OF QUALITY ASSURANCE

In my review of the data I have found no discrepancies between the information presented in this report and the records that were kept during the conduct of this study.

2/1/12
Date

[redacted]

[redacted]

Serum
Code [redacted]

DETERMINATION OF THE CUMULATIVE IRRITATING PROPENSITIES OF SERUM [redacted] IN VIVO

1.00 OBJECTIVE:

.01 To determine whether an article submitted for study was capable of causing visible skin damage under the conditions of the regimen described in this protocol.

.02 To provide the sponsor with a basis for obtaining an estimate of the magnitude of the hazard of primary and/or cumulative irritation that may be expected when the product represented by the study sample becomes available for wide-spread use by the general public..

2.00 METHOD:

.01 WEEKS #1, #2, and #3

a. The study articles (test and control) were applied under an appropriate, occlusive patch on each subject on ten occasions, i.e. on Monday, Tuesday, Wednesday, Thursday, and Friday during Weeks #1 and #2.

b. The patches were removed following approximately 24 hours of contact on Tuesday, Wednesday, Thursday, and Friday.

c. Patches applied on Friday remained untouched over the weekend and were removed the following Monday.

d. The sites were graded for irritation following patch removal.

3.00 SPONSOR: [redacted]

Project Director: [redacted]

Authorization: Letter dated January 5, 2012 from [redacted]

4.00 STUDY PRODUCT:

Type of Product:	Serum	
Sponsor Identification:	Code [redacted]	
Date received:	1/6/12	
Form used in study:	As supplied	[redacted] N° 29800
Standard:	Cream #3	[redacted] N° 29804
SLS Control:		[redacted] N° 29805
Blank Control:		[redacted] N° 29806

5.00 DATES OF STUDY:

Started: 9 January 2012
Completed: 23 January 2012

6.00 SELECTION OF SUBJECTS:

.01 RECRUITMENT:

a. Candidates were recruited from local townships and boroughs.

b. All candidates were required to come to the clinic to give informed consent.

c. A medical history was obtained from each candidate.

.02 INFORMED CONSENT:

All individuals who expressed interest in participating were given a prepared document which informed a prospective subject of the following items and required that the individual sign it before she/he participated.

a. How many subjects were to be enrolled in the study.
b. What type of study articles would be applied to the skin.
c. How the test was to be performed.
d. That the test was being performed to obtain information about the effects of the study article on human skin.
e. That the test was not being performed to benefit the subject's skin, health, or quality of life.
f. That exposure to one or more of the study articles may have adverse effects and, to the extent that was known, the different ways that participation could be detrimental to a subject's skin, health, or quality of life.
g. That not all adverse effects could be foreseen and made known to the prospective subject at the time the informed consent document was presented to her/him.
h. The commitments which she/he was asked to make to ensure that the data that would be generated would be meaningful.
i. The rights endowed on a subject for her/his protection.
j. What avenues of recourse were available if the subject felt that she/he had been wrongly used.
k. What considerations a subject would be entitled to receive and the conditions for receiving them.

.03 DETERMINATION OF ELIGIBILITY:

a. **Inclusion Criteria:** Acceptance was dependent on satisfying every inclusion criterion.
   i. The candidate was at least eighteen years old, and
   ii. agreed to comply fully with the instructions and the schedule of the study regimen, and expressed awareness that a participant would incur risks that would affect her/his well-being, and
   iii. denied that the amount of the stipend had induced her/him to participate against her/his better judgment, and
   iv. had read the informed consent agreement, and
   v. had assured the interviewer that she/he had no questions about the informed consent's contents that had not been answered to her/his satisfaction, and
   vi. had signed the consent form willingly and without reservation.

b. **Exclusion Criteria:** Any one of the following items was cause for rejection:
   i. The candidate had an illness that contraindicated participation; or
   ii. a condition that rendered the skin unsuitable for use in this study; or
   iii. was using dosages of anti-inflammatory medications that could alter the skin's tolerance; or
   iv. had a documented history of intolerance to the category of articles submitted for study; or
   v. seemed incapable of grasping the meaning and intent of the provisions in the consent form,
   vi. was a female who was pregnant or was breastfeeding an infant.

.04 PANEL INFORMATION:

a. [redacted]

b. **Demographics:**

SEX	Number	Age
Female	19	23 – 81
Male	9	23 – 81

c. **Dedication:** This was an exclusive panel, i.e. the subjects were not engaged in the evaluation of materials submitted by sponsors other Avon Products, Inc.

[redacted]

Serum Code [redacted]

7.00 SITE INFORMATION:

.01 LOCATION:

Serum; Code [redacted] was assigned Band #1 on the left side of the back of each subject.
Cream #3; Code [redacted] was assigned Band #5 on the left side of the back of each subject.
Positive Control; SLS 0.25% was assigned Band #6 on the left side of the back of each subject.
Negative Control; Blank Patch was assigned Band #7 on the left side of the back of each subject.

.02 IDENTIFICATION OF A CONTACT SITE:

At each visit the skin around the contact site was marked to facilitate examinations after the device was removed and positioning of subsequently-applied devices as precisely as was feasible on the same site.

8.00 PATCHES:

.01 TYPE OF PATCH:

Occlusive patches consisted of a 2cm x 2cm absorbent, non-woven fabric pad centered on the adhesive-coated surface of a 4cm x 4cm square of a water impermeable plastic film.

.02 PREPARATION OF A PATCH:

a. All patches were prepared in the clinic by experienced technicians.
b. Test and Standard material bearing patches: The webril pad of a patching device was infused with approximately 200µl of the test material.
c. Sodium Lauryl Sulfate (SLS) bearing patches: The webril pad of a patching device was infused with approximately 200µl of a 0.25% SLS solution.
d. Untreated Control patches: The patching device was prepared without any further preparation.

.03 ASSURING QUALITY OF PREPARED PATCHES:

Periodically, prepared patches selected at random from the patch table were examined and weighed to ascertain whether the patches had been properly prepared.

.04 APPLYING A PATCHING PATCH:

a. All patches were applied in the clinic by experienced, trained technicians.
b. A prepared patch, bearing the number of the site to which it had been assigned, was positioned on its assigned site on a subject with the surface of the treated/untreated pad in contact with the skin.
c. Firm pressure was applied to the outer surface of the patch to bring the surface of the pad into intimate contact with the skin.
d. The flanges of the patch were firmly affixed to the skin surrounding the pad thus sealing in the pad and its contents.
e. The skin around the patch was marked with a skin-marking pen. These marks made it easier for the technicians to locate the skin that had been previously exposed after the patching patches had been removed.
f. A technician examined a subject's back before the subject was dismissed to make sure that each site was covered with the appropriately numbered patch.

.05 REMOVING A PATCH:

a. A technician removed the patch as gently as was feasible.
b. If a residue impeded examination of a site, appropriate measures to remove the residue were used.
c. If a situation demanded that contact be terminated before subjects were scheduled to return to the clinic, each subject was called without delay and instructed to remove the patch herself/himself.

.01 UNDERSTANDING THE MAGNITUDE OF AN IRRITANT EFFECT:

Although numbers are used to designate the intensities of gross skin changes that are occasioned by applied study articles, direction only is intended, e.g., a Grade 2 denotes a more intense response than a Grade 1 denotes, but not necessarily one that is twice as intense. By the same token, a Grade 3 response should not be considered three times as harsh as a Grade 1 response.

.02 CRITERIA FOR GRADING OF ADVERSE EFFECTS:

Response	Visible Change	Grade
Absent	None	0
Inflammation		
	Redness	
	-mild	1
	-well defined, possible (barely perceptible) edema	2
	Redness plus	
	-edema	3
	-edema with vesiculation and ulceration	4

10.00 EFFECTS ATTRIBUTABLE TO THE STUDY ARTICLE:

a. Applications were continued on an assigned site as long as a certain level of skin damage that mandated abandonment of the site was not attained.
b. Applications were stopped for the remainder of the study when an intense effect (grade 3 or greater) was elicited. In that event, the site was automatically assigned the grade (3 or greater) that caused the termination for the remainder of the study.

11.00 DAILY REGIMEN:

.01 INITIAL/INDUCTION PHASE – WEEK #1

Monday:

i. When a subject presented herself/himself at the clinic, a technician examined the area of skin assigned to the study article to ascertain that it was fit to receive the applications to follow. The technician noted that the condition of the skin met all baseline criteria and directed the subject into the patch room.
ii. In the patching room, a second technician cleansed the skin.
iii. The technician applied a patch that has been loaded with 200µl of the appropriate study product to its assigned contact site. The same procedure was used to apply the SLS control patch and the untreated control patch.
iv. The technician marked the skin around the patches.
v. The technician dismissed the subject with instructions to return at approximately the same time on Tuesday.

Tuesday:

i. When a subject returned, a technician ascertained whether the patches were securely attached and reinforced the site locating marks.
ii. The technician removed the patches and graded the reactions at each site in accordance with the criteria presented in section 9.02.
iii. The technician directed the subject into the patching room.

iv. In the patching room, a second technician assessed any responses to assure that they had not worsened since the initial examination. If the site was judged to have a response of grade 2 or less, a freshly prepared patch was reapplied. If the site was judged to have a response of grade 3 or greater, all further patching of that site was terminated and the assessed score was arbitrarily assigned to that site for the remainder of the study.
v. The technician reinforced the site locating marks.
vi. The technician dismissed the subject with instructions to return at approximately the same time on Wednesday.

Wednesday:

i. The procedure was the same as for Tuesday of Week 1 except that the subject was directed to return on Thursday.

Thursday:

i. The procedure was the same as for Tuesday of Week 1 except that the subject was directed to return on Friday.

Friday:

i. The procedure was the same as for Tuesday of Week 1 except that the subject was dismissed for the weekend with instructions to allow the patches to remain in place and to return on the following Monday.

Saturday, Sunday:

i. No procedures were performed.

.02 INITIAL/INDUCTION PHASE – WEEK #2

Monday:

i. When a subject returned, a technician ascertained whether the patches were securely attached and reinforced the site locating marks.
ii. The technician removed the patches and graded the reactions at each site in accordance with the criteria presented in section 9.02.
iii. The technician directed the subject into the patching room.
iv. In the patching room, a second technician assessed any responses to assure that they had not worsened since the initial examination. If the site was judged to have a response of grade 2 or less, a freshly prepared patch was reapplied. If the site was judged to have a response of grade 3 or greater, all further patching of that site was terminated and the assessed score was arbitrarily assigned to that site for the remainder of the study.
v. The technician reinforced the site locating marks.
vi. The technician dismissed the subject with instructions to return at approximately the same time on the following day.

Tuesday, Wednesday, Thursday, Friday:

i. The procedures were the same as described on corresponding days of Week 1.

Saturday and Sunday:

i. No procedures were performed.

.03 INITIAL/INDUCTION PHASE – WEEK #3

Monday:

i. When a subject returned, a technician ascertained whether the patches were securely attached and situated on their assigned site positions.
ii. The technician removed the patches and graded each site for irritation in accordance with the criteria outlined in section 9.02. The grades were recorded.
iii. If appropriate, a site(s) was treated with a topical steroid, Betamethasone Valerate.
iv. The subject was dismissed from the study unless follow-up treatment was indicated.

[redacted]

Serum Code [redacted]

12.00 PROCEDURE DEVIATIONS:

None were necessary.

13.00 RESULTS: (Cf. Appendix I)

All of the twenty-eight subjects completed the study in accordance with the protocol design and all had complete attendance.

01. Sample: Serum [redacted]

No irritation was noted on twenty-seven of the twenty-eight subjects. A maximum score of Grade 1 intensity was noted on two occasions on one subject.

02. Sample: Cream #3 [redacted]

No irritation was noted on ten of the twenty-eight subjects. A maximum score of Grade 1 intensity was noted on four subjects; of grade two intensity on one subject; and of grade 3 intensity on thirteen subjects.

03. Sample: SLS Control 0.25%:

A maximum score of Grade 1 intensity was noted on one subject; of grade two intensity on one subject; and of grade 3 intensity on twenty-six subjects.

04. Sample: Untreated Control:

No irritation was noted on any of the twenty-six subjects.

05. Calculations Summary Table:

	TVR[1]	MCIS[2]	MDIS[3]	CII[4]
Serum [redacted]	2	0.07	0.007	0.002
Cream #3 [redacted]	215	7.68	0.768	0.256
0.25% SLS solution	513	18.32	1.832	0.611
Blank device	0	0.00	0.00	0.000

i. TVOR = Total Value of Responses = sum of daily scores for all subjects,
ii. MCIS = Mean Cumulative Irritation Score. = Total number of responses divided by number of subjects
iii. MDIS = Mean Daily Irritation Score = Mean Cumulative Irritation Score divided by number of applications.
iv. CII = Cumulative Irritation Index = Mean Daily Irritation Score divided by 3.

06. Clinical Significance:

CII	
0.00 to <0.07 =	Negligible or non significant irritation
0.07 to <0.16 =	Minimal or weak irritancy potential
0.16 to <0.23 =	Mild irritancy potential
0.23 to <0.34 =	Moderate irritancy potential
≥0.34 =	Severe irritancy potential

14.00 CONCLUSIONS:

.01 SERUM; CODE [redacted] was capable of producing inconsistent faint irritation on one subject.

.02 SERUM; CODE [redacted] has a negligible or non significant irritation potential.

.03 SERUM; CODE [redacted] is not contraindicated for usages entailing repeated applications on human skin.

[redacted]

Serum
Code [redacted]

APPENDIX I

15 Day CIT [redacted] [redacted] Serum # [redacted] Site: L-1 [redacted]

Subj. #	Study Day															Total
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
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	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	1	0	1			0	0	0	0	0			0	2
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
total	0	0	1	0	1			0	0	0	0	0			0	2
mean	0	0	0.038	0	0.038			0	0	0	0	0			0	0.007

15 Day CIT [redacted] [redacted] Cream #3 # [redacted] Site: L-5 [redacted]

	Study Day															
Subj. #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
1	0	0	0	0	0			0	0	0	0	0			0	0
2	0	0	0	0	1			2	3	3	3	3			3	18
3	0	0	1	0	2			3	3	3	3	3			3	21
4	0	0	0	0	0			1	1	2	3	3			3	13
5	0	0	0	0	0			0	2	3	3	3			3	14
6	0	0	0	0	2			3	3	3	3	3			3	20
7	0	0	0	0	0			1	1	1	1	1			0	5
8	0	0	0	0	0			1	1	0	0	0			0	2
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			3	3	3	3	3			3	18
13	0	0	0	0	0			0	0	0	0	0			0	0
14	0	0	0	0	0			0	0	3	3	3			3	12
15	0	0	0	0	0			0	0	0	0	0			0	0
16	0	0	0	0	0			0	0	0	1	3			3	7
17	0	0	0	0	0			0	0	0	0	0			0	0
18	0	0	0	1	1			1	1	1	3	3			3	14
19	0	0	0	0	0			0	0	2	2	2			2	8
20	0	0	0	0	1			0	3	3	3	3			3	16
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			1	2	3	3	3			3	15
24	0	0	0	0	0			1	2	2	3	3			3	14
25	0	0	0	0	0			1	1	3	3	3			3	14
26	0	0	0	0	0			0	0	0	0	1			0	1
27	0	0	0	0	0			0	0	0	1	1			1	3
28	0	0	0	0	0			0	0	0	0	0			0	0
total	0	0	1	1	7			18	26	35	41	44			42	215
mean	0	0	0.036	0.036	0.25			0.643	0.929	1.25	1.464	1.571			1.5	7.679

15 Day CIT - [redacted] [redacted] 0.25% SLS Control Site: L-6 [redacted]

	Study Day															
Subj. #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
1	0	0	0	0	0			0	0	2	3	3			3	11
2	0	0	0	0	2			3	3	3	3	3			3	20
3	0	0	1	3	3			3	3	3	3	3			3	25
4	0	0	0	3	3			3	3	3	3	3			3	24
5	0	0	1	3	3			3	3	3	3	3			3	25
6	0	0	1	3	3			3	3	3	3	3			3	25
7	0	0	0	0	2			3	3	3	3	3			3	20
8	0	0	0	2	3			3	3	3	3	3			3	23
9	0	0	0	0	0			2	3	3	3	3			3	17
10	0	0	0	0	0			2	3	3	3	3			3	17
11	0	0	0	0	1			1	0	0	3	3			3	11
12	0	0	0	0	0			0	0	3	3	3			3	12
13	0	0	0	0	0			1	1	3	3	3			3	14
14	0	0	0	0	0			3	3	3	3	3			3	18
15	0	0	0	0	0			1	3	3	3	3			3	16
16	0	0	0	0	3			3	3	3	3	3			3	21
17	0	0	0	0	0			3	3	3	3	3			3	18
18	0	0	1	3	3			3	3	3	3	3			3	25
19	0	0	0	0	1			2	3	3	3	3			3	18
20	0	0	0	2	3			3	3	3	3	3			3	23
21	0	0	0	0	0			0	1	0	3	3			3	10
22	0	0	0	1	2			3	3	3	3	3			3	21
23	0	0	0	1	1			2	3	3	3	3			3	19
24	0	0	0	2	2			3	3	3	3	3			3	22
25	0	0	0	1	2			0	0	0	0	0			0	3
26	0	0	0	0	0			1	3	3	3	3			3	16
27	0	0	0	1	3			3	3	3	3	3			3	22
28	0	0	0	0	1			1	3	3	3	3			3	17
total	0	0	4	25	41			58	68	74	81	81			81	513
mean	0	0	0.143	0.893	1.464			2.071	2.429	2.643	2.893	2.893			2.893	18.321

15 Day CIT - [redacted] [redacted] Blank Control Site: L-7 [redacted]

Subj. #	Study Day															Total
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
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	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
	0	0	0	0	0			0	0	0	0	0			0	0
mean	0	0	0	0	0			0	0	0	0	0			0	0.000

[redacted]

FINAL REPORT

CLIENT: [redacted]

ATTENTION: [redacted]

TEST: Repeated Insult Patch Test
Protocol No.: 1.01

TEST MATERIAL: Cream, Code [redacted]

contains 3.0% Trimethylsiloxyphenyl Dimethicone

EXPERIMENT REFERENCE NUMBER: [redacted]

Reviewed by: [redacted] M.D.
Medical Director
Board Certified Dermatologist

Approved by: [redacted] Ph.D., C.C.R.C., C.C.R.A.
Director, Clinical Evaluations

Approved by: [redacted] R.N.
Executive Vice President, Clinical Evaluations

[redacted]

[redacted]

QUALITY ASSURANCE UNIT STATEMENT

Study Number: [redacted]

The [redacted] Quality Assurance Unit (QAU) is responsible for monitoring the conduct, content and reporting of all clinical laboratory studies that are conducted at [redacted]

This study has been conducted in accordance with ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable regulations, [redacted] Standard Operating Procedures, and the approved Study Protocol.

The [redacted] QAU has reviewed all data, records, and documents relating to this study and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this study and also this Final Report have been reviewed and are deemed to be acceptable, and the study conforms to all of the requirements as indicated above.

[redacted]

Quality Assurance Representative

10/14/09

Date

[redacted]

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 sixteen (116) qualified subjects, male and female, ranging in age from 16 to 79 years, were selected for this evaluation. One hundred three (103) 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: Cream, Code [redacted]

Study Schedule:

Panel #	Initiation Date	Completion Date
[redacted]	August 31, 2009	October 8, 2009
	August 31, 2009	October 8, 2009

[a]With parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. Approximately 0.2 g of the test material, or an amount sufficient to cover the contact surface, was applied to the 3/4" x 3/4" absorbent pad portion of an adhesive dressing and allowed to volatilize for several minutes. This was then applied to the appropriate treatment site to form an 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 a holiday weekend, which occurred during the Induction Phase, subjects, who required a makeup day, 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.

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**	**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 within normal limits throughout the test interval.

Subject demographics are presented in Table 2.

Summary:

Under the conditions of this study, test material, Cream, Code [redacted] did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1
Panel [redacted]

Individual Results

Cream, Code [redacted]

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	---DID NOT COMPLETE STUDY---				
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

24* = Supervised removal of 1st Induction and Challenge Patch

Table 1
(continued)
Panel [redacted]

Individual Results

Cream, Code [redacted]

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	----------DID NOT COMPLETE 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	DNC
48	0	0	0	0	0	0	0	0	0	0	---DNC---	
49	0	----------DID NOT COMPLETE STUDY----------										
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

24* = Supervised removal of 1st Induction and Challenge Patch
DNC = Did not complete study

Table 1
(continued)
Panel [redacted]

Individual Results

Cream, Code [redacted]

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	----------DID NOT COMPLETE STUDY----------									
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	----------DID NOT COMPLETE STUDY----------											
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	----------DID NOT COMPLETE STUDY----------											
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[m]	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
m = Additional makeup day granted at the discretion of the clinic supervisor

Table 1
(continued)
Panel [redacted]

Individual Results

Cream, Code [redacted]

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	----------DID NOT COMPLETE STUDY----------											
34	----------DID NOT COMPLETE STUDY----------											
35	----------DID NOT COMPLETE STUDY----------											
36	----------DID NOT COMPLETE STUDY----------											
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	**0.5**	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	**2**[E2]	**0.5**	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	----------DID NOT COMPLETE STUDY----------						
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
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

24* = Supervised removal of 1st Induction and Challenge Patch

Table 2
Panel [redacted]

Subject Data

Subject Number	Initials	Age	Sex
1	[redacted]	30	F
2		41	F
3		43	M
4		39	F
5		53	F
6		45	M
7		20	F
8		26	M
9		23	F
10		63	F
11		70	F
12		45	F
13		31	F
14		63	F
15		17	F
16		51	M
17		62	F
18		63	M
19		62	F
20		62	M
21		34	F
22		27	F
23		31	F
24		49	F
25		79	F
26		52	F
27		26	F
28		20	M
29		75	F

Table 2
(continued)
Panel [redacted]

Subject Data

Subject Number	Initials	Age	Sex
30	[redacted]	32	M
31		19	F
32		43	F
33		36	F
34		26	F
35		26	M
36		32	F
37		70	F
38		52	M
39		32	F
40		59	F
41		33	M
42		55	F
43		38	F
44		42	F
45		43	M
46		49	F
47		53	M
48		43	M
49		42	F
50		20	F
51		58	F
52		55	F
53		16	F
54		70	F
55		60	F
56		75	M

Table 2
(continued)
Panel [redacted]

Subject Data

Subject Number	Initials	Age	Sex
1	[redacted]	69	F
2		37	F
3		22	F
4		30	M
5		72	F
6		31	F
7		69	F
8		24	M
9		36	F
10		22	F
11		50	F
12		57	F
13		57	F
14		36	F
15		41	F
16		47	F
17		35	F
18		42	F
19		53	F
20		60	F
21		49	M
22		32	M
23		23	F
24		48	F
25		55	M
26		50	F
27		44	F
28		48	F
29		30	F

Table 2
(continued)
Panel [redacted]

Subject Data

Subject Number	Initials	Age	Sex
30	[redacted]	31	F
31		37	F
32		38	M
33		26	F
34		16	M
35		20	F
36		25	M
37		45	F
38		17	F
39		22	F
40		30	F
41		32	F
42		24	F
43		62	F
44		35	F
45		27	F
46		35	M
47		42	M
48		56	F
49		54	F
50		68	F
51		59	F
52		58	F
53		45	M
54		36	F
55		20	F
56		32	M
57		48	F
58		66	F
59		27	F
60		66	F

[redacted]

[redacted]

Report: [redacted]

Determination Of The Photo-Allergic Potential Of Serum: Code [redacted] In Humans

containing 2.0% Trimethylsiloxyphenyl Dimethicone

Prepared for:

[redacted]

March 21, 2012

[redacted]

Serum Code [redacted]

[redacted]

SITE OF STUDY

[redacted]

STAFF

[redacted], BA	President
[redacted] MDCM	Medical Director
[redacted], MD	Dermatologist
[redacted]	Director, Dermatological Studies
[redacted]	Senior Technician
[redacted]	Senior Technician
	Director, Quality Assurance

STATEMENT OF COMPLIANCE WITH GOOD CLINICAL PRACTICES

This study was conducted in conformance with the standards of Good Clinical Practices that are applicable to the protection of subjects undergoing procedures such as those conducted in this study.

3/23/12
Date

[redacted]
Director, Dermatological Studies

22 March 2012
Date

[redacted] MDCM
Medical Director

3-23-12
Date

[redacted] MD
Dermatologist

STATEMENT OF QUALITY ASSURANCE

In my review of the data I have found no discrepancies between the information presented in this report and the records that were kept during the conduct of this study.

3/24/12
Date

[redacted]

Determination of the Photo-Allergic Potential of Serum: Code [redacted] in Humans

1.0 OBJECTIVE: The objective of this study was to determine the Photo-allergenic potential of a topically applied test material on human volunteers.

2.0 SPONSOR: [redacted]

Project Director: [redacted]

Authorization: Letter dated January 19, 2012 from [redacted]

3.0 IRB: This study was not submitted to an IRB for review.

4.0 STUDY PRODUCT:

Type of Product:	Serum
Sponsor Identification:	Code [redacted]
Date received:	1/20/12
Form used in study:	As Supplied
[redacted] N°:	29898

5.00 DATES OF STUDY:

Started:	23 January 2012
Completed:	24 February 2012

6.00 SELECTION OF SUBJECTS:

.01 Recruitment:

a. Candidates were recruited from local townships and boroughs.
b. All candidates were required to come to the clinic to give informed consent.
c. If a current medical history was not already in our data base, one was obtained from the candidate.

.02 INFORMED CONSENT:

All individuals who expressed interest in participating were given a prepared document which informed a prospective subject of the following items and required that the individual sign it before she/he participated.

a. How many subjects were to be enrolled in the study.
b. What type of study articles would be applied to the skin.
c. How the test was to be performed.
d. That the test was being performed to obtain information about the effects of the study article on human skin.
e. That the test was not being performed to benefit the subject's skin, health, or quality of life.
f. That exposure to one or more of the study articles may have adverse effects and, to the extent that was known, the different ways that participation could be detrimental to a subject's skin, health, or quality of life.
g. That not all adverse effects could be foreseen and made known to the prospective subject at the time the informed consent document was presented to her/him.
h. The commitments which she/he was asked to make to ensure that the data that would be generated would be meaningful.
i. The rights endowed on a subject for her/his protection.
j. What considerations a subject would be entitled to receive and the conditions for receiving them.

.03 Inclusion Criteria: Subjects:

1. were between 18 and 60 years of age, and
2. had lightly pigmented skin (Fitzpatrick Skin Type I, II, III), and
3. had expressed willingness to persevere and see the study to its conclusion despite any discomforts or inconveniences that participation might impose upon them, and
4. had no plans that would prevent them from complying with the scheduled study regimen, and
5. had professed to understand the contents of the informed consent form and signed it willingly.

Exclusion Criteria: Subjects:

1. who had a systemic illness that contraindicated participation, or
2. who had a skin disease with manifestations that could be confused with the adverse effects that might be elicited by the study sample, or
3. who had an ongoing intake or use of medications that could either enhance or suppress the skin-damaging propensities of the study sample, or
4. who had a documented history of hypersensitivity or intolerance to the products submitted for study, products marketed for similar usages, or any components thereof, or
5. who were pregnant or lactating, or
6. who failed to properly execute an informed consent document.

.04 PANEL INFORMATION:

a. **Panel N°:** [redacted]

b. **Demographics: (c.f. Appendix II)**

SEX	Number	Age Range
Female	24	19 – 67
Male	2	28 – 60

c. **Dedication:** This was an exclusive panel, i.e. the subjects were not engaged in the evaluation of materials submitted by sponsors other [redacted]

7.00 SITE INFORMATION:

.01 LOCATION:

Serum; Code [redacted] was assigned to Band #D on the back of each subject.

.02 IDENTIFICATION OF A CONTACT SITE:

At each visit the skin around the contact site was marked to facilitate examinations after the device was removed and positioning of subsequently-applied devices as precisely as was feasible on the same site.

8.00 PATCHES:

.01 TYPE OF PATCH:

Occlusive patches consisted of a 2cm x 2cm absorbent, non-woven fabric pad centered on the adhesive-coated surface of a 4cm x 4cm square of a water impermeable plastic film.

.02 PREPARATION OF A PATCH:

a. All patches were prepared in the clinic by experienced technicians.

b. Test material bearing patches: The webril pad of a patching device was infused with 40 µL of the test material.

9.00 Equipment:

Light Source: Model 16S Solar Simulator, Solar Light Co.
Power Supply: Model XPS 200, Solar Light Co.
Dose Controller: Model PMA 2100, SN:2574, Solar Light Co.
UV-B Detector: PMA 2104 with beam splitter adaptor
UV-A Detector: PMA 2114 with beam splitter adaptor, Detector shutter XPS200S1
Filters: WG-320 1mm, WG-345 2.5mm, UG-111mm, Dichroic Reflector
Micropipette: Nichiryo Model 8100 Syringe Dispenser

10.00 Procedure Design:

The procedure used in this study was a subject-blind evaluation of the test material(s) in a selected group of volunteers from the local population. The procedure involved a four phase design:

Phase 1 Determination of MED (Minimum Erythemic Dose).

The MED of each subject was determined by a sequence of time exposures to adjacent circular sites on the lower back. Each exposure time varied by a geometric increase of 25% over that of the previous exposure time. The MED was determined to be the shortest exposure time at which erythema was perceived 24± 4 hours after exposure.

FitzPatrick Skin Type	Exposure Times (seconds)
I	8, 10, 13, 16, 20, 25
II	10, 13, 16, 20, 25, 31
III	13, 16, 20, 25, 31, 39

Phase 2 Induction Phase.

Naive skin sites on the back of each subject were designated for repeated occlusive application of each test/control material(s). Following 24 hours of contact, each site was irradiated with two (2) MED's UVA/UVB. This patch/irradiation sequence was performed 2x/week over a three week period for a total of 6 patch applications.

Phase 3 Rest (Non-treatment) Phase:

A 10 day hiatus followed the last irradiation of week #3.

Phase 4 Challenge Phase:

A duplicate set of naive sites adjacent to the induction sites was selected for contact with the test/control material(s). Each site was covered with a sample treated occlusive patch. One additional (control) site was selected and patched with a blank (untreated) occlusive patch. All patches were removed after 24 hours. One set of treated sites and the blank irradiated control site were irradiated with 1/2 MED UVA/UVB followed by 4.0 joules/cm^2 UVA. The duplicate set of treated sites did not receive any irradiation and served as a treated control. All skin sites were evaluated and scored in accordance with the standard criteria 48 and 72 hours after irradiation.

[redacted] Serum Code [redacted]

11.00 **Procedure: Week 1**

Monday: Approximately forty (40) microliters of each test/control material were applied on a patching device and affixed to its respectively assigned contact site on the back of each subject. Subjects were dismissed with instructions to return in approximately 24 hours.

Tuesday: All patching devices were removed and the sites were wiped to remove excess material. Each site was immediately exposed to 2 MED's of UVA/UVB. The subjects were dismissed with instructions to return in 48 hours.

Wednesday: No procedures were performed.

Thursday: The procedure was identical to that conducted on Monday of week 1.

Friday: The procedure was identical to that conducted on Tuesday of week 1. The subjects were dismissed for the weekend with instructions to return on the following Monday.

Procedure: Weeks 2 and 3

The procedures conducted during week 2 and week 3 were identical to those described on corresponding days of week 1.

Procedure: Week 4

Week 4 provided a rest (non-treatment) period for all subjects who had completed the requirements of the induction regimen. This phase also allowed subjects the opportunity to makeup a patch/irradiation cycle which had been missed during the first three weeks.

Procedure: Week 5

Monday: A duplicate set of sample/control treated patching devices were positioned on the back adjacent to the original induction sites. An additional blank (non-treated) device was also affixed to a naive site. The subjects were dismissed with instructions to return in 24 hours.

Tuesday: All patching devices were removed and excess material was gently wiped away with a clean tissue. One set of the sample/control treated sites and the blank (non-treated) site (irradiated control) were irradiated with 1/2 MED UVA/UVB followed by 4 joules/cm^2 of UVA. The second set of sample/control treated sites was not irradiated and served as a treated un-irradiated control. Subjects were dismissed with instructions to return in 48 hours.

[redacted]

Serum Code [redacted]

[redacted]

Wednesday: No procedures were scheduled for this day.

Thursday: All sites, i.e., treated irradiated, treated un-irradiated, and untreated irradiated, were examined and scored in accordance with the standard grading scale.

Friday: All sites, i.e., treated irradiated, treated unirradiated, and untreated irradiated, will be examined and scored in accordance with the standard grading scale. Subjects are discharged from the study unless follow-up and/or treatment is required.

12.00 Scoring Scale:

0 = not sensitized

1 = Mild sensitization (Viz. erythema with mild edema

2 = Moderate sensitization (erythema with infiltration, edematous spreading reaction. beyond the borders of the patch, with, or without vesiculation.

3 = Strong Sensitiztion (large vesiculo-bullous reaction.

13.00 Procedure Deviations:

None were necessary.

14.00 Results:

Cf. Appendix I

15.00 Conclusions:

.01 The data provide no basis for characterizing **Serum: Code** [redacted] as a photocontact allergen.

.02 The data do not contraindicate the repeated application of **Serum: Code** [redacted] on areas of skin that would be exposed to sunlight.

APPENDIX I

Results
Responses Noted During the Challenge Phase

[redacted] Serum Code [redacted] [redacted]

RESULTS

RESPONSES NOTED DURING THE CHALLENGE PHASE

Subject Number	MED (sec)	Site D1 IRRADIATED CONTACT SITE						Site S1 IRRADIATED NON-CONTACT SITE						Site D2 NON-IRRADIATED CONTACT SITE				
		After Contact c sample	Hours after irradiation with 0.5 MED UVB + 4 Joules UVA/cm²					After Contact c Sham	Hours after irradiation with 0.5 MED UVB + 4 Joules UVA/cm²					After 24H Contact c Sample	Hours after removal of the treated Patch			
		24 h	0	24	48	72	120	24 h	0	24	48	72	120	24 h	24	48	72	120
01	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
02	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
03	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
04	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
05	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
06	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
07	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
08	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
09	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
10	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
11	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
12	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
13	31	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
14	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
15	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
16	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
17	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
18	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
19	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
20	16	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
21	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
22	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
23	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
24	20	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
25	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC
26	25	0	0	0	0	0	NEC	0	0	0	0	0	NEC	0	0	0	0	NEC

NEC - No examination conducted

A1 – Sample treated site, Irradiated
A2 – Sample treated site, Un-irradiated
S1 – Untreated, Irradiated Control

[redacted]

Serum Code [redacted]

[redacted]

APPENDIX II

Demographics

[redacted] Serum Code [redacted] [redacted]

Demographics

Subject No.	Initials	Age	Sex	Skin Type
01	[redacted]	54	F	III
02		54	F	III
03		34	F	III
04		55	F	III
05		49	F	II
06		67	F	III
07		54	F	I
08		55	F	II
09		60	M	III
10		55	F	I
11		50	F	III
12		37	F	II
13		39	F	III
14		19	F	II
15		44	F	II
16		47	F	III
17		56	F	I
18		26	F	I
19		46	F	II
20		49	F	I
21		47	F	III
22		28	M	III
23		48	F	II
24		53	F	III
25		44	F	III
26		26	F	III

[redacted]

Serum Code [redacted]

[redacted]

[redacted]

RESEARCH AND DEVELOPMENT
[redacted] DEPARTMENT

[redacted] REPORT: HUMAN PATCH TEST

This test follows the procedure described in SOP, HPT.1 **TO:** [redacted]

PRODUCT PROFILE NO: [redacted] REPORT DATE: December 17th, 2019 LAB REF.: [redacted]

TEST DATES: December 11th, 2019 – December 13th, 2019

1. TEST MATERIAL: [redacted] Late Night Ampoules [redacted] F# [redacted]

contains 0.5% Diphenylsiloxy Phenyl Trimethicone

2. CONTROL MATERIAL: [redacted] White Serum F# [redacted]

3. TEST PROCEDURE:

Single-Insult (24hr.) X Occlusive Patch X Semi-Occlusive Patch X. ([redacted])

4. CONCENTRATION:

Full-Strength X Aqueous _____ Solution _____ Dispersion_____ Aqueous Paste_____.
Other:_____.

X Volatiles were allowed to evaporate ~15 minutes prior to occlusion on the patch. ([redacted])
_____Patch was hydrated just prior to application to skin.

5. TEST RESULTS:

TEST MATERIAL	*SUBJECTS*	*IRRITATION SCORE**									
		0	±	1	1+	2	2+	3	3+	4	PII
[redacted] Late Night Ampoules [redacted] F# [redacted]	20	19	1	0	0	0	0	0	0	0	0.03
[redacted] White Serum F# [redacted]	20	20	0	0	0	0	0	0	0	0	0.00

____ Skin staining noted. Erythematous response was read "through" the Stain.

6. CONCLUSIONS:

A. There were no significant differences in irritancy observed between the Test Material (s) and the Reference Control (s). X.

B. _____.

Study Conducted By: [redacted].

* SCORE
0 = No evidence of any effect.
± (Barely Perceptible) = minimal faint uniform or spotty erythema
1 (Mild) = Pink uniform erythema covering most of the contact site.
2 (Moderate) = Pink-red erythema visibly uniform in entire contact area.
3 (Marked) = Bright red erythema with accompanying edema petechiae or papules.
4 (Severe) = Deep red erythema with vesiculation or weeping with or without edema.

+, 1+, 2+ and 3+ = Intermediate scores contributing 0.5, 1.5, 2.5 and 3.5 respectively, to the P.I.I.
P.I.I. - Primary Irritation Index - a value depicting the average skin response of the test panel as a whole. It is calculated by choosing the higher of the two Irritation Scores per panelist, adding them all together and dividing by the total number of test subjects.

CC:

[redacted]

[redacted] contains 0.5% Diphenylsiloxy Phenyl Trimethicone

Test Material #10: Ampoule; Code# [redacted]

PURPOSE: To evaluate the potential of the Test Material, as a result of repeated applications, to induce dermal sensitization in human subjects.

IRB APPROVAL: Both the [redacted] Standard Protocol #100 and the Informed Consent were approved by the Clarus Institutional Review Board (CIRB) on January 15, 2019. A Sponsor-signed Protocol is retained in [redacted] files.

SPONSOR: [redacted]

SPONSOR AUTHORIZATION: November 21, 2019

SAFETY ASSURANCE: November 21, 2019

PRINCIPAL INVESTIGATOR: [redacted], MD

CO-INVESTIGATORS: [redacted], MD, Board-Certified Dermatologist
[redacted] MD, PhD, Board-Certified Dermatologist
[redacted], DO, Board-Certified Dermatologist

TEST FACILITY: [redacted]

TEST MATERIAL: Test Material Ampoule; Code# [redacted] a beige liquid, was received on November 22, 2019, with the following instructions: Test as received; patch occlusively.

SUBJECTS: A total of 120 subjects were enrolled; 112 subjects completed the test. Two subjects, #025 ([redacted] #44106) and #109 ([redacted] #36975), were discontinued prior to being patched due to screen failure. Six subjects discontinued due to personal reasons / Investigator termination. No subject discontinued due to test material reaction.

- continued -

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

METHOD:	This test was conducted according to [redacted] Standard Protocol #100 and [redacted] Standard Operating Procedures (including any Sponsor alterations).
TEST DATES:	December 2, 2019 through January 10, 2020.
SCORING SYSTEM:	See Tables I-II.
RESULTS:	See Tables I-II. No adverse reactions or adverse events were reported / observed in any of the subjects. During the Induction Phase, two subjects exhibited low-level (±) reactions. During the Challenge, two other subjects exhibited low-level (±) reactions.
CONCLUSION:	In this Repeated Insult Patch Test, Test Material Ampoule; Code# [redacted] did not induce dermal sensitization in human subjects.
QUALITY ASSURANCE (QA):	The QA Unit performed an in-phase audit of this study.

[redacted]

[redacted] MD, PhD
Co-Investigator
Board-Certified Dermatologist

[redacted] LPN
Project Manager

[redacted] MD
Principal Investigator

Date: 1-14-20

[redacted]

Test Material #10: Ampoule; Code# [redacted]

SUBJECTS: Each potential subject completed an [redacted] Subject History Form ([redacted] Form: SHF), including relevant medical history (an updated History Form is secured approximately every 18 months). At each subject's first visit to [redacted] the subject completed a Permission To Release Personal Health Information Form in conformity with the Health Insurance Portability and Accountability Act (HIPAA) and provided proof of age. Each accepted subject was assigned a permanent [redacted] Identification Number. No subject was used if he or she exhibited any dermatological or other medical or physical condition that would preclude topical application of the Test Material. Upon enrollment, no subject reported using any medication that would interfere with the sensitization results. No known pregnant nor nursing women were used on this RIPT. No minor subjects were used on this RIPT.

An appropriate clearance period had elapsed since a subject was patched on a Repeated Insult Patch Test (RIPT) or a Photoallergy Test (PA) before being used in this RIPT.

Legally valid written IRB-approved Informed Consent, in conformity with: 21 CFR 50.25, Subtitle A, Protection of Human Subjects, was secured from each subject.

METHOD: Induction Phase: A webril/adhesive patch was used occlusively. Approximately 0.2 gm of the Test Material was applied to each patch. As per [redacted] Standard Operating Procedures (SOP) [redacted] Form:SOP/RIPT), the left side of the back was usually the test area for the Induction Phase. The subject's skin was marked with gentian violet surgical marker at the left side of the test site. The test site was recorded on the anatomical diagram of each subject's individual Data Form. In addition, at that time, the prospective placement of the Challenge test site was also recorded on the anatomical diagram.

Each subject was instructed that the patch was to remain in place and kept dry for approximately 24 hours, at which time the patch was to be removed by the subject. An approximately 24-hour period, during which no test material was applied, followed the weekday patch removals; an approximately 48-hour period followed the weekend patch removals.

Each subject returned to [redacted] on the appropriate day. The test site was observed by the [redacted] technician, and the reaction scored and recorded (see **SCORING SYSTEM**, below). The identical test site was then repatched until nine (9) Induction patchings were completed.

In accordance with [redacted] SOP, if a subject was unable to make up a missed patching during the same week, the subject was either patched four days the following week or was patched at the end of the Induction Phase. Any absences and make-up days are noted by the dates on the individual Data Form.

A series of nine (9) Induction patchings was completed over a period of approximately three weeks.

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

METHOD: (continued)

Rest Period: A Rest Period of approximately two weeks followed the last Induction patching; no test material was applied during the Rest Period. Subjects were instructed to notify [redacted] if they experienced any reaction during the Rest Period.

Challenge Phase: At the Challenge Phase, the original Induction test site was observed and each subject queried as to whether any reaction was experienced during the Rest Period. Any reactions were recorded on the Data Form. A webril/adhesive patch was used occlusively. Approximately 0.2 gm of the Test Material was applied to each patch. As per [redacted] RIPT SOP, the opposite side of the back was usually the virgin test site for the Challenge Phase.

As per [redacted] RIPT SOP, the Challenge patch was applied to the virgin site only. Each subject was again instructed to keep the patch on and dry.

Each subject returned to [redacted] approximately 24 hours later (Challenge Reading 1), at which time the patch was removed and the Challenge site scored and recorded by the [redacted] technician. The original test site was also observed. (See **RESULTS**, below.)

Each subject returned to [redacted] at approximately 48 hours (Challenge Reading 2), approximately 72 hours (Challenge Reading 3) and approximately 96 hours (Challenge Reading 4) post-patching for additional observations; reactions were scored and recorded.

One subject, #077 ([redacted] #35264), missed Challenge Reading 4 due to change in work schedule. She returned to [redacted] on Monday, January 13, 2020 and the test site was negative. A verbal report from Subject #077 stated 'no reaction' on what would have been Challenge Reading 4.

SCORING SYSTEM: See Tables I-II. The test sites were scored using the modified scoring scale of the International Contact Dermatitis Research Group System: Fisher, Alexander A., *Contact Dermatitis*, Lea & Febiger, Philadelphia, 2008: p 27.

RESULTS: See Tables I-II. No adverse reactions or adverse events related to the Test Material were exhibited / reported by any subject during this test. Erythema, edema, dryness, staining, peeling and hyperpigmentation / hypopigmentation are possible, expected endpoints and not considered Adverse Reactions. This test was conducted under the supervision of a Board-Certified Dermatologist, a Co-Investigator. At Challenge Reading 3, the Dermatologist participated in the scoring of the subjects. A total of 112 subjects completed the test; 29 male and 83 female. The subjects range in age from 18 to 70.

RETENTION: All original Data Forms will be retained at [redacted] for a period of three years, or such other time as may be required by law. A laboratory retainer bottle of the Test Material shall be retained, in ambient conditions, for at least two years, or as required by law. Per the Sponsor, [redacted] shall appropriately dispose of any remaining Test Material.

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE I: SUMMARY OF REACTIONS

TOTAL NUMBER OF SUBJECTS ENROLLED: 120
TOTAL NUMBER OF SUBJECTS COMPLETED: 112

Reaction	Induction Reading									Challenge Reading			
Grade	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**1**	**2**	**3**	**4**
0	116	116	115	116	114	114	112	112	112	111	112	111	110
±	1	1	2	1	1	1	1	1	1	1		1	1
1													
1E													
2													
2E													
3E													
4E													
-													1
N9R													
Total	117	117	117	117	115	115	113	113	113	112	112	112	112

SCORING SYSTEM:

0	= No visible reaction
±	= Faint, minimal erythema
1	= Erythema
2	= Intense erythema, induration
3	= Intense erythema, induration, vesicles
4	= Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	= Edema
-	= No reading
N9R	= No 9th reading

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

Sub	HRL	Ini	Sex	Age	Induction Reading									Challenge Reading			
					1	2	3	4	5	6	7	8	9	1	2	3	4
1	32534	[redacted]	M	51	0	0	0	0	0	0	0	0	0	0	0	0	0
2	42520		F	43	0	0	±	0	0	0	0	0	0	0	0	0	0
3	46194		M	51	0	0	0	0	0	0	0	0	0	0	0	0	0
4	43107		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
5	39333		M	42	0	0	0	0	0	0	0	0	0	0	0	0	0
6	47730		F	42	0	0	0	0	0	0	0	0	0	0	0	0	0
7	36775		F	59	0	0	0	0	0	0	0	0	0	0	0	0	0
8	48083		F	38	0	0	0	0	0	0	0	0	0	0	0	0	0
9	48911		F	68	0	0	0	0	0	0	0	0	0	0	0	0	0
10	44753		F	33	0	0	0	0	0	0	0	0	0	0	0	0	0
11	48546		F	61	0	0	0	0	0	0	0	0	0	0	0	0	0
12	37651		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
13	46915		M	54	0	0	0	0	0	0	0	0	0	0	0	±	±
14	26247		F	45	0	0	0	0	0	0	0	0	0	0	0	0	0
15	30474		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
16	48260		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
17	48538		M	55	0	0	0	0	0	0	0	0	0	0	0	0	0
18	46658		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
19	42500		M	36	0	0	0	0	0	0	0	0	0	0	0	0	0
20	42000		M	69	0	0	0	0	0	0	0	0	0	0	0	0	0
21	27580		M	61	0	0	0	0	X	X	X	X	X	X	X	X	X
22	48736		M	51	0	0	0	0	0	0	0	0	0	0	0	0	0
23	48545		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
24	48711		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
25	44106		F	28	X	X	X	X	X	X	X	X	X	X	X	X	X

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
26	44105	[redacted]	M	25	0	0	0	0	X	X	X	X	X	X	X	X	X
27	48537		M	64	0	0	0	0	0	0	0	0	0	0	0	0	0
28	39712		F	52	0	0	0	0	0	0	0	0	0	0	0	0	0
29	36446		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
30	38698		F	69	0	0	0	0	0	0	0	0	0	0	0	0	0
31	38931		M	65	0	0	0	0	0	0	0	0	0	0	0	0	0
32	41077		F	67	0	0	0	0	0	0	0	0	0	0	0	0	0
33	48935		M	52	0	0	0	0	0	0	0	0	0	0	0	0	0
34	46635		F	55	0	0	0	0	0	0	0	0	0	0	0	0	0
35	44094		M	66	0	0	0	0	0	0	0	0	0	0	0	0	0
36	41747		F	67	0	0	0	0	0	0	0	0	0	0	0	0	0
37	39784		M	56	0	0	0	0	0	0	0	0	0	0	0	0	0
38	43041		F	43	0	0	0	0	0	0	0	0	0	0	0	0	0
39	28073		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
40	48927		F	42	0	0	0	0	0	0	0	0	0	0	0	0	0
41	48683		M	46	0	0	0	0	0	0	0	0	0	0	0	0	0
42	45800		F	48	0	0	0	0	0	0	0	0	0	0	0	0	0
43	29897		M	70	0	0	0	0	0	0	0	0	0	0	0	0	0
44	44049		F	56	0	0	0	0	0	0	0	0	0	X	X	X	X
45	23059		F	39	0	0	0	0	0	0	0	0	0	0	0	0	0
46	22173		F	66	0	0	0	0	0	0	0	0	0	0	0	0	0
47	46023		F	22	0	0	0	0	0	0	0	0	0	0	0	0	0
48	36839		F	52	0	0	0	0	0	0	0	0	0	0	0	0	0
49	48511		F	64	0	0	0	0	0	0	0	0	0	0	0	0	0
50	48510		F	66	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

Sub	HRL	Ini	Sex	Age	Induction Reading									Challenge Reading			
					1	2	3	4	5	6	7	8	9	1	2	3	4
51	11683	[redacted]	F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
52	45717		F	53	0	0	0	0	0	0	0	0	0	0	0	0	0
53	30536		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
54	48920		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
55	16853		F	64	0	0	0	0	0	0	0	0	0	0	0	0	0
56	17629		F	66	0	0	0	0	0	0	0	0	0	0	0	0	0
57	48170		M	37	0	0	0	0	0	0	0	0	0	0	0	0	0
58	44076		F	62	0	0	0	0	0	0	0	0	0	0	0	0	0
59	28011		F	35	0	0	0	0	0	0	0	0	0	0	0	0	0
60	26748		F	57	0	0	0	0	0	0	0	0	0	0	0	0	0
61	46024		F	22	0	0	0	0	0	0	0	0	0	0	0	0	0
62	48727		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
63	24835		F	54	0	0	0	0	0	0	0	0	0	±	0	0	0
64	44196		F	28	±	±	±	±	±	±	±	±	±	0	0	0	0
65	48372		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
66	30173		F	53	0	0	0	0	0	0	0	0	0	0	0	0	0
67	48941		M	34	0	0	0	0	0	0	0	0	0	0	0	0	0
68	48721		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
69	40966		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
70	22059		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
71	21072		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
72	40823		F	39	0	0	0	0	0	0	0	0	0	0	0	0	0
73	21911		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
74	48572		F	30	0	0	0	0	0	0	0	0	0	0	0	0	0
75	43597		F	66	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

Sub	HRL	Ini	Sex	Age	Induction Reading									Challenge Reading			
					1	2	3	4	5	6	7	8	9	1	2	3	4
76	48905	[redacted]	M	32	0	0	0	0	0	0	X	X	X	X	X	X	X
77	35264		F	63	0	0	0	0	0	0	0	0	0	0	0	0	-
78	09771		M	61	0	0	0	0	0	0	0	0	0	0	0	0	0
79	47859		F	68	0	0	0	0	0	0	0	0	0	0	0	0	0
80	48776		M	18	0	0	0	0	0	0	0	0	0	0	0	0	0
81	48515		F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
82	44606		F	24	0	0	0	0	0	0	0	0	0	0	0	0	0
83	48399		F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
84	47591		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
85	12073		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
86	41840		F	42	0	0	0	0	0	0	0	0	0	0	0	0	0
87	47085		M	21	0	0	0	0	0	0	0	0	0	0	0	0	0
88	29690		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
89	29691		M	42	0	0	0	0	0	0	0	0	0	0	0	0	0
90	47084		M	59	0	0	0	0	0	0	0	0	0	0	0	0	0
91	24505		F	36	0	0	0	0	0	0	0	0	0	0	0	0	0
92	46328		M	37	0	0	0	0	0	0	0	0	0	0	0	0	0
93	41910		F	40	0	0	0	0	0	0	0	0	0	0	0	0	0
94	37127		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
95	19700		M	61	0	0	0	0	0	0	0	0	0	0	0	0	0
96	19762		F	40	0	0	0	0	0	0	X	X	X	X	X	X	X
97	17505		F	36	0	0	0	0	0	0	0	0	0	0	0	0	0
98	47953		M	53	0	0	0	0	0	0	0	0	0	0	0	0	0
99	29587		F	55	0	0	0	0	0	0	0	0	0	0	0	0	0
100	39319		M	59	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
101	26901	[redacted]	F	35	0	0	0	0	0	0	0	0	0	0	0	0	0
102	43425		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
103	36841		F	30	0	0	0	0	0	0	0	0	0	0	0	0	0
104	47091		M	45	0	0	0	0	0	0	0	0	0	0	0	0	0
105	21929		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
106	47538		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
107	30316		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
108	37205		F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
109	36975		M	45	X	X	X	X	X	X	X	X	X	X	X	X	X
110	47936		F	45	0	0	0	0	0	0	0	0	0	0	0	0	0
111	47307		F	56	0	0	0	0	0	0	0	0	0	0	0	0	0
112	31684		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
113	46234		F	68	0	0	0	0	0	0	0	0	0	0	0	0	0
114	48649		F	69	0	0	0	0	0	0	0	0	0	0	0	0	0
115	47127		F	43	X	X	X	X	X	X	X	X	X	X	X	X	X
116	37963		F	32	0	0	0	0	0	0	0	0	0	0	0	0	0
117	08557		F	54	0	0	0	0	0	0	0	0	0	0	0	0	0
118	27445		F	50	0	0	0	0	0	0	0	0	0	0	0	0	0
119	47126		M	28	0	0	0	0	0	0	0	0	0	0	0	0	0
120	47125		M	29	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

SCORING SYSTEM*:

0	=	No visible reaction
±	=	Faint, minimal erythema
1	=	Erythema
2	=	Intense erythema
3	=	Intense erythema, induration, vesicles
4	=	Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	=	Edema
DR	=	Dryness
P	=	Peeling
S	=	Staining
^	=	Hyperpigmentation / Hypopigmentation
TR	=	Tape Reaction
C	=	Change of test site
N9R	=	No 9th reading
-	=	No patch application and / or reading
X	=	Discontinued

*International Contact Dermatitis Research Group System: Fisher, Alexander A., *Contact Dermatitis*, Lea & Febiger, Philadelphia, 2008: p 27. (Modified)

[redacted]

[redacted]

[redacted]

Test Material #10: Ampoule; Code# [redacted]

QUALITY ASSURANCE MEMORANDUM

This Final Report was reviewed for accuracy and conformity with both [redacted] Standard Protocol #100 and [redacted] Standard Operating Procedures (including any Sponsor alterations) and any written communication from the Sponsor.

Inspections were accomplished by a random sampling approach and reported to the Project Manager and the Principal Investigator immediately following their completion.

Any known protocol deviations have been noted in the Final Report and/or Individual Data Form.

The raw data for this study are retained at [redacted]

[redacted]

[redacted]

Quality Assurance Manager

QUALITY ASSURANCE UNIT

Date: 1/14/20

[redacted]

May 2, 2019

[redacted]

ATTN: [redacted]

Dear [redacted]

All dermal patch tests at [redacted] are conducted under the supervision of [redacted], MD, Principal Investigator, and the following Board-Certified Dermatologists: [redacted], MD, [redacted], MD, PhD and [redacted] DO, Co-Investigators. The Principal Investigator and Co-Investigators delegate authority to qualified individuals who are trained. The training is documented and updated as necessary, and at least annually. Protocols are structured upon the guidelines outlined in Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, April 1996, as appropriate for cosmetic products. The Board-Certified Dermatologists oversee testing, scoring, review documents and sign reports.

[redacted]
[redacted] MD
Principal Investigator
Board-Certified Ophthalmologist

[redacted]
[redacted], MD
Board-Certified Dermatologist

[redacted]
[redacted], MD, PhD, Co-Investigator
Board-Certified Dermatologist

[redacted]
[redacted] DO, Co-Investigator
Board-Certified Dermatologist

[redacted]

RESEARCH AND DEVELOPMENT
[redacted] DEPARTMENT

[redacted] REPORT: HUMAN PATCH TEST

This test follows the procedure described in SOP, HPT.1 **TO:** [redacted]

PRODUCT PROFILE NO: [redacted] DATE: July 20, 2009 LAB REF.: [redacted]

1. TEST MATERIAL: [redacted] Eye Primer F# [redacted] contains 10.0% Phenyl Trimethicone

2. CONTROL MATERIAL: [redacted] Mousse Foundation Stick SPF10 F# [redacted]

3. TEST PROCEDURE:

Single-Insult (24hr.) X Occlusive (Blenderm) Patch X Semi-Occlusive Patch_____.

4. CONCENTRATION:

Full-Strength X Aqueous _____ Solution _____ Dispersion_____ Aqueous Paste_____.
Other:_____.

_____Volatiles were allowed to evaporate to occlusion on the patch.
_____Patch was hydrated just prior to application to skin.

5. TEST RESULTS:

TEST MATERIAL	*SUBJECTS*	*IRRITATION SCORE**									
		0	±	1	1+	2	2+	3	3+	4	PII
[redacted] Eye Primer F# [redacted]	21	21	0	0	0	0	0	0	0	0	0.00
[redacted] Mousse Foundation Stick SPF10 F# [redacted]	21	21	0	0	0	0	0	0	0	0	0.00

___ Skin staining noted. Erythematous response was read "through" the Stain.

6. CONCLUSIONS:

A. There were no significant differences in irritancy observed between the Test Material (s) and the Reference Control (s). X.

B. _____.

Study Conducted By: [redacted] Approved By: [redacted]

* SCORE
0 = No evidence of any effect.
± (Barely Perceptible) = minimal faint uniform or spotty erythema
1 (Mild) = Pink uniform erythema covering most of the contact site.
2 (Moderate) = Pink-red erythema visibly uniform in entire contact area.
3 (Marked) = Bright red erythema with accompanying edema petechiae or papules.
4 (Severe) = Deep red erythema with vesiculation or weeping with or without edema.

+, 1+, 2+ and 3+ = Intermediate scores contributing 0.5, 1.5, 2.5 and 3.5 respectively, to the P.I.I.
P.I.I. - Primary Irritation Index - a value depicting the average skin response of the test panel as a whole. It is calculated by choosing the higher of the two Irritation Scores per panelist, adding them all together and dividing by the total number of test subjects.

CC:

[redacted]

FINAL REPORT

Report Date: July 13, 2010

[redacted]

Sample: SPF Cream coded [redacted]

[redacted]

[redacted]

Title: **A 14-Day Cumulative Irritation Assay**

Sponsor: [redacted] product containing 3.2363% Phenyl Trimethicone

[redacted]Submission Form dated: June 6, 2010

Principal Investigator: [redacted] M.D. (Board Certified Dermatologist)

Testing Facility: [redacted]

[redacted] M.D.
Principal Investigator

July 13, 2010
Date

[redacted]

F I N A L R E P O R T

STUDY TITLE:

A 14-Day Cumulative Irritation Assay

PROTOCOL:

[redacted]

GUIDELINES FOR THE CONDUCT OF THE STUDY:

All procedures were conducted in compliance with the regulations of the Food and Drug Administration (FDA) ([21CFR 50, 56, 312] ICH-GCP Consolidated Guidelines, May 9, 1997 Federal Register) and in accordance with [redacted] Standard Operating Procedures (SOP's).

SPONSOR:

[redacted]

SPONSOR STUDY:

[redacted] Submission Form (ASF) dated June 21, 2010

SPONSOR REPRESENTATIVE:

[redacted]

OBJECTIVE:

This test is designed to furnish data on the primary irritancy potential of topically applied substances in human skin.

DESIGN RATIONALE:

A repeat insult patch test study wherein the test materials were applied under occlusive dressings to designated test sites on the upper back or upper arm continuously and repeatedly to the same site for a period of 14 days[2,3].

PRINCIPAL INVESTIGATOR:

[redacted], M.D. (Board Certified Dermatologist)
Medical Director, [redacted]
Telephone: [redacted]
FAX: [redacted]

[redacted] **ADMINISTATIVE STRUCTURE**:

[redacted] (Panel Recruitment/Initial Screening)
[redacted] (Patcher)
[redacted] (Expert Grader)
[redacted] (Quality Assurance)

TESTING FACILITY:

[redacted]

DATES OF STUDY CONDUCT:

The study was conducted from June 21, 2010 through July 5, 2010.

PANEL COMPOSITION:

Healthy, normal, adult Caucasian volunteers over the age of 18 years of both sexes with no blemishes, excess hair or other marks on their upper back or upper arms that would obscure grading of the test sites served as subjects.

Inclusion Criteria:

1. Healthy adult male and female volunteers between the ages of 18 and 65 years.

2. Subjects willing to follow the study requirements and provide a signed informed consent.

Exclusion Criteria:

1. History of recurrent dermatological diseases, e.g., psoriasis, atopic eczema, chronic urticaria, vitiligo, etc.
2. History of allergy or hypersensitivity to cosmetics, toiletries, or other dermatological products.
3. History of allergy or hypersensitivity to sunscreens.
4. History of allergy or hypersensitivity to any type of tape.
5. Scars, moles or other blemishes over the upper arm or back, which could interfere with the study.
6. Subjects receiving systemic or topical drugs including steroidal or non-steroidal anti-inflammatory drugs, or medications which could interfere with the development of an inflammatory response, e.g., immunosuppressive agents or retinoids
7. Subjects with any significant internal diseases, e.g., cardiac, pulmonary, renal, hepatic, etc.
8. Pregnancy or mothers who were breastfeeding or planning a pregnancy
9. Other conditions considered by the Investigator as sound reasons for disqualification from enrollment into the study.

INFORMED CONSENT:

After the protocol, reasons for the study, possible associated risks and potential benefits or risks of the treatment had been completely explained, signed, informed subject consent was obtained from each volunteer prior to the start of the study. Copies of all consent forms are on file at [redacted]

TEST MATERIAL:

One test sample labeled Lotion coded [redacted] (1 jar) was supplied by the sponsor and tested as supplied viz. neat (as is). In addition, one other test product labeled "SPF Lotion" and coded [redacted] was included in this panel for comparison.

HANDLING OF STUDY DOCUMENTS:

All study related documents, case report forms (CRF's), consent forms and any data generated was kept under secure lock in the technician's office during the study.

CASE REPORT FORMS:
All case report forms (CRFs) were completed in actual time during each patient's visit.

RECORDING OF DATA AND CORRECTIONS:
All data and information was recorded on specific case report forms (CRF's) and this information was recorded/or legibly printed in black ink. Any errors were crossed out with a single line and the correct entry made in ink and initialed and dated by the Investigator or by the Study Coordinator.

SUBJECT ASSIGNMENT:
Volunteer subjects were screened and qualifying subjects were selected as described above and assigned a subject number. The initials of each subject accepted into the study were recorded sequentially as they were enrolled.

METHOD AND PROCEDURES:
Approximately 0.05ml of the test material was spread uniformly onto a 15mm diameter circular disc of non-absorbing cotton cloth (Webril). The treated circular disc of Webril cotton cloth was then applied to a designated skin site measuring 15mm in diameter on the upper arm or upper back. The site was then covered with occlusive tape (Blenderm, 3M) and the entire patch fastened to the skin with Scanpor Tape to ensure intimate contact with the skin. This procedure was repeated daily Mondays through Fridays after evaluation of the test site with a daily fresh application of the test material for a total of 14 days. The patch remained in place over the weekends (Saturdays and Sundays). In addition to the test product and the comparator product (SPF coded 24593-08), one site was also treated with 0.05ml of 0.25% SLS (sodium lauryl sulfate) as a positive control and another site was treated with a plain Webril patch (cotton cloth) and served as a negative control.

ASSESSMENT AND GRADING OF RESPONSES:

Irritant reactions which may have been provoked during the study were recorded daily. All test sites were graded daily after removal of the patches for possible irritation using the following scale:

0 = normal looking skin
1 = very faint erythema with indistinct borders
2 = minimal or mild erythema with at least one discernable border
3 = moderate erythema with sharply distinct borders
4 = deep, intense erythema
5 = deep, intense erythema with edema (a palpable, raised or elevated lesion)

Other Notations: **V** = Vesicles
E = Erosions
F = Fissuring

Test sites achieving a grade 3 or greater score were discontinued and that grade (3 or 4) was carried through for the remainder of the test days for the purpose of calculating the cumulative irritation index of the test product.

RESULTS:

A total of 25 healthy Caucasian volunteers who qualified were enrolled into this study. There was a total of 22 females and 03 males ranging in age from 18 to 65 years. All 25 volunteers completed this investigation as outlined in [redacted] standard 14-Day Cumulative Irritation Assay protocol. The demography is shown in Table 1. No adverse effects of any kind were observed in any of the test panelists.

Irritation:

The individual daily and cumulative irritation scores for each test site are shown in the tables in Appendix A. The comparator product labeled SPF Lotion and coded [redacted] produced a total cumulative irritation score of “0” and a cumulative irritation index (CII) of 0.00. The test product labeled SPF Cream and coded [redacted] produced a total cumulative score of “0” and a CII of “0.00”. By contrast, the 0.25% SLS resulted in a CII of 0.33 (moderate irritation potential), while negligible irritation was seen with the plain

cotton patch (a total cumulative score of “0” and a CII of 0.00). The mean irritation scores and Cumulative Irritation Indices are summarized in Table 2.

CONCLUSIONS:

The test product coded [redacted] (SPF Cream) was found to possess a “negligible” irritation potential in human skin while the comparator product coded [redacted] SPF Lotion) was also found to possess a negligible irritation potential in human skin.

REFERENCE:

(1) Jackson, E.M.:
A Modified Cumulative Patch Test to Substantiate Hypoallergenic Claims. Cosmetic Dermatology. Vol. 7, pages 44-46, 1994.

(2) Philips, L., Steinberg, M., Maibach, H.I. and Akers, W.A.:
A Comparison of Rabbit and Human Skin Response to Certain Irritants. Toxicol.Appl.Pharmacol. 21: 369-382, 1972.

(3) Lanman, B.M., Elvers, W.B. and Howard, C.S.: The Role of Human Patch Testing in a Product Development Program. In: Proceedings, Joint Conference on Cosmetic Sciences. The Toilet Goods Association, Inc., Washington, DC, pp. 135-145, 1968.

TABLE 1

DEMOGRAPHIC DATA

Subject Number:	Subject Initials:	Age:	Sex:	Race:
01	[redacted]	47	F	C
02	[redacted]	45	F	C
03	[redacted]	22	F	C
04	[redacted]	34	F	C
05	[redacted]	46	F	C
06	[redacted]	42	M	C
07	[redacted]	42	F	C
08	[redacted]	65	F	C
09	[redacted]	63	F	C
10	[redacted]	62	F	C
11	[redacted]	21	F	C
12	[redacted]	47	F	C
13	[redacted]	20	F	C
14	[redacted]	18	F	C
15	[redacted]	18	F	C
16	[redacted]	19	F	C
17	[redacted]	22	F	C
18	[redacted]	19	M	C
19	[redacted]	34	F	C
20	[redacted]	45	F	C
21	[redacted]	42	F	C
22	[redacted]	24	M	C
23	[redacted]	19	F	C
24	[redacted]	20	F	C
25	[redacted]	20	F	C

C = Caucasian

TABLE 2

Mean and Cumulative Irritation Indices of Two Coded Test Products in a 14-Day Cumulative Irritation Assay

(N=25)

	TEST PRODUCTS			
	SPF Cream coded #[redacted]	**SPF Lotion coded #[redacted]**	**Plain Webril**	**0.25% SLS**
Sum of Cumulative Scores	0	0	0	244
Mean Cumulative Irritation Score	0	0	0	9.76
Mean Daily Irritation Score	0	0	0	0.98
Cumulative Irritation Index	0	0	0	0.33
Irritation Potential	Negligible	Negligible	Negligible	Moderate

APPENDIX A

Cumulative Irritation Scores for Each Test Site

DAILY AND CUMULATIVE IRRITATION SCORES															
Sample: **SPF Cream coded** [redacted]															
DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Cumulative
Subject Number	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	Score
1	0	0	0	0			0	0	0	0	0			0	0
2	0	0	0	0			0	0	0	0	0			0	0
3	0	0	0	0			0	0	0	0	0			0	0
4	0	0	0	0			0	0	0	0	0			0	0
5	0	0	0	0			0	0	0	0	0			0	0
6	0	0	0	0			0	0	0	0	0			0	0
7	0	0	0	0			0	0	0	0	0			0	0
8	0	0	0	0			0	0	0	0	0			0	0
9	0	0	0	0			0	0	0	0	0			0	0
10	0	0	0	0			0	0	0	0	0			0	0
11	0	0	0	0			0	0	0	0	0			0	0
12	0	0	0	0			0	0	0	0	0			0	0
13	0	0	0	0			0	0	0	0	0			0	0
14	0	0	0	0			0	0	0	0	0			0	0
15	0	0	0	0			0	0	0	0	0			0	0
16	0	0	0	0			0	0	0	0	0			0	0
17	0	0	0	0			0	0	0	0	0			0	0
18	0	0	0	0			0	0	0	0	0			0	0
19	0	0	0	0			0	0	0	0	0			0	0
20	0	0	0	0			0	0	0	0	0			0	0
21	0	0	0	0			0	0	0	0	0			0	0
22	0	0	0	0			0	0	0	0	0			0	0
23	0	0	0	0			0	0	0	0	0			0	0
24	0	0	0	0			0	0	0	0	0			0	0
25	0	0	0	0			0	0	0	0	0			0	0
Σ	**0**	**0**	**0**	**0**			**0**	**0**	**0**	**0**	**0**			**0**	**0**

Mean Cumulative Irritation Score:	0.00	
Mean Daily Irritation Scores:	0.00	
Cumulative Irritation Index (CII):	0.00	

DAILY AND CUMULATIVE IRRITATION SCORES															
Sample: **SPF Lotion coded [redacted] (standard)**															
DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Cumulative
Subject Number	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	Score
1	0	0	0	0			0	0	0	0	0			0	0
2	0	0	0	0			0	0	0	0	0			0	0
3	0	0	0	0			0	0	0	0	0			0	0
4	0	0	0	0			0	0	0	0	0			0	0
5	0	0	0	0			0	0	0	0	0			0	0
6	0	0	0	0			0	0	0	0	0			0	0
7	0	0	0	0			0	0	0	0	0			0	0
8	0	0	0	0			0	0	0	0	0			0	0
9	0	0	0	0			0	0	0	0	0			0	0
10	0	0	0	0			0	0	0	0	0			0	0
11	0	0	0	0			0	0	0	0	0			0	0
12	0	0	0	0			0	0	0	0	0			0	0
13	0	0	0	0			0	0	0	0	0			0	0
14	0	0	0	0			0	0	0	0	0			0	0
15	0	0	0	0			0	0	0	0	0			0	0
16	0	0	0	0			0	0	0	0	0			0	0
17	0	0	0	0			0	0	0	0	0			0	0
18	0	0	0	0			0	0	0	0	0			0	0
19	0	0	0	0			0	0	0	0	0			0	0
20	0	0	0	0			0	0	0	0	0			0	0
21	0	0	0	0			0	0	0	0	0			0	0
22	0	0	0	0			0	0	0	0	0			0	0
23	0	0	0	0			0	0	0	0	0			0	0
24	0	0	0	0			0	0	0	0	0			0	0
25	0	0	0	0			0	0	0	0	0			0	0
Σ	**0**	**0**	**0**	**0**			**0**	**0**	**0**	**0**	**0**			**0**	**0**

Mean Cumulative Irritation Score:	0.00
Mean Daily Irritation Scores:	0.00
Cumulative Irritation Index (CII):	0.00

DAILY AND CUMULATIVE IRRITATION SCORES															
Sample: **Plain Cotton Webril**															
DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Cumulative
Subject Number	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	Score
1	0	0	0	0			0	0	0	0	0			0	0
2	0	0	0	0			0	0	0	0	0			0	0
3	0	0	0	0			0	0	0	0	0			0	0
4	0	0	0	0			0	0	0	0	0			0	0
5	0	0	0	0			0	0	0	0	0			0	0
6	0	0	0	0			0	0	0	0	0			0	0
7	0	0	0	0			0	0	0	0	0			0	0
8	0	0	0	0			0	0	0	0	0			0	0
9	0	0	0	0			0	0	0	0	0			0	0
10	0	0	0	0			0	0	0	0	0			0	0
11	0	0	0	0			0	0	0	0	0			0	0
12	0	0	0	0			0	0	0	0	0			0	0
13	0	0	0	0			0	0	0	0	0			0	0
14	0	0	0	0			0	0	0	0	0			0	0
15	0	0	0	0			0	0	0	0	0			0	0
16	0	0	0	0			0	0	0	0	0			0	0
17	0	0	0	0			0	0	0	0	0			0	0
18	0	0	0	0			0	0	0	0	0			0	0
19	0	0	0	0			0	0	0	0	0			0	0
20	0	0	0	0			0	0	0	0	0			0	0
21	0	0	0	0			0	0	0	0	0			0	0
22	0	0	0	0			0	0	0	0	0			0	0
23	0	0	0	0			0	0	0	0	0			0	0
24	0	0	0	0			0	0	0	0	0			0	0
25	0	0	0	0			0	0	0	0	0			0	0
Σ	0	0	0	0			0	0	0	0	0			0	0

Mean Cumulative Irritation Score:	0.00
Mean Daily Irritation Scores:	0.00
Cumulative Irritation Index (CII):	0.00

DAILY AND CUMULATIVE IRRITATION SCORES															
Sample: **Sodium Lauryl Sulfate (SLS) 0.25%**															
DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Cumulative
Subject Number	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	Score
1	0	1	1	1			1	1	1	2	3			-	14
2	0	0	0	0			0	1	1	2	2			2	8
3	0	0	0	0			1	1	1	2	2			2	9
4	0	0	0	0			0	1	1	2	2			2	8
5	0	0	1	1			1	1	2	2	3			-	14
6	0	0	0	0			0	1	2	3	-			-	12
7	0	0	0	0			0	0	1	1	2			2	6
8	0	0	0	1			1	1	1	2	3			-	12
9	0	0	0	0			1	1	2	2	3			-	12
10	0	0	0	0			0	1	1	2	3			-	10
11	0	0	0	0			1	1	1	2	2			2	9
12	0	0	1	1			1	1	2	2	3			-	14
13	0	0	0	0			0	1	1	2	2			3	9
14	0	0	0	0			0	0	1	1	3			-	8
15	0	0	0	0			0	1	1	1	2			2	7
16	0	0	0	0			0	0	0	1	1			2	4
17	0	0	0	0			0	0	1	2	2			2	7
18	0	0	0	1			1	1	1	2	2			2	10
19	0	1	1	1			1	2	2	3	-			-	17
20	0	0	0	0			0	1	2	2	2			2	9
21	0	1	1	1			1	1	1	2	2			2	12
22	0	0	0	0			0	1	1	2	2			2	8
23	0	0	0	0			0	0	0	0	0			0	0
24	0	0	0	1			1	1	2	2	3			-	13
25	0	1	1	1			1	1	1	2	2			2	12
Σ	**0**	**4**	**6**	**9**			**12**	**21**	**30**	**46**	**57**			**59**	**244**

Mean Cumulative Irritation Score:	9.76
Mean Daily Irritation Scores:	0.98
Cumulative Irritation Index (CII):	0.33

[redacted]

FINAL REPORT

[redacted]

Sample: Concealer coded [redacted]

[redacted]

[redacted]

Title: An Evaluation of the Contact-Sensitizing Potential of Topically-Coded Products in Human Skin by means of the Human Maximization Assay

Sponsor: [redacted] product containing 26.18% Phenyl Trimethicone

ASF Date: [redacted] Submission Form dated January 22, 2014

Principal Investigator: [redacted], M.D. (Board Certified Dermatologist)

Senior Consultant: [redacted], M.D. (Board Certified Dermatologist)

Testing Facility: [redacted]

[redacted] M.D.
Principal Investigator

3-11-14
Date

[redacted]

[redacted]

FINAL REPORT

STUDY TITLE:

An assessment of the contact-sensitizing potential of a coded topically-applied test agent using a Human Maximization Assay.

[redacted]**PROTOCOL**:

[redacted]

GUIDELINES FOR THE CONDUCT OF THE STUDY:

All procedures were conducted in compliance with the regulations of the Food and Drug Administration (FDA) 21 CFR 50, 56, 312 ICH-GCP Consolidated Guidelines, May 9, 1997 Federal Register and in accordance with KGL's Standard Operating Procedures (SOPs).

STUDY OBJECTIVE:

The objective of this study was to assess the skin sensitizing potential of any preparation designed for topical use by means of the Maximization Test (see references #1 and #2).

DESIGN RATIONALE:

A repeat insult patch test wherein the test product was applied under an occlusive dressing to an SLS (sodium lauryl sulfate) pre-treated site on the arm or back repeatedly to the same designated area for five 48-hour induction periods followed 10 days later by a single challenge to a naïve skin site on the opposite arm or the opposite side of the back.

CONDUCTION DATES:

This study was conducted from January 27, 2014 through February 27, 2014.

PRINCIPAL INVESTIGATOR:

[redacted], M.D. (Board Certified Dermatologist)
Medical Director, [redacted]
Telephone: [redacted]
Emergency Cell - 24-hours - [redacted]
E-mail: [redacted]

SENIOR CONSULTANT:

[redacted] (Board Certified Dermatologist)

Telephone: [redacted]

STUDY SPONSOR:

[redacted]

SPONSOR CONTACT:

[redacted]

Telephone: [redacted]

FAX: [redacted]

SPONSOR STUDY:

[redacted] Submission Form dated January 22, 2014

TESTING FACILITY:

[redacted]

[redacted] **ADMINISTRATIVE STRUCTURE**:

[redacted] (Panel Recruitment/Initial Screening)

[redacted] (Technician/Screening, Patch Applications/Removals, Recognize/Report AE's)

[redacted] (Evaluator)

[redacted] (Quality Control)

INFORMED CONSENT:

Prior to acceptance into the study, each subject was informed by the Investigator or his designee of the nature and purpose of the study, possible side-effects and any other relevant information. The study procedures and possible risks and discomfort were explained to each

panelist during the interview using popular understandable language and terms, and the panelists were encouraged to ask questions regarding the study. Each interviewed panelist who qualified was then asked to read and sign the consent form prior to enrollment. Original consent forms are on file at [redacted]

TEST MATERIAL:

The test product, supplied by the sponsor, was labeled Concealer coded [redacted]. One (1) jar of the test product was supplied. The Concealer was tested as supplied viz., neat.

TEST PRODUCT ACCOUNTABILITY:

The test sample was received in good condition by our Quality Assurance Department. The test material was checked for (1) amount (2) product number or code (3) material container etc. The material was individually listed on the Test Product Inventory form signed by the receiver. The test sample was stored under ambient conditions (locked room) in an inaccessible location under the supervision of the investigator.

DISPOSITION OF REMAINING CLINICAL SUPPLIES:

All remaining test material(s) will be disposed of in accordance with applicable governmental regulations and in accordance with [redacted] SOPs following completion of the study and submission of the final written report to the Sponsor.

PANEL COMPOSITION:

Healthy, adult volunteers over the age of 18 years were recruited for this study. Panelists had no blemishes, excess hair or other marks on their volar forearms, upper outer arms or back that would obscure grading of the test site. Both male and female panelists were eligible. None of the subjects had a medical or dermatological illness and none were sensitive to sunscreens or to topical preparations and/or cosmetics. A completed panelist was a panelist who satisfied the inclusion/exclusion criteria and who completed the scheduled study procedures.

Inclusion Criteria:

1. Healthy adult male and female panelists between the ages of 18 and 70 years.
2. All panelists who were willing to follow the study requirements and voluntarily gave their informed consent.

Exclusion Criteria:

1. Panelists with any significant internal diseases e.g., cardiac, pulmonary, renal, hepatic, etc.
2. History of allergy or hypersensitivity to fragrances, cosmetics, tapes, toiletries or other dermatological products
3. History of recurrent dermatological diseases, e.g., psoriasis, atopic eczema, chronic urticaria
4. Pregnancy or mothers breastfeeding or planning a pregnancy
5. Scars, moles or other blemishes over the arms or back which could interfere with the study
6. Subjects receiving systemic or topical drugs or medications which could interfere with delayed immunologic responses e.g., corticosteroids, retinoids, immunosuppressants
7. Other conditions considered by the investigator as sound reasons for disqualification from enrollment into the study

SUBJECT ASSIGNMENT:

Volunteer subjects were screened and selected as described above and assigned a study number. The initials of each panelist accepted into the study were recorded as they were enrolled.

RECORDING OF DATA:

The case report forms (CRFs) for this study were provided by the Investigator. All case report forms were completed in actual time, during each panelist's visit. Original CRFs will be retained by the investigator along with the original signed informed consent forms.

HANDLING OF STUDY DOCUMENTS:

All study related documents, case report forms (CRFs), original informed consent forms and any data generated were kept under secure lock in the technician's office for the duration of the study.

STUDY PROCEDURES:

Method and Procedures[1,2]

Patches were applied to the arm or back of each panelist. The entire test was composed of three distinct phases: (1) an Induction phase and (2) a Rest Phase and (3) a Challenge phase.

(1) **Induction Phase**:

Approximately 0.05ml of aqueous SLS (0.25%) was applied to a designated site under a 15mm disc of webril cotton cloth and the patch was fastened to the skin with occlusive tape (Blenderm, 3M and Scanpor) for a period of 24 hours. After 24 hours, the SLS patch was removed. Prior to application to the SLS treated site, the test product (0.05ml) was applied to a cotton webril pad. The loaded webril pad was then applied to the same site before the site was again covered with occlusive tape (induction patch). The induction patch was left in place for 48 hours (or for 72 hours when placed over a weekend) following which it was removed and the site again examined for irritation. If no irritation was present, a 0.25% aqueous SLS patch was again reapplied to the same site for 24 hours, followed by reapplication of a fresh induction patch with the test material to the same site. This sequence viz. 24 hour SLS pre-treatment followed by 48 hours of test material application was continued for a total of 5 induction exposures. If irritation developed at any time-point during the induction phase as previously outlined, the 24-hour SLS pre-treatment patch was eliminated and only the test material was reapplied to the same site after a 24-hour rest period during which no patch was applied.

The aim during this phase of the study was to maintain at least a minimal degree of irritation in order to enhance penetration through the corneum barrier.

(2) **Rest Phase**:

No exposure to the test material was made during this rest period, which lasted approximately 10 days after the last induction patch.

(3) **Challenge Phase**:

After this 10 day rest period, the subjects were challenged with a single application of the test material to a new skin site on the opposite arm or opposite side of the back in order to determine if sensitization had developed.

Pre-treatment with SLS was performed prior to challenge. Approximately 0.05ml of a 1.0% aqueous solution was applied to a fresh skin site under a 15mm disc of Webril cotton and covered with occlusive tape. The SLS patch was left in place for one hour. It was then removed and 0.05ml of the test material was applied to the same site, as outlined above. The challenge patch was then covered by occlusive tape and left in place for 48 hours. After

that period, the patch was removed and the site graded, and again 24 hours later for any reactions.

SCORING SCALE:

0 = not sensitized

1 = mild sensitization (viz. erythema and a little edema)

2 = moderate sensitization (erythema with infiltration, raised, spreading beyond the borders of the patch, with or without vesiculation)

3 = strong sensitization (large vesiculo-bullous reaction).

Based on these findings the number of subjects with positive responses were tabulated for the test material. The test system shown below was used to classify the allergenic potential of the test substance.

SENSITIZATION RATES:	GRADES:	CLASSIFICATION:
0 - 2/25	1	Weak
3 - 7/25	2	Mild
8 - 13/25	3	Moderate
14 - 20/25	4	Strong
21 - 25/25	5	Extreme

ADVERSE EVENTS:

No untoward adverse reactions or unanticipated reactions were observed in any of the panelists. There were no serious adverse reactions reported by any panelist in this study.

PROTOCOL DEVIATION:

During the third week of induction due to a major winter storm, the testing facility was closed on Thursday, February 13, 2014. So as not to compromise the study, the product test patch that was applied on Tuesday, February 11, 2014, remained on the skin and was read on Friday, February 14, 2014.

RESULTS:

A total of twenty-seven (27) healthy adult panelists who qualified and satisfied the inclusion/exclusion criteria were enrolled into the study. There were 25 females and 2 males

ranging in age from 19 to 66 years. One subject #27 (initials [redacted] a female) failed to maintain the scheduled study visits and was lost to follow-up. She was subsequently dropped from the study for lack of compliance. The remaining 26 panelists completed this investigation as outlined in the standard study protocol. The demographic data are shown in Table 1. No unexpected reactions were seen in any of the panelists during the induction phase.

The results of the challenge are shown in the enclosed table (Table 2). No instances of contact allergy were recorded at either 48 or 72 hours after the application of the challenge patches.

CONCLUSION:

Under the conditions of this test, the test sample labeled Concealer and coded [redacted] does not possess a detectable contact-sensitizing potential and hence is not likely to cause contact sensitivity reactions under normal use conditions.

References:

(1) Kligman, A.M.: The Maximization Test. J.I.D., Vol. 47, No. 5, pp. 393-409, 1966.

(2) Kligman, A.M. and Epstein W.: Updating the Maximization Test for Identifying Contact Allergens. Contact Dermatitis. Vol. 1, 231-239, 1975.

TABLE 1

DEMOGRAPHIC DATA

Subject Number:	Subject Initials:	Age:	Sex:	Race:
01	[redacted]	53	F	C
02		61	F	C
03		53	F	C
04		40	F	C
05		32	F	C
06		41	F	C
07		66	F	C
08		48	F	C
09		60	F	C
10		21	F	C
11		47	F	C
12		49	M	C
13		38	F	C
14		46	F	C
15		20	F	C
16		62	F	B
17		63	M	B
18		62	F	C
19		39	F	C
20		27	F	C
21		66	F	C
22		33	F	B
23		65	F	C
24		48	F	C
25		19	F	A
26		47	F	C
27		23	F	C

C = Caucasian
B = Black
A = Asian

TABLE 2

RESULTS OF THE MAXIMIZATION SCHEDULED CHALLENGE

Sample: Concealer coded [redacted] (tested as supplied)

Subject Number:	48-Hour Evaluation	72-Hour Evaluation
01	0	0
02	0	0
03	0	0
04	0	0
05	0	0
06	0	0
07	0	0
08	0	0
09	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
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	-	-

Challenge Evaluations:

48-Hour Evaluation – February 26, 2014
72-Hour Evaluation – February 27, 2014

[redacted] **FINAL REPORT**

Final Report Date: February 20, 2012

[redacted] **Protocol: #**[redacted]

[redacted]

[redacted]

Title: An Assessment of the Photosensitization Potential of Three Topical Coded Test Products Using a Human Photocontact Allergenicity Assay

lotion 2 contains 7.5% Phenyl Trimethicone

Sponsor: [redacted]

Sponsor Study: [redacted]

Principal Investigator: [redacted] (Board Certified Dermatologist)

[redacted]

[redacted]

[redacted] M.D.
Principal Investigator

February 20, 2012
Date

[redacted]

FINAL REPORT

TITLE:

An Assessment of the Photosensitization Potential of Three Topical Test Products Using a Human Photocontact Allergenicity Assay.

[redacted] **PROTOCOL**:

[redacted]

GUIDELINES FOR THE CONDUCT OF THE STUDY:

All procedures were conducted in compliance with the regulations of the Food and Drug Administration (FDA) ([21 CFR 50, 56, 312) ICH-GCP Consolidated Guidelines, May 9, 1997 Federal Register) and in accordance with [redacted] Standard Operating Procedures (SOP's).

OBJECTIVE:

The objective of this study was to determine the photosensitization (photocontact allergenicity) potential of three topical cosmetic products to determine if these materials have a detectable photocontact allergenic potential when topically applied to human skin (see references #1 and #2).

DESIGN RATIONALE:

This was a repeat insult patch test wherein the test materials and ultraviolet radiation (solar simulated radiation) were administered to the same designated test sites over the mid or lower back area repeatedly for a total of six (6) induction exposures over a 3 week period followed by a challenge phase after a rest period of 10 to 14 days. The evaluator was blinded as to the identity of the test products.

CONDUCTION DATES:

This study was conducted from January 9, 2012 through February 10, 2012.

PRINCIPAL INVESTIGATOR:

[redacted], M.D. (Board Certified Dermatologist)

Medical Director, [redacted]

[redacted]

[redacted]

[redacted] ADMINISTRATIVE STRUCTURE:

[redacted] (Receptionist/Panel Recruitment/Initial Screening)

[redacted] (Technician/Patch Applications and Removals/UV Irradiation)

[redacted] (Laboratory Supervisor/Expert Grader)

[redacted] (Sr. Associate Director/Quality Assurance)

TESTING FACILITY:

[redacted]

SPONSOR:

[redacted]

Contact: [redacted]

Telephone: [redacted]

SPONSOR STUDY:

[redacted] Submission Form dated: January 4, 2012

INFORMED CONSENT:

Prior to acceptance into the study, each subject was informed by the Investigator or his designee of the nature and purpose of the study, possible side-effects and any other relevant information. The study procedures and possible risks and discomfort were explained to each panelist during the interview using popular understandable language and terms, and the panelists were encouraged to ask questions regarding the study. Each interviewed panelist who qualified was then asked to sign a consent form prior to enrollment. A copy of the study schedule of events, visits and dates was then given to the volunteer.

TEST MATERIALS:

The test samples used in this study were supplied by the sponsor. The products consisted of separate containers labeled Yellow Liquid coded [redacted] (1 jar); Lotion #1 coded [redacted] (1 jar) and Lotion #2 coded [redacted] (1 jar). The product coded [redacted] was allowed to air-dry for ~30 minutes prior to occlusion. All three test products were then tested neat, as supplied.

TEST DRUG ACCOUNTABILITY:

The test samples were received in good condition by our Quality Assurance Department. The test materials were checked for (1) amount (2) product number or code (3) material container etc. The materials were individually listed on a special sheet signed by the receiver, the laboratory supervisor and the investigator (physician). The test materials were stored at ambient conditions in an inaccessible location under the supervision of the investigator.

DISPOSITION OF REMAINING CLINICAL SUPPLIES:

All remaining test materials will be disposed of in accordance with established procedures following completion of the study and after the final written report has been issued to the Sponsor.

PANEL COMPOSITION:

Healthy, Caucasian, adult volunteers with no excess hair or other marks on their back that would obscure grading of the test sites were recruited for this study. These were fair skin individuals with skin types I, II, or III defined as follows (Federal Register 43: 38260, 1978):

Type I - Always burns easily; never tans
Type II - Always burns easily; tans minimally
Type III - Burns moderately; tans gradually

None of the subjects had a medical or dermatological illness and none were sensitive to sunlight or to topical preparations and/or cosmetics.

Inclusion Criteria:

1. Healthy adult male and female volunteers (skin types I to III) between the ages of 18 and 65 years.
2. All subjects were willing to follow the study requirements and voluntarily gave their informed consent.

Exclusion Criteria:

1. History of sun hypersensitivity and photosensitive dermatoses.
2. History of recurrent dermatological diseases, e.g., psoriasis, atopic eczema, chronic urticaria.
3. Subjects with any significant internal diseases, e.g., cardiac, pulmonary, renal, hepatic, etc.
4. History of allergy or hypersensitivity to cosmetics, toiletries, or other dermatological products.
5. History of allergy or hypersensitivity to sunscreens.
6. History of allergy or hypersensitivity to any type of tape.
7. Scars, moles or other blemishes over the lower back, which could have interfered with the study.
8. Subjects receiving systemic or topical drugs including steroidal or non-steroidal anti-inflammatory drugs, or medications which could have interfered with the development of an inflammatory response, e.g., immunosuppressive agents or retinoids.
9. Subjects receiving potentially photosensitizing medications, e.g., thiazides, tetracyclines, phenothiazines, etc.
10. Pregnancy or mothers who were breastfeeding or planning a pregnancy.
11. Other conditions considered by the Investigator as sound reasons for disqualification from enrollment into the study.

SUBJECT ASSIGNMENT:

Volunteer subjects were screened and selected as described above and assigned a study number. The initials of each subject accepted into the study were recorded sequentially as they were enrolled.

RECORDING OF DATA:

The case report forms (CRF's) for this study were provided by the Investigator. All case report forms were completed in actual time, during each subject's visit. All scores were recorded on the Case Report Forms. Copies of the CRF's will be retained by the investigator along with the original signed informed consent forms.

HANDLING OF STUDY DOCUMENTS

All study related documents, case report forms (CRF's), original informed subject consent forms and any data generated were kept under secure lock in the technician's office for the duration of the study.

TEST SITE:

The test site was the mid or lower back. The test sites were inspected prior to test product application to ensure that the skin was normal in appearance and free of irritation or other blemishes.

METHOD[1,2]:

Test patches were applied to the lower back of each subject. The entire test was composed of three distinct phases: (1) Pre-testing phase (2) Induction phase and (3) Challenge phase.

(1) PRE-TESTING PHASE:

After signing an informed consent form (on Day 1), the Minimal Erythema Dose (MED) of each subject was determined by exposing one side of the midback to a series of exposures (1cm diameter circular areas) in 25% increments from the xenon arc solar simulator, the details of which are listed below. The subject's MED is the shortest exposure time that produces a minimally visible faint erythema 20 to 24 hours later.

(2) INDUCTION PHASE:

Approximately 40mgs. of each test material was spread uniformly over a 2x2cm square of non-woven cotton cloth (Webril, Curity). The loaded patches were then applied to the designated test area and covered with occlusive tape (Blenderm, 3M). The patches were left in place for twenty-four (24) hours. At the end of that period, the patches were

removed and the sites wiped off with dry gauze and exposed to two minimal erythema doses (MED's) from the xenon arc solar simulator. The sites were then left open for a forty-eight (48) hour period, after which the subjects returned to the testing facility and the patches were again reapplied to the same designated test sites under dressings as outlined above. Twenty-four (24) hours later, the patches were removed and the sites re-exposed to 2 MED's of solar simulated radiation. This sequence was repeated to the same test sites twice weekly for a total of three weeks (total of 6 exposures).

(3) CHALLENGE:

Ten (10-14) days following the last induction dose, the subjects returned to the testing facility for a single challenge exposure. The test materials were applied as previously specified (40mgs) in **duplicate** to new designated skin sites each measuring 2x2cm on the opposite side of the lower back, under dressings, as previously described, for a period of approximately 24 hours. One set of patches was then removed and any excess test material wiped off with dry gauze. The sites were then irradiated with 1/2 an MED of solar simulated radiation (SSR) plus 4J/cm^2 of UVA which was obtained by filtering the beam from the solar simulator to eliminate short (UVB) wavelengths (see Light Source). The duplicate set of patches remained unirradiated and served as control treated sites.

EVALUATION OF SKIN REACTIONS:

All test sites were examined for reactions at 48 and 72 hours following exposure of the sites to UV radiation. Each subject reported back to the testing facility at the two time points to have the responses appraised by an evaluator other than the person applying the test products, and who was unaware of the nature of the test substances.

Skin reactions were scored according to the following scale:

0 = Not sensitized
1 = Mild sensitization (viz. erythema and a little edema)
2 = Moderate sensitization (erythema with infiltration, spreading reaction beyond the borders of the patch, with or without vesiculation)
3 = Strong sensitization (large vesicula-bullous reaction)

LIGHT SOURCE[3]:

This was a 150-watt compact xenon arc source equipped with UV-reflecting dichroic mirror and a 1mm thick Schott WG-320 filter to produce simulation of the solar spectrum (290nm-400nm). A 1mm thick UG5 filter was added to remove reflected heat and remaining visible radiation. Total irradiance at skin level was measured with a calibrated Eppley Thermopile. The size of the irradiated field was approximately a 1-cm diameter circle. UVA was obtained from this same source by passing the beam through a 1mm Schott WG345 filter (Schott Glass Technologies). This provided a continuous spectrum between 320 and 420nm with a peak between 360-370nm. Total irradiance at skin level was 217.5mW/cm^2. The UVA intensity was 75.0mW/cm^2.

ADVERSE EXPERIENCES:

No adverse experiences or unanticipated reactions of any kind were observed or reported during the study.

RESULTS:

A total of 27 healthy, Caucasian volunteers who qualified were enrolled into this study. There were 24 females and 3 males ranging in age from 20 to 60 years. One volunteer #13 (initials RJP, a female) voluntarily withdrew for personal reasons unrelated to the study. The remaining 26 volunteers completed this investigation, as specified in the protocol. The demography is shown in Table 1.

No side-effects or unexpected reactions of any kind were observed. Following the challenge phase, no reactions suggestive of photocontact allergy were seen in any of the panelists at either 48 or 72 hours post exposure. The results of the challenge are summarized in the enclosed tables (Tables 2 through 7).

CONCLUSIONS:

Under the presently described test conditions, the test materials labeled [redacted]); [redacted]) and Lotion #2 ([redacted]) do not possess a detectable photocontact-sensitizing potential in human skin.

REFERENCES

(1) Kaidbey, KH and Kligman AM: Photomaximization test for identifying photoallergic contact sensitizers. Contact Dermatitis, 6: 161-169, 1980.

(2) Kaidbey, KH and Kligman AM: Identification of contact photosensitizers by human assay. In "Current concepts in cutaneous toxicity, edited by V.A. Drill and P. Lazar. Academic Press Inc., pp. 55-68, 1980

(3) Berger DS: Specification and design of solar ultraviolet simulators. J.Invest.Dermtol. 53: 192-199, 1969.

TABLE 1

DEMOGRAPHIC DATA

Subject Number:	Subject Initials:	Age:	Sex:	Race:
01	[redacted]	57	F	C
02	[redacted]	48	F	C
03	[redacted]	57	F	C
04	[redacted]	28	F	C
05	[redacted]	53	M	C
06	[redacted]	48	M	C
07	[redacted]	57	F	C
08	[redacted]	37	F	C
09	[redacted]	36	F	C
10	[redacted]	60	F	C
11	[redacted]	50	F	C
12	[redacted]	44	F	C
13	[redacted]	47	F	C
14	[redacted]	60	F	C
15	[redacted]	47	F	C
16	[redacted]	41	F	C
17	[redacted]	43	F	C
18	[redacted]	31	F	C
19	[redacted]	35	F	C
20	[redacted]	57	F	C
21	[redacted]	31	F	C
22	[redacted]	27	M	C
23	[redacted]	38	F	C
24	[redacted]	29	F	C
25	[redacted]	31	F	C
26	[redacted]	54	F	C
27	[redacted]	20	F	C

C = Caucasian

TABLE 6

RESULTS OF PHOTOMAXIMIZATION TESTING (48 Hour Grading)

Sample: Lotion #2 coded [redacted] (tested as supplied)

Subject Number:	Unirradiated Control	UV Irradiated
001	0	0
002	0	0
003	0	0
004	0	0
005	0	0
006	0	0
007	0	0
008	0	0
009	0	0
010	0	0
011	0	0
012	0	0
013	-	-
014	0	0
015	0	0
016	0	0
017	0	0
018	0	0
019	0	0
020	0	0
021	0	0
022	0	0
023	0	0
024	0	0
025	0	0
026	0	0
027	0	0

GRADING SCALE:

0 = Not sensitized
1 = Mild sensitization (viz. erythema and a little edema)
2 = Moderate sensitization (erythema with infiltration, spreading reaction beyond the borders of the patch, with or without vesiculation)
3 = Strong sensitization (large vesiculo-bullous reaction)

TABLE 7

RESULTS OF PHOTOMAXIMIZATION TESTING (72 Hour Grading)

Sample: Lotion #2 coded [redacted] (tested as supplied)

Subject Number:	Unirradiated Control	UV Irradiated
001	0	0
002	0	0
003	0	0
004	0	0
005	0	0
006	0	0
007	0	0
008	0	0
009	0	0
010	0	0
011	0	0
012	0	0
013	-	-
014	0	0
015	0	0
016	0	0
017	0	0
018	0	0
019	0	0
020	0	0
021	0	0
022	0	0
023	0	0
024	0	0
025	0	0
026	0	0
027	0	0

GRADING SCALE:

0 = Not sensitized
1 = Mild sensitization (viz. erythema and a little edema)
2 = Moderate sensitization (erythema with infiltration, spreading reaction beyond the borders of the patch, with or without vesiculation)
3 = Strong sensitization (large vesiculo-bullous reaction)

[redacted]

RESEARCH AND DEVELOPMENT
[redacted] DEPARTMENT

[redacted] **REPORT: HUMAN PATCH TEST**

This test follows the procedure described in SOP, HPT.1 **TO:** [redacted]

PRODUCT PROFILE NO: [redacted] DATE: October 24, 2008 LAB REF.: [redacted]

1. TEST MATERIAL: [redacted] Lip Color # [redacted]

contains 9.06% Diphenyl Dimethicone

2. CONTROL MATERIAL: [redacted] Liquid Lip Color – [redacted] F# [redacted]

3. TEST PROCEDURE:

Single-Insult (24hr.) __X__ Occlusive (Blenderm) Patch __X__ Semi-Occlusive Patch _____.

4. CONCENTRATION:

Full-Strength __X__ Aqueous _____ Solution _____ Dispersion _____ Aqueous Paste _____.
Other: _____.

__X__ Volatiles were allowed to evaporate 30 minutes prior to occlusion on the patch (1013552-002 only).
_____ Patch was hydrated just prior to application to skin.

5. TEST RESULTS:

TEST MATERIAL	*SUBJECTS*	*IRRITATION SCORE**									
		0	±	1	1+	2	2+	3	3+	4	PII
[redacted] Lip Color F# [redacted]	20	20	0	0	0	0	0	0	0	0	0.00
[redacted] Liquid Lip Color – [redacted] F# [redacted]	20	20	0	0	0	0	0	0	0	0	0.00

____ Skin staining noted. Erythematous response was read "through" the Stain.

6. CONCLUSIONS:

A. There were no significant differences in irritancy observed between the Test Material (s) and the Reference Control (s). __X__.

B. _____.

Study Conducted By: [redacted] Approved By: [redacted]

* SCORE
0 = No evidence of any effect.
± (Barely Perceptible) = minimal faint uniform or spotty erythema
1 (Mild) = Pink uniform erythema covering most of the contact site.
2 (Moderate) = Pink-red erythema visibly uniform in entire contact area.
3 (Marked) = Bright red erythema with accompanying edema petechiae or papules.
4 (Severe) = Deep red erythema with vesiculation or weeping with or without edema.

+, 1+, 2+ and 3+ = Intermediate scores contributing 0.5, 1.5, 2.5 and 3.5 respectively, to the P.I.I.
P.I.I. - Primary Irritation Index - a value depicting the average skin response of the test panel as a whole. It is calculated by choosing the higher of the two Irritation Scores per panelist, adding them all together and dividing by the total number of test subjects.

CC: [redacted]