

Essex Testing Clinic, Inc.



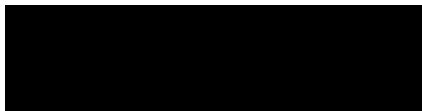
FINAL REPORT

CLINICAL SAFETY EVALUATION

REPEATED INSULT PATCH TEST

CastAway SPF 30 Formula# 

Sponsor



Sponsor Representative

Darwin Tandam

Clinical Testing Facility

**Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044**

**Sponsor Code: N66
ETC Panel No.: 19148
ETC Entry No.: 38679**

Date of Final Report

5-16-19

SIGNATURE PAGE
CLINICAL SAFETY EVALUATION
REPEATED INSULT PATCH TEST
CastAway SPF 30 Formula# [REDACTED]



John A. Erienne, MD
Board-Certified Dermatologist
Medical Investigator



Date

QUALITY ASSURANCE STATEMENT

This study (ETC Panel No.: 19148; ETC Entry No.: 38679) was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects – Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

For purposes of this clinical study:

- Informed Consent was obtained.
- Informed Consent was not obtained.
- An IRB review was not required.
- An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This report is considered a true and accurate reflection of the testing methods and source data.

Sherril L. Sayles
Sherril L. Sayles, MS
Manager, Quality Assurance

13 May 2019
Date

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TABLE 1 - INDIVIDUAL SCORES

CLINICAL SAFETY EVALUATION

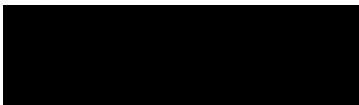
REPEATED INSULT PATCH TEST

CastAway SPF 30 Formula# [REDACTED]

1.0 OBJECTIVE

The objective of this study was to determine the irritation and/or sensitization potential of the test article after repeated application under semi-occlusive patch test conditions to the skin of human subjects (non-exclusive panel).

2.0 SPONSOR



2.1 Sponsor Representative

Darwin Tandam

3.0 CLINICAL TESTING FACILITY

The study was conducted by:

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

4.0 CLINICAL INVESTIGATORS

Study Director: Annemarie E. Hollenback, BA
Principal Investigator: Toni F. Miller, PhD, DABT, BCFE
Medical Investigator: John A. Erianne, MD, Board-Certified Dermatologist

5.0 STUDY DATES

Study initiation: March 20, 2019

Final evaluation: April 26, 2019

6.0 ETHICS

6.1 Ethical Conduct of the Study

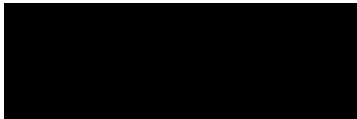
This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures.

6.2 Subject Information and Consent


This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

7.0 TEST MATERIAL

The test article used in this study was provided by:



It was received on March 4, 2019 and identified as follows:

<u>ETC Entry No.</u>	<u>Test Article ID</u>	<u>Description</u>
38679	CastAway SPF 30 Formula# 	White Lotion

8.0 TEST SUBJECTS

At least 50 male and female subjects ranging in age from 18 to 79 years, were to be empanelled for this test.

The subjects chosen were to be dependable and able to read and understand instructions. The subjects were not to exhibit any physical or dermatologic condition that would have precluded application of the test article or determination of potential effects of the test article.

9.0 TEST PROCEDURE

The 9 Repeated Insult (semi-occlusive) Patch Test (9-RIPT)¹ was conducted as follows:

9.1 Induction Phase

A sufficient amount of the test article (an amount to adequately cover the surface of the patch unit - approximately 0.1 g – 0.15 g) was placed onto an approximate 2 cm x 2 cm square of Webril® cotton fabric (approximately 25 – 38 mg/cm² of test material) affixed to Scanpor (Allerderm) semi-occlusive surgical tape. The patch was then applied to the back of each subject between the scapulae and waist, adjacent to the spinal mid-line. This procedure was performed by a trained technician/examiner and repeated every Monday, Wednesday and Friday until 9 applications of the test article had been made.

The subjects were instructed to remove the patch 24 hours after application. Twenty-four hour rest periods followed the Tuesday and Thursday removals and 48-hour rest periods followed each Saturday removal. Subjects returned to the Testing Facility and the site was scored by a trained examiner just prior to the next patch application.

If a subject developed a positive reaction of a level 2 erythema or greater during the Induction phase or if, at the discretion of the Study Director, the skin response warranted a change in site, the patch was applied to a previously unpatched, adjacent site for the next application. If a level 2 reaction or greater occurred at the new site, no further applications were made. However, any reactive subjects were subsequently Challenge patch tested.

9.2 Challenge Phase

After a rest period of approximately 2 weeks (no applications of the test article), the Challenge patch was applied to a previously unpatched (virgin) test site. The site was scored 24 and 72 hours after application. All subjects were instructed to report any delayed skin reactivity that occurred after the final Challenge patch reading. When warranted, selected test subjects were called back to the Clinic for additional examinations and scoring to determine possible increases or decreases in Challenge patch reactivity.

Dermal responses for both the Induction and Challenge phases of the study were scored according to the following 6-point scale:

- 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 uniform in the entire contact site)
- 3 = Marked (Bright red erythema with/without petechiae or papules)
- 4 = Severe (Deep red erythema with/without vesiculation or weeping)

All other observed dermal sequelae (eg, edema, dryness, hypo- or hyperpigmentation) were appropriately recorded on the data sheet and described as mild, moderate or severe.

¹ Marzulli FN, Maibach HI. (1976) Contact allergy: predictive testing in man. *Contact Dermatitis*. 2, 1-17. Essex Testing Clinic, Inc.

9.0 TEST PROCEDURE (CONT'D)

9.3 Data Interpretation

Edema, vesicles, papules and/or erythema that persist or increase in intensity either during the Induction and/or Challenge phase may be indicative of allergic contact dermatitis. Allergic responses normally do not resolve or improve markedly at 72-96 hours.

Exceptions to typical skin reactions may occur. These may include, but not be limited to, symptoms of allergic contact sensitivity early in the Induction period to one or more test products. When this occurs in one subject, such a reaction usually suggests either an idiosyncratic response or that the subject had a pre-exposure/sensitization to the test material or component(s) of the test material or a cross-reactivity with a similar product/component. Data for such reactions will be included in the study report but will not be included in the final study analysis/conclusion of sensitization.

10.0 RESULTS AND DISCUSSION

(See Table 1 for Individual Scores)

A total of 58 subjects (10 males and 48 females ranging in age from 19 to 79 years) were empanelled for the test procedure. Fifty-two (52/58) subjects satisfactorily completed the test procedure on Test Article: CastAway SPF 30 Formula# [REDACTED]. Six (6/58) subjects discontinued for personal reasons unrelated to the conduct of the study. Discontinued subject data are shown up to the point of discontinuation, but are not used in the Conclusions section of this final report.

Induction Phase Summary

Test Article	Induction Scores (Number of Responses)						Evidence of Irritation
	0.5	1	2	3	4	Other	
CastAway SPF 30 Formula# [REDACTED]	0	0	0	0	0	0	No

Challenge Phase Summary

Test Article	Challenge Scores (Number of Responses)						Evidence of Sensitization
	0.5	1	2	3	4	Other	
CastAway SPF 30 Formula# [REDACTED]	0	0	0	0	0	0	No

CastAway

There was no skin reactivity observed at any time during the course of the study.

11.0 CONCLUSIONS

Under the conditions of a repeated insult (semi-occlusive) patch test procedure conducted in 52 subjects, Test Article: CastAway SPF 30 Formula# [REDACTED] was "Dermatologist-Tested" and was not associated with skin irritation or allergic contact dermatitis in human subjects.

TABLE 1
INDIVIDUAL SCORES
REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVE
 Test Article: CastAway SPF 30 Formula# XXXXXXXXXX

Subj. No.	Induction Evaluation Number									Challenge Virgin Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
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	Discontinued			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	Discontinued			0	0	0	0	0
26	Discontinued										
27	Discontinued										
28	0	Discontinued									
29	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0

Scale: 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 uniform in the entire contact site)
 3 = Marked (Bright red erythema with/without petechiae or papules)
 4 = Severe (Deep red erythema with/without vesiculation or weeping)

TABLE 1 (CONT'D)

INDIVIDUAL SCORES

REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVE

Test Article: CastAway SPF 30 Formula# XXXXXXXXXX

Subj. No.	Induction Evaluation Number									Challenge Virgin Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
31	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0
55	Discontinued			0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0

- Scale: 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)
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