CONSUMER PRODUCT TESTING COMPANY
cptclabs.com

FINAL REPORT

CLIENT: Encapsun Technologies
7222 South Tamiami Trail – Unit 104
Sarasota, FL 34231

ATTENTION: Dan Traynor

TEST: Repeated Insult Patch Test
Protocol No.: CP-01.01S
Protocol Date: 01/22/25

TEST MATERIAL: 15-081 Repellent

STUDY NUMBER: C26-0119.01

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

Approved by: Michael Traudt, Ph.D.
Vice President, Clinical and Photobiology Services

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FDA Registration# 1000151293
DEA Registration# RC0199744 Schedule I-V
US EPA/NJ DEP Registration# NJ0982726648
ISO/IEC 17025:2017 Accreditation # 80071

QUALITY ASSURANCE UNIT STATEMENT

Study Number: C26-0119.01

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

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

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of five (5) years. At any time prior to the completion of the fifth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period with no further notice in a manner that renders them useless.

Quality Assurance Representative

5-12-26
Date

Objective: To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

Subjects: Fifty-six (56) qualified subjects, male and female, ranging in age from 19 to 79 years, were selected for this evaluation. All fifty-six (56) subjects completed this clinical trial.

Inclusion Criteria:

1. Subjects must have read, signed, and dated an Informed Consent Form that included a HIPAA statement;
2. Subjects who were male or female, aged 16-79 years, inclusive;
3. Subjects who were considered reliable and capable of understanding and following directions; and
4. Subjects aged 16 or 17 years must have read, signed, and dated an Adolescent Assent Form after their parent or legal guardian had read, signed, and dated an Informed Consent Form.

Exclusion Criteria:

1. Subjects who were in ill health, as determined by the Principal Investigator;
2. Subjects who were taking medication, other than birth control, that, in the opinion of the Investigator, could have influenced the purpose, integrity, or outcome of the trial;
3. Subjects who had used any prescribed or OTC anti-inflammatory, antihistamine, corticosteroid, immunosuppressant, or antibiotic drug within 7 days prior to initiation of the trial or during their participation on this trial;
4. Female subjects who were pregnant, planning to become pregnant, or lactating during the trial;
5. Subjects with any visible disease, sunburn, scars, excessive tattoos, etc., that might have been confused with a skin reaction to the test material or, as determined by the Principal Investigator, might have interfered with the evaluation;
6. Subjects who had a history of adverse reactions to cosmetics, adhesive tapes, OTC drugs, or other personal care products; or
7. Subjects who introduced the use of any new cosmetic, toiletry, or personal care products during the trial.

Test Material: 15-081 Repellent

Trial Schedule:

Panel #	Initiation Date	Completion Date
20260032	March 16, 2026	May 1, 2026

Methodology:

The informed consent process fully apprised each potential subject of the risks and benefits associated with the research clinical trial and of the confidentiality requirements relating to the subject's clinical trial records. If the potential subject agreed to participate in the research clinical trial, then the potential subject executed the Informed Consent Form (ICF) after which the potential subject entered the clinical trial as a subject. Staff who conducted the informed consent process also executed the form. Each subject received a signed copy of the fully executed ICF. If at any time during the clinical trial the subject had questions, the ICF directed the subject to a Subject Rights Advocate, whose contact information was in the ICF. Subjects completed a Medical History Form to determine initial qualification.

The upper back between the scapulae served as the treatment area. Approximately 0.2 ml of the test material, or an amount sufficient to cover the contact surface, was applied to the 1 in^2 absorbent pad portion of a clear, adhesive dressing and allowed to volatilize for approximately 15 minutes. This was then applied to the appropriate treatment site to form a semi-occlusive patch.

Induction Phase:

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home, one day after application. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications 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 one day following each Tuesday and Thursday removal, and two days following each Saturday removal.

Methodology (continued):

Challenge Phase:

At least 10 days following the final Induction Phase patch removal, 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 Day 1 and Day 3 post-application.

Evaluation Criteria (Erythema and additional Dermal Sequelae):

0	=	**No visible skin reaction**	**E**	=	**Edema**
0.5	=	**Barely perceptible**	**D**	=	**Dryness**
1	=	**Mild**	**S**	=	**Staining**
2	=	**Moderate**	**P**	=	**Papules**
3	=	**Marked**	**V**	=	**Vesicles**
4	=	**Severe**	**B**	=	**Bullae**
			U	=	**Ulceration**
			Sp	=	**Spreading**

Erythema was scored numerically according to this key. If present, additional Dermal Sequelae were indicated by the appropriate letter code and a numerical value for severity.

Adverse Events: There were no adverse events.

Amendments: There were no amendments.

Deviations: There were no deviations.

Results:

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

Observations remained within normal limits throughout the test interval.

Subject demographics are presented in Table 2.

Summary:

Under the conditions of this clinical trial, test material, 15-081 Repellent, indicated no potential for dermal irritation or allergic contact sensitization.

Table 1
Panel #20260032

Individual Results

15-081 Repellent

Subject Number	Day1*	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site Day 1*	Day 3
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	**1**[E1]	**0.5**	**0.5**	**0.5**	**0.5**[D1]	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

Day 1* = Supervised removal

E = Edema
D = Dryness

Table 1
(continued)
Panel #20260032

Individual Results

15-081 Repellent

Subject Number	Day1*	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site Day 1*	Day 3
30	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal

Table 2
Panel #20260032

Subject Demographics

Subject Number	ID#	Age	Gender	Fitzpatrick Photo Type
1	94419	48	F	III
2	97551	73	F	IV
3	94130	62	M	III
4	94629	77	F	II
5	67498	75	F	III
6	90189	75	F	III
7	92635	79	M	III
8	94435	78	F	III
9	91727	49	M	IV
10	40879	79	F	III
11	83981	73	F	II
12	87404	71	F	III
13	41757	76	M	III
14	93921	59	F	II
15	50139	74	F	IV
16	64547	73	F	II
17	94090	57	M	III
18	94487	73	F	IV
19	3560	76	F	II
20	97602	24	F	III
21	96480	19	F	III
22	96040	51	F	II
23	96456	66	F	IV
24	97604	46	F	V
25	60209	50	F	III
26	96399	41	M	V
27	97345	46	F	IV
28	89963	45	F	VI
29	9002	67	F	II

Table 2
(continued)
Panel #20260032

Subject Demographics

Subject Number	ID#	Age	Gender	Fitzpatrick Photo Type
30	97346	28	F	VI
31	97347	29	M	IV
32	97215	60	F	IV
33	95419	49	M	IV
34	35232	57	F	IV
35	80751	64	F	II
36	97625	41	F	III
37	81306	39	F	VI
38	70991	67	M	IV
39	92883	56	F	IV
40	28646	46	M	III
41	96015	48	F	VI
42	97200	51	M	III
43	27990	61	M	III
44	45583	44	F	IV
45	10890	53	F	IV
46	71910	64	F	V
47	63339	48	M	V
48	29523	69	F	III
49	45295	59	F	I
50	49528	53	F	III
51	4184	62	F	III
52	81938	61	M	IV
53	57582	61	F	IV
54	5444	50	F	IV
55	95050	44	F	IV
56	97422	38	M	IV