CLINICAL STUDY REPORT

Report Status	Final
Report Date	27 September 2023
Study Number	ECRLNJ2023-0601
Protocol Number	CL 1.0 2022
Study Title	Repeated Insult Patch Test
Test Material	Hair Reducing Fade Oil
Sponsor	Umber By J. Lenay LLC 20511 Atascocita Shores Dr Humble, TX 77346
Sponsor Representative	Chris Nelson Owner
Investigating Laboratory	Eurofins | CRL, Inc. 371 Hoes Lane, Suite 100 Piscataway, New Jersey 08854 Telephone: (732) 981-1616 Fax: (732) 981-0520
Principal Investigator	Winston Moy, MD Diplomate, American Board of Dermatology
Study Initiation Date	02 August 2023
Study Completion Date	15 September 2023

PRINCIPAL INVESTIGATOR SIGNATURE

Study Title: Repeated Insult Patch Test

Clinical Study Number: ECRLNJ2023-0601

I have read the study report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Winston Moy MD

Winston Moy MD
2023.09.27 13:53:03
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Principal Investigator Signature/Date

QUALITY ASSURANCE AUDIT STATEMENT

Eurofins | CRL, Inc. follows established, standardized procedures for clinical testing designed to ensure the well-being of clinical study subjects and the generation of reliable study data. The study was conducted in accordance with the study protocol and Eurofins | CRL, Inc. Standard Operating Procedures. In addition, the study was conducted following applicable ICH GCP standards to ensure reliability of data, subject safety and confidentiality. All data included in the report is accurately represented. The clinical study master file was reviewed by the Principal Investigator and the Quality Assurance representative.

Natalie McCrea

Digitally signed by
Natalie McCrea
Date: 2023.09.27
13:04:58 -04'00'

Signature of QA Auditor and Date

1.0 ETHICS

1.1. ETHICAL CONDUCT OF THE STUDY

ECRL follows established, standardized procedures for clinical testing designed to ensure the well-being of clinical study subjects and the generation of reliable study data. It is the responsibility of the Study Sponsor to ensure the study complies with applicable Drug, Cosmetic or Medical Device regulations, which vary by product. The Study Sponsor is solely responsible for product marketing claims based on its interpretation of ECRL studies.

1.2. PARTICIPANT INFORMATION AND INFORMED CONSENT

Each subject was given a copy of the Informed Consent Form (ICF) had the nature and the purpose of the study explained to them by ECRL personnel. Prior to entry into the study, the subject gave voluntary written consent to participate by signing the ICF. The Principal Investigator retained the original signed Informed Consent Form in the subject's file and gave a copy of the Informed Consent Form to the subject.

1.3. SUBJECT CONFIDENTIALITY

The Principal Investigator ensures that the research subject's confidentiality was maintained. Subjects are identified by their study ID number only. Documents are kept in strict confidence by the Principal Investigator. Any use of personally identifiable data or private health information must be justified by the Principal Investigator.

2.0 OBJECTIVE

The objective of this study was to determine the potential of a test material to elicit dermal irritation and/or induce sensitization following repeated patch applications.

3.0 TEST MATERIAL AND RECORD RETENTION

The test material received from the Sponsor was identified by Eurofins | CRL, Inc. (ECRL) study and panel numbers. The test material was identified as follows:

Test Material	Test Condition	Patch Type
Hair Reducing Fade Oil	TAR / Protect from Light / Keep Room Temperature / Shake Well	Occlusive

TAR = Tested as Received

The Sponsor assumed responsibility for the purity, stability, characterization, and adequate preservation of the test material. The Sponsor provided assurance that the test material submitted has been determined to be safe for use in humans.

3.1. STORAGE AND RETENTION

Test material and study documentation will be retained as listed in the sponsor specific sample submission form.

4.0 SUBJECT SELECTION

A total of 120 male and female subjects, ranging in age from 18 to 70 years who met all of the inclusion criteria and none of the exclusion criteria as outlined in the study protocol, were selected for study participation.

5.0 STUDY EVALUATIONS

The following Dermal Scoring System was used:

Dermal Score	Description
0	No visible skin reaction
±	Barely perceptible erythema
1+	Mild erythema
2+	Well defined erythema
3+	Severe erythema and edema
4+	Erythema and edema with vesiculation

Letter Codes			
e = Edema	S = Spreading of reaction beyond patch site	D = Oozing, crusting, and/or superficial erosions	F = Follicular irritation with or without pustule formation (folliculitis)
P = Peeling	V = Vesiculation	d = Dryness/scaling	SD= Site Discontinued
Pa = Papules	B = Burning	Ho = Hypopigmentation	ST = Site Terminated
I = Itching	Sc = Scabbing	Hr = Hyperpigmentation	NP = No patching
X = Subject Absent	Ex = Excoriation	C = Changed Site	-- = No reading

6.0 TEST METHOD

This study was conducted according to clinical study protocol CL 1.0 2022.

7.0 STUDY RESULTS

7.1. COMPLETED AND DISCONTINUED SUBJECTS

A total of 106 subjects completed the study. Discontinued subjects are listed below:

Subject Number	Reason for Discontinuation
03	Lost to Follow Up
04	Lost to Follow Up
10	Lost to Follow Up
14	Lost to Follow Up
22	Lost to Follow Up
23	Lost to Follow Up
49	Lost to Follow Up
55	Lost to Follow Up
71	Lost to Follow Up
76	Personal Reasons
103	Lost to Follow Up
109	Personal Reasons
110	Lost to Follow Up
113	Lost to Follow Up

7.2. DERMAL EVALUATIONS

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I for subjects that elicited dermal reactions, missed a visit, and/or were discontinued.

All other subjects did not exhibit any dermal reactions throughout the course of the entire study and had scores of ‘0’.

7.3. PROTOCOL DEVIATIONS

No protocol deviations occurred over the duration of the study.

7.0 STUDY RESULTS (CONTINUED)

7.4. PROTOCOL AMENDMENTS

There were no protocol amendments during this study.

7.5. ADVERSE EVENTS

No adverse events were reported over the duration of the study.

8.0 CONCLUSION

Based on the test population of 106 subjects and under the conditions of this study, the test material identified as Hair Reducing Fade Oil did not demonstrate a potential for eliciting dermal irritation or inducing sensitization.

Table I - Summary of Dermal Scores

Subject Number	Induction Scores									Challenge Scores			
	1	2	3	4	5	6	7	8	9	24 Hr.	48 Hr.	72 Hr.	96 Hr.
3	0	0	0	0	0	0	DISCONTINUED						
4	0	0	0	0	0	0	DISCONTINUED						
10	DISCONTINUED												
14	0	0	0	0	0	0	0	0	0	DISCONTINUED			
19	0	0	0	0	0	0	0	0	0	0	0	X	0
22	0	0	0	0	0	0	0	0	0	DISCONTINUED			
23	0	0	0	DISCONTINUED									
25	0	0	0	0	0	0	0	0	0	0	X	0	0
33	0	0	0	0	0	0	0	0	0	0	X	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	X
49	0	0	0	0	0	0	0	0	0	DISCONTINUED			
55	0	DISCONTINUED											
71	0	0	0	0	0	0	0	0	0	0	0	X	DISC*
76	0	0	DISCONTINUED										
91	0	0	0	0	0	0	0	0	0	0	0	0	---
94	0	0	0	0	0	0	0	0	0	X	0	0	0
103	0	0	0	0	0	0	0	0	0	DISCONTINUED			
108	0	0	0	0	0	0	0	0	0	0	0	0	X
109	0	0	0	0	0	0	0	0	0	0	DISCONTINUED		
110	0	0	0	0	0	0	0	0	0	0	0	X	DISC*
113	0	0	0	0	0	0	0	0	0	DISCONTINUED			
119	0	0	0	0	0	0	0	0	0	0	X	0	0

*DISC = DISCONTINUED

**All other 98 subjects except the above listed did not exhibit any dermal reactions throughout the course of the entire study and had scores of '0'.*

Appendix I - Subject Demographics

Subject Number	Age	Sex
01	52	M
02	28	F
03	31	F
04	37	M
05	49	F
06	24	M
07	60	F
08	61	M
09	56	F
10	31	F
11	41	F
12	24	M
13	50	M
14	52	M
15	54	F
16	47	M
17	61	F
18	54	F
19	32	F
20	46	F
21	52	M
22	18	F
23	52	F
24	45	F
25	64	F
26	52	F
27	48	F
28	66	F
29	62	M
30	70	F

Subject Number	Age	Sex
31	57	F
32	63	M
33	19	F
34	55	F
35	57	M
36	18	F
37	68	F
38	42	F
39	54	F
40	59	F
41	40	F
42	56	M
43	69	F
44	64	F
45	20	M
46	40	F
47	58	F
48	54	F
49	27	F
50	29	M
51	57	F
52	67	F
53	53	F
54	44	F
55	38	M
56	55	M
57	41	F
58	54	F
59	57	F
60	38	F

Appendix I – Subject Demographics (Continued)

Subject Number	Age	Sex
61	66	M
62	23	M
63	57	F
64	43	F
65	60	M
66	51	F
67	23	F
68	51	M
69	52	M
70	60	F
71	21	M
72	37	F
73	61	F
74	47	F
75	65	F
76	51	F
77	52	F
78	42	F
79	36	F
80	36	F
81	34	M
82	35	F
83	43	F
84	23	F
85	42	M
86	62	M
87	29	F
88	29	M
89	55	F
90	61	M

Subject Number	Age	Sex
91	57	M
92	50	F
93	38	F
94	46	M
95	52	F
96	38	F
97	56	M
98	46	F
99	49	M
100	37	M
101	61	F
102	42	F
103	22	M
104	34	F
105	32	M
106	33	F
107	25	F
108	61	M
109	50	M
110	67	M
111	42	F
112	40	F
113	53	M
114	45	M
115	46	F
116	68	F
117	53	F
118	21	M
119	31	F
120	28	F