Data Supplement

Barley

CIR EXPERT PANEL MEETING
DECEMBER 7-8, 2020

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst, CIR
Date: November 30, 2020
Subject: Safety Assessment on Barley-Derived Ingredients as Used in Cosmetics – Wave 2

Enclosed is a human repeated insult patch test (HRIPT) for a lotion containing 1.8% Hordeum Distichon (Barley) Extract. There were 102 subjects that completed the study and the test material was applied undiluted under semi-occlusive patches. It was determined that the test material may elicit slight dermal irritation but it was not a dermal sensitizer.

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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: November 24, 2020

SUBJECT: Hordeum Distichon (Barley) Extract

Clinical Research Laboratories, Inc. 2012. Repeated insult patch test (lotion containing 1.8% Hordeum Distichon (Barley) Extract.

Clinical
Research
Laboratories, Inc.

[redacted]

Final Report

Repeated Insult Patch Test

Lotion contains 1.8% Hordeum Distichon Barley Extract

CLIENT: [redacted]

ATTENTION: Megan Nicoletti
Senior Clinical Test Scientist

TEST MATERIAL: Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

CRL STUDY NUMBER: CRL52612-3

AUTHORIZED SIGNATURES:

Bruce E. Kanengiser, M.D.
President/Medical Director

Michael J. Muscatiello, Ph.D.
Executive Vice President/COO

Anita Lee Cham, M.D.
Dermatologist

REPORT DATE: June 21, 2012

371 Hoes Lane, Suite 100 • Piscataway, NJ 08854 • (732) 981-1616 • FAX (732) 981-0520

Clinical Research Laboratories, Inc.

Good Clinical Practice
Quality Assurance Audit Statement

Clinical Study Number: CRL52612-3

Start Date: April 30, 2012

Completion Date: June 8, 2012

The clinical study listed above was conducted in accordance with Clinical Research Laboratories, Inc. Standard Operating Procedures, which incorporate the principles of Good Clinical Practice defined by applicable guidelines and regulations established by U.S. Regulatory Agencies. The conduct of the study was monitored for compliance, and the associated records, including source documents or raw data, were reviewed for documentation practices and accuracy by a Project Manager/Study Director and/or a Quality Assurance Representative. Standard Quality Assurance audit procedures for this final report and study related documents were conducted.

Thomas Jeannon
Signature of QA Auditor

6/21/12
Date

[redacted]

Clinical Research Laboratories, Inc.

FINAL REPORT

REPEATED INSULT PATCH TEST

PURPOSE

The purpose of this study was to determine the dermal irritation and sensitization potential of a test material.

INVESTIGATIVE SITE

Clinical Research Laboratories, Inc.
371 Hoes Lane, Suite 100
Piscataway, New Jersey 08854
732-981-1616

TEST MATERIAL

The following test material was provided by [redacted] and was received by Clinical Research Laboratories, Inc. on April 25, 2012:

Test Material	Test Condition	Patch Type
Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48	Test as Received	Semi-occlusive*

The test material was coded with the following CRL identification number:

CRL52612-3

STUDY DATES

This study was initiated on April 30, 2012 and was completed on June 8, 2012.

* Semi-occlusive Strip (Brady Medical, Mesquite,TX)

Clinical Research Laboratories, Inc.

[redacted]

PANEL SELECTION

Each subject was assigned a permanent CRL identification number. All subjects signed an Informed Consent Form in compliance with 21 CFR Part 50: "Protection of Human Subjects" and a HIPAA Authorization Form in compliance with 45 CFR Parts 160 and 164. All subjects completed a Subject Profile/Medical History Form provided by Clinical Research Laboratories, Inc. prior to the study (Subject Demographics - Appendix I). Subjects who met the following Inclusion Criteria and none of the Exclusion Criteria were impaneled:

Inclusion Criteria

a. Male and female subjects between the ages of 18 and 70 years;

b. Subjects who do not exhibit any skin diseases which might be confused with a skin reaction from the test material;

c. Subjects who agree to avoid exposure of the test sites to the sun and to refrain from visits to tanning salons during the course of this study;

d. Subjects who agree to refrain from getting patches wet during the course of the study;

e. Subjects willing to sign an Informed Consent in conformance with 21CFR Part 50: "Protection of Human Subjects;"

f. Subjects who have completed a HIPAA Authorization Form in conformance with 45CFR Parts 160 and 164;

g. Subjects in generally good health who have a current Subject Profile/Medical History on file;

h. Subjects who are dependable and able to follow directions as outlined in the protocol.

Exclusion Criteria

a. Female subjects who are pregnant or nursing;

b. Subjects who are currently using any systemic or topical corticosteroids, anti-inflammatory drugs, or antihistamines on a regular basis;

c. Subjects exhibiting any skin disorder, sunburn, scars, excessive tattoos, etc. in the test area.

[redacted]

TEST METHOD

The study was conducted according to Protocol CL 1.0. Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. The test material, which was prepared as described in the Test Material section of the report, was applied to the upper back (between the scapulae) and was allowed to remain in direct skin contact for a period of 24 hours.

Patches were applied to the same site on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. This schedule may have been modified to allow for missed visits or holidays. If a subject was unable to report on an assigned test date, the test material was applied on 2 consecutive days during the Induction Phase and/or a makeup day was added at the end of the Induction Phase.

The sites were graded by a CRL technician for dermal irritation 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, unless the patching schedule was altered as described above.

The sites were graded according to the following scoring system:

Dermal Scoring Scale

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

If a "2+" reaction or greater occurred, the test material was applied to an adjacent virgin site. If a "2+" reaction or greater occurred on the new site, the subject was not patched again during the Induction Phase but was challenged on the appropriate day of the study. At the discretion of the Study Director, patch sites with scores less than a "2+" may have been changed.

Following approximately a 2-week rest period, the challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96-hour reading.

Clinical Research Laboratories, Inc.

[redacted]

STUDY RELATED COMMENT

Subject #115 was not assigned.

RESULTS

This study was initiated with 116 subjects (of which 54 subjects had self-perceived sensitive skin). Fourteen subjects discontinued study participation for reasons unrelated to the test material. A total of 102 subjects completed the study.

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I.

CONCLUSION

Based on the test population of 102 subjects and under the conditions of this study, the test material identified as Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48 may have a slight potential for eliciting dermal irritation but no potential for sensitization.

RETENTION

Test materials and all original forms of this study will be retained by Clinical Research Laboratories, Inc. as specified in CRL Standard Operating Procedures 30.6 and 30.6C, unless designated otherwise by the Sponsor.

Clinical Research Laboratories, Inc.

[redacted]

TABLE I

Summary of Dermal Scores

Test Material:	Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
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	1+*
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	1+	1+*
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	±Hr	0HrP	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	1+	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	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
24	0	0	0	0	0	0	0	0	0	Discontinued		
25	0	0	0	0	0	Discontinued						

Hr = Hyperpigmentation
P = Peeling
*A ± reaction was observed at the 96 hour evaluation.

Clinical Research Laboratories, Inc.

[redacted]

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
26	0	0	0	0	0	1+d	1+P	1+	1+	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
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	Discontinued											
32R	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	X	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
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	DISC.
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	Discontinued											
49	Discontinued											
50	0	0	0	0	0	0	0	0	0	0	0	0

d = Dryness
DISC. = Discontinued
P = Peeling
X = Subject Absent

Clinical Research Laboratories, Inc.

[redacted]

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
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
54	0	0	0	0	0	0	0	0	X	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
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
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	±Hr	0	0	0	0	0

Hr = Hyperpigmentation
X = Subject Absent

Clinical Research Laboratories, Inc.

[redacted]

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
76	0	0	0	0	0	0Hr	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	1+d	±dHr	1+d	1+d	1+dHr	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	0	0	0
84	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0
93	Discontinued											
94	0	Discontinued										
95	0	0	Discontinued									
96	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0
98	Discontinued											
99	0	0	Discontinued									
100	0	Discontinued										

d = Dryness
Hr = Hyperpigmentation

Clinical Research Laboratories, Inc.

[redacted]

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Lotion, TRT-03-67, BB1012-0, BPS12-04-PT48

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
101	0	1+	0	0	0	0	0	1+	0	0	0	0
102	0	0	0	0	0	0	±	±	0	0	0	0
103	0	0	0	Discontinued								
104	0	0	0	±	0	0	2+C	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	Discontinued										
109	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	X	0*
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	0	0	0
113	0	0	0	1+	1+P	2+eC	0	0	0	0	0	0
114	0	0	0	0	0	±Hr	0	0	0	0	0	0
116	0	0	0	0	0	0	0	0	0	0	0	0

C = Changed Site
e = Edema
Hr = Hyperpigmentation
P = Peeling
X = Subject Absent
*No reaction was observed at the 96 hour reading.

Clinical Research Laboratories, Inc.

[redacted]

Appendix I

Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex	Skin Type
1	EL	18765	47	F	N
2	AP	26576	68	M	N
3	BM	24122	70	F	S
4	RF	28256	53	F	N
5	GJ	01177	61	F	N
6	CK	02313	52	F	N
7	SS	10495	68	F	N
8	AP	26554	57	F	S
9	GD	03816	56	M	S
10	JP	29387	53	M	N
11	BP	29422	43	M	N
12	LO	29949	50	M	S
13	GH	28483	62	F	S
14	IN	03306	66	F	N
15	SG	23926	50	F	N
16	FM	02793	55	M	S
17	VD	23036	55	F	N
18	AB	20464	43	F	N
19	MG	28729	58	M	N
20	EM	29900	41	F	S
21	DG	16132	59	F	N
22	RV	29265	64	F	N
23	JE	06932	55	F	N
24	DM	19176	50	F	N
25	DT	01334	55	F	N
26	LB	29951	46	F	S
27	MC	29765	49	F	S
28	RD	23029	63	M	N
29	JJ	28551	49	F	S

Subject Number	Subject Initials	CRL ID #	Age	Sex	Skin Type
30	SS	29111	69	F	N
31	SW	29988	37	F	S
32	AP	27517	61	F	N
32R	AB	19290	42	F	S
33	AM	29899	26	F	S
34	JD	26979	56	M	N
35	TH	17294	49	F	S
36	CS	27750	62	F	N
37	TP	23674	22	M	N
38	HH	29630	49	F	N
39	KS	29922	60	F	N
40	YP	29904	39	F	S
41	DC	29906	43	F	S
42	DP	04921	47	F	N
43	DI	02673	67	F	N
44	LC	29103	47	F	N
45	KB	23476	34	F	S
46	AS	29062	39	F	S
47	BM	18748	64	F	N
48	PH	30190	42	F	N
49	GH	30189	47	M	S
50	CD	30191	36	F	S
51	HJ	29957	47	F	N
52	AK	21288	65	F	N
53	SR	29907	53	F	S
54	NS	24150	21	F	S
55	BD	29457	42	F	S
56	JS	02800	56	F	N
57	KW	30192	62	F	S

N=Normal
S=Sensitive

Clinical Research Laboratories, Inc.

[redacted]

Appendix I
(Continued)

Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex	Skin Type
58	RS	05543	46	M	S
59	AK	06659	55	F	S
60	SP	30194	32	F	S
61	CD	30195	49	F	N
62	RG	30193	55	F	N
63	GG	29681	47	F	S
64	SS	30196	46	F	S
65	MF	01230	47	F	N
66	ZA	15076	47	F	N
67	CR	20675	55	F	S
68	SH	17712	52	M	N
69	JC	16105	38	M	N
70	OF	16412	29	F	S
71	JG	24987	52	M	N
72	LN	24351	46	F	N
73	VM	29566	33	M	S
74	YW	23766	53	F	N
75	TP	02453	52	M	N
76	MC	25724	22	F	N
77	TD	22974	39	F	S
78	MC	25723	45	F	N
79	RL	29487	26	M	S
80	LJ	28816	59	M	N
81	BW	28412	18	F	S
82	LC	22990	37	F	N
83	BE	26475	55	F	N
84	JP	22148	36	F	S
85	VR	25692	23	F	S
86	MH	29639	61	F	N

Subject Number	Subject Initials	CRL ID #	Age	Sex	Skin Type
87	JD	30199	44	F	S
88	HB	30200	35	F	N
89	JS	00467	50	F	N
90	SR	30201	19	F	S
91	RR	30202	50	F	S
92	KC	30049	30	F	N
93	LC	30204	23	F	S
94	MJ	29982	51	F	S
95	AA	30170	54	F	S
96	CP	30206	54	F	N
97	TB	30207	32	F	S
98	PM	10030	57	F	S
99	AR	26781	23	F	S
100	BP	24767	47	F	N
101	TS	30158	38	F	N
102	CV	25979	24	F	N
103	DV	30209	44	F	S
104	SB	29894	56	F	N
105	KN	24674	39	F	S
106	HH	28978	19	M	N
107	YD	28385	34	F	S
108	KW	24884	22	M	N
109	DH	25303	21	M	N
110	DL	29100	33	M	S
111	JJ	29115	20	F	S
112	LE	26516	70	F	S
113	EP	27875	58	F	S
114	IG	27436	26	F	S
116	DD	30212	43	M	N

N=Normal
S=Sensitive