



## SUMMARY REPORT

**A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 101 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF 1 TEST ARTICLE FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS.**

CONDUCTED ACCORDING TO PCR MASTER PROTOCOL: PCRRIP1 (20JAN2022)

PCR Corp. Study Number: DOSRIP1T

### TEST ARTICLE:

#### 1. Hypoallergenic Braiding Hair

### Confidentiality Statement:

This confidential document is the property of PCR Corp and Dosso Beauty. No information contained herein may be disclosed without the prior written approval of PCR Corp or Dosso Beauty.

Please Note: PCR Corp is an abbreviation for Princeton Consumer Research Corp.

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Final Report: 7<sup>th</sup> April 2025

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I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by PCR Corp were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt  
(Principal Investigator)

*B. Drewitt*

Date... 08 / 04 / 2025

Rachel Christian  
(Project Manager)

*Rachel Christian*

Date... 07 / 04 / 2025

**QUALITY ASSURANCE STATEMENT**

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Bryan Baker  
(Quality Assurance Associate)

*B. Baker*

Date... 08 / 04 / 2025

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**1. KEY STUDY PERSONNEL AND RESPONSIBILITIES**

<b>Key Personnel</b>	<b>General Responsibilities</b>
<b>Principal Investigator (PI)</b> Barrie Drewitt PCR Corp Baypoint Commerce Center 9600 Koger Blvd N St Petersburg FL 33702 USA  Tel: +1 (727) 576 7300	The Principal Investigator (PI) responsible for ensuring sufficient resources were available to conduct the study and was responsible for the study design, review of the study protocol, authorisation and summary report.
<b>Study Supervisor (SS)</b> Ashley Flores PCR Corp 310 S MacDill Ave Suite 100 Tampa FL 33609 USA  Tel: +1 813 864 7364	The Study Supervisor (SS) responsible for the conduct of the study on a daily basis.
<b>Project Manager (PM)</b> Rachel Christian PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom  Tel: +44 (0)1245 934050	The Project Manager (PM) involved with the study authorisation, compilation of study results and summary report.
<b>Sponsor Contact</b> Kadidja Dosso Dosso Beauty 5102 Rochelle Ave Commercial 2 Philadelphia, PA 19128  kadidja@dosso beauty.com	

## 2. INTRODUCTION AND OBJECTIVE

The objective of this study was to investigate the irritation and sensitisation potential of 1 cosmetic test article, in a shared panel of 101 healthy volunteers by means of repeated cutaneous occlusive patch applications based on the modified Draize method of Jordan and King (1977)<sup>1</sup> to support claims such as "Hypoallergenic", "Non-Irritating", "Allergy Tested", "Clinically Tested", "Clinically Proven", "Kind to Skin", "Mild for Skin", "Safe for Skin", "Dermatologically Tested" and "Safe for Sensitive Skin."

## 3. STUDY DESIGN

The study was conducted single blind, at a single centre according to Master Protocol: PCRRIP1.

The test article was patched under occlusive conditions using Finn chambers or equivalent occlusive patches. A total of nine induction patches worn for 47 hours or 71 hours (patching occurred Mondays, Wednesdays, and Fridays) for three weeks (a make-up day was allowed to ensure subjects had all 9 induction patches). Subjects had a rest period of 14 days. Challenge patches were applied for 48 hours, and readings were made 1 hour, and 48 hours post removal.

## 4. TEST MATERIALS

### 4.1 TEST ARTICLES

The test article was supplied by the Sponsor and labelled as follows:

TA#	Test Article Name/Description	ID Code (Batch/Lot #)	Dilution/special handling*
1	Hypoallergenic Braiding Hair	N/A	

## 5. STUDY ETHICS

### 5.1 DECLARATION OF HELSINKI

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013)<sup>2</sup>.

### 5.2 INDEMNITY PROVISION

The Sponsor shall be responsible, without regard to legal liability, and shall indemnify PCR Corp, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury arising out of the administration or use of the test article, or of any procedure required under this protocol as a result of a subject participating in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

### 5.3 ICH GCP

The study was conducted in accordance with applicable International Council for Harmonization. 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)<sup>3</sup> in as much as they apply to cosmetic and consumer product testing/research.

## 6. QUALITY ASSURANCE

The study was conducted according to the Sponsor Authorisation, the master protocol, the Standard Operating Procedures of PCR Corp and according to the applicable ICH Guidelines on Good Clinical Practice, and other recognised guidelines. An audit of the final report was completed, for accuracy and completeness of presentation. Additionally, the study may be subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and PCR Corp procedures.

PCR Corp Quality Assurance would have informed PCR Corp management of any findings that may have affected the integrity of the study.

## 7. RETENTION OF DATA

All raw data generated by PCR Corp during the study, including the sponsor authorisation form and final summary report, will be retained in the PCR Corp Archive for a minimum period of three years from study completion as is PCR Corp policy for cosmetic products. In the event of original data being transferred to the Sponsor at their request, exact copies will be so retained. At no time will archived data be destroyed without prior written approval of the Sponsor. All study data will be available at any time, by appointment, for inspection by the Sponsor or their authorised representative. The study master protocol will be archived and retained indefinitely at PCR Corp.

## 8. REFERENCES

1. Jordan W.P. and King S. E. (1977) Contact Dermatitis 3, 19-26.
2. World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA 310 (20): 2191–2194. doi:10.1001/jama.2013.281053.
3. ICH E6\_R2, INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE, Current Step 4 version dated 9 November 2016.

## 9. RESULTS

### 9.1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, located in Tampa between w/c 11<sup>th</sup> March 2024 and w/c 22<sup>nd</sup> April 2024.

### 9.2 SUBJECTS

104 male and female subjects were enrolled into the study. 101 subjects completed the study. The age and gender of these subjects is presented below.

### 9.3 ADVERSE EVENTS, ADVERSE REACTIONS, SUBJECTS NOT COMPLETING THE STUDY AND DEVIATIONS

No adverse events or reactions were reported.

3 subjects withdrew for personal reasons.

There were no deviations that occurred during the conduct of the study.

### 9.4 ASSESSMENTS

Individual reactions to the test article are presented in Appendix 1.

As demonstrated by the individual skin responses to the test article:

**Test Article 1** – Hypoallergenic Braiding Hair elicited no visible erythematous reactions during the induction phase of the study.

There were no questionable reactions observed during the Challenge Phase (Days 38 and 40) by any of the subjects to the test article. These results support the assessment that under the conditions of the study, the test article has demonstrated a low potential for irritation and sensitization.

## 10. CONCLUSIONS

The test article can be considered as safe for use under the conditions of the study, and claims such as "Hypoallergenic", "Non-Irritating", "Allergy Tested", "Clinically Tested", "Clinically Proven", "Kind to Skin", "Mild for Skin", "Safe for Skin", "Dermatologically Tested" and "Safe for Sensitive Skin" are substantiated.

**APPENDIX 1: INDIVIDUAL RESPONSES****Test Article 1: Hypoallergenic Braiding Hair**

Subject Number	Code	2	3	4	5	6	7	8	9	10	1 hour	47 hour
1	1	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0
6	1	0	0	0	0	0	0	0	0	0	0	0
7	1	0	0	0	0	0	0	0	0	0	0	0
8	1	0	0	0	0	0	0	0	0	0	0	0
9	1	0	0	0	0	0	0	0	0	0	0	0
10	1	0	0	0	0	0	0	0	0	0	0	0
11	1	0	0	0	0	0	0	0	0	0	0	0
12	1	0	0	0	0	0	0	0	0	0	0	0
13	1	0	0	0	0	0	0	0	0	0	0	0
14	1	0	0	0	0	0	0	0	0	0	0	0
15	1	0	0	0	0	0	0	0	0	0	0	0
16	1	0	0	0	0	0	0	0	0	0	0	0
17	1	0	0	0	0	0	0	0	0	0	0	0
18	1	0	0	0	0	0	0	0	0	0	0	0
19	1	0	0	0	0	0	0	0	0	0	0	0
20	1	0	0	0	A 1	0	0	0	0	0	0	0
21	1	0	0	0	0	0	0	0	0	0	0	0
22	1	0	0	0	0	0	0	0	0	0	0	0
23	1	0	0	0	0	0	0	0	0	0	0	0
24	1	0	0	0	0	0	0	0	0	0	0	0
25	1	0	0	0	0	0	0	0	0	0	0	0
26	1	0	0	0	0	0	0	0	0	0	0	0
27	1	0	0	0	0	0	0	0	0	0	0	0
28	1	0	0	0	0	0	0	0	0	0	0	0
29	1	0	0	0	0	0	0	0	0	0	0	0
30	1	0	0	0	0	0	0	0	0	0	0	0
31	1	0	0	0	0	0	0	0	0	0	0	0
32	1	0	0	0	0	0	b/o	b/o	b/o	b/o	b/o	b/o
33	1	0	0	0	0	0	0	0	0	0	0	0
34	1	0	0	0	0	0	0	0	0	0	0	0
35	1	0	0	0	0	0	0	0	0	0	0	0
36	1	0	0	0	0	0	0	0	0	0	0	0
37	1	0	0	0	0	0	0	0	b/o	b/o	b/o	b/o
38	1	0	0	0	0	0	0	0	0	0	0	0
39	1	0	0	0	0	0	0	0	0	0	0	0
40	1	0	0	0	0	0	0	0	0	0	0	0
41	1	0	0	0	0	0	0	0	0	0	0	0
42	1	0	0	0	b/o	b/o	b/o	b/o	b/o	b/o	b/o	b/o
43	1	0	0	0	0	0	0	0	0	0	0	0
44	1	0	0	0	0	0	0	0	0	0	0	0
45	1	0	0	0	0	0	0	0	0	0	0	0
46	1	0	0	0	0	0	0	0	0	0	0	0
47	1	0	0	0	0	0	0	0	0	0	0	0
48	1	0	0	0	0	0	0	0	0	0	0	0
49	1	0	0	0	0	0	0	0	0	0	0	0
50	1	0	0	0	0	0	0	0	0	0	0	0
51	1	0	0	0	0	0	0	0	0	0	0	0
52	1	0	0	0	0	0	0	0	0	0	0	0
53	1	0	0	0	0	0	0	0	0	0	0	0
54	1	0	0	0	0	0	0	0	0	0	0	0
55	1	0	0	0	0	0	0	0	0	0	0	0
56	1	0	0	0	0	0	0	0	0	0	0	0
57	1	0	0	0	0	0	0	0	0	0	0	0
58	1	0	0	0	0	0	0	0	0	0	0	0
59	1	0	0	0	0	0	0	0	0	0	0	0
60	1	0	0	0	0	0	0	0	0	0	0	0
61	1	0	0	0	0	0	0	0	0	0	0	0
62	1	0	0	0	0	0	0	0	0	0	0	0
63	1	0	0	0	0	0	0	0	0	0	0	0
64	1	0	0	0	0	0	0	0	0	0	0	0
65	1	0	0	0	0	0	0	0	0	0	0	0
66	1	0	0	0	0	0	0	0	0	0	0	0
67	1	0	0	0	0	0	0	0	0	0	0	0
68	1	0	0	0	0	0	0	0	0	0	0	0
69	1	0	0	0	0	0	0	0	0	0	0	0
70	1	0	0	0	0	0	0	0	0	0	0	0
71	1	0	0	0	0	0	0	0	0	0	0	0
72	1	0	0	0	0	0	0	0	0	0	0	0
73	1	0	0	0	0	0	0	0	0	0	0	0
74	1	0	0	0	0	0	0	0	0	0	0	0
75	1	0	0	0	0	0	0	0	0	0	0	0
76	1	0	0	0	0	0	0	0	0	0	0	0
77	1	0	0	0	0	0	0	0	0	0	0	0
78	1	0	0	0	0	0	0	0	0	0	0	0
79	1	0	0	0	0	0	0	0	0	0	0	0
80	1	0	0	0	0	0	0	0	0	0	0	0
81	1	0	0	0	0	0	0	0	0	0	0	0
82	1	0	0	0	0	0	0	0	0	0	0	0
83	1	0	0	0	0	0	0	0	0	0	0	0
84	1	0	0	0	0	0	0	0	0	0	0	0
85	1	0	0	0	0	0	0	0	0	0	0	0
86	1	0	0	0	0	0	0	0	0	0	0	0
87	1	0	0	0	0	0	0	0	0	0	0	0
88	1	0	0	0	0	0	0	0	0	0	0	0
89	1	0	0	0	0	0	0	0	0	0	0	0
90	1	0	0	0	0	0	0	0	0	0	0	0
91	1	0	0	0	0	0	0	0	0	0	0	0
92	1	0	0	0	0	0	0	0	0	0	0	0
93	1	0	0	0	0	0	0	0	0	0	0	0
94	1	0	0	0	0	0	0	0	0	0	0	0
95	1	0	0	0	0	0	0	0	0	0	0	0
96	1	0	0	0	0	0	0	0	0	0	0	0
97	1	0	0	0	0	0	0	0	0	0	0	0
98	1	0	0	0	0	0	0	0	0	0	0	0
99	1	0	0	0	0	0	0	0	0	0	0	0
100	1	0	0	0	0	0	0	0	0	0	0	0
101	1	0	0	0	0	0	0	0	0	0	0	0
102	1	0	0	0	0	0	0	0	0	0	0	0
103	1	0	0	0	0	0	0	0	0	0	0	0
104	1	0	0	0	0	0	0	0	0	0	0	0
MEAN		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
STDEV		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00



**APPENDIX 2: SUBJECT DEMOGRAPHICS**

Subject/ Rando #	Gender	Age	Sensitive Skin	Skin Type
01	Male	57	NO	Normal
02	Female	61	YES	Normal
03	Female	63	NO	Normal
04	Female	42	YES	Dry
05	Female	70	YES	Normal
06	Female	61	YES	Oily
07	Female	63	YES	Normal
08	Female	52	YES	Combination
09	Female	35	YES	Combination
10	Female	53	NO	Normal
11	Female	53	NO	Normal
12	Female	43	NO	Oily
13	Female	48	NO	Dry
14	Female	60	NO	Normal
15	Female	49	NO	Oily
16	Male	43	YES	Normal
17	Female	59	NO	Oily
18	Female	65	YES	Normal
19	Male	65	NO	Normal
20	Female	64	YES	Dry
21	Female	34	NO	Combination
22	Female	52	NO	Oily
23	Female	57	YES	Oily
24	Male	62	NO	Dry
25	Female	58	NO	Combination
26	Female	68	YES	Dry
27	Female	60	YES	#REF!
28	Female	38	NO	Normal
29	Female	48	NO	Dry
30	Female	46	NO	Normal
31	Male	45	NO	Dry
32	Female	34	YES	Combination
33	Female	50	NO	Combination
34	Male	40	YES	Normal
35	Female	26	YES	Combination
36	Female	31	NO	Oily
37	Female	50	NO	Combination
38	Female	35	NO	Normal
39	Female	67	YES	Combination
40	Female	36	YES	Oily
41	Female	39	NO	Normal
42	Female	41	NO	Normal
43	Female	58	NO	Normal
44	Female	31	YES	Normal
45	Female	48	YES	Dry
46	Female	68	YES	Normal

47	Female	36	YES	Normal
48	Female	48	NO	Dry
49	Female	35	NO	Oily
50	Female	56	YES	Combination
51	Female	19	YES	Normal
52	Male	22	NO	Combination
53	Female	19	NO	Normal
54	Male	22	YES	Oily
55	Female	22	NO	Combination
56	Male	45	NO	Normal
57	Male	24	NO	Normal
58	Male	23	NO	Normal
59	Female	33	YES	Normal
60	Male	25	NO	Normal
61	Female	23	YES	Oily
62	Male	43	NO	Normal
63	Male	27	YES	Normal
64	Female	26	NO	Dry
65	Female	35	NO	Oily
66	Male	30	YES	Combination
67	Male	34	YES	Dry
68	Female	55	NO	Normal
69	Female	34	YES	Normal
70	Female	30	NO	Normal
71	Female	34	NO	Combination
72	Female	33	YES	Combination
73	Male	32	NO	Normal
74	Female	39	YES	Normal
75	Female	64	NO	Combination
76	Female	33	YES	Oily
77	Male	53	NO	Dry
78	Female	35	YES	Dry
79	Female	24	YES	Normal
80	Female	25	YES	Dry
81	Female	32	YES	Combination
82	Female	24	NO	Oily
83	Female	24	NO	Dry
84	Female	20	NO	Normal
85	Female	25	YES	Normal
86	Female	23	YES	Combination
87	Male	24	NO	Normal
88	Female	29	NO	Oily
89	Female	35	NO	Combination
90	Female	22	YES	Normal
91	Female	24	YES	Dry
92	Male	30	NO	Dry
93	Male	31	YES	Combination
94	Male	63	NO	Normal
95	Male	47	NO	Combination
96	Male	39	NO	Dry

97	Male	36	NO	Normal
98	Male	31	NO	Dry
99	Male	25	YES	Oily
100	Female	35	YES	Oily
101	Female	35	NO	Oily
102	Female	59	NO	Normal
103	Male	31	NO	Combination
104	Female	35	YES	Normal

### **APPENDIX 3: INCI LISTINGS**

#### **Test Article 1: Hypoallergenic Braiding Hair**

kanekalon Fiber