SUMMARY REPORT

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 54 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF ONE (1) TEST ARTICLE FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

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

PCR Corp. Study Number: MUSRIP1M

TEST ARTICLE: **1. Hicream 24K GOLD EYE MASK**

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

Prepared for:

Musment Inc.
191 Main Street Unit 2061
Port Washington
Nassau
NY
11050
USA

Prepared by:

PCR Corp
8 Richmond Road
Dukes Park
Chelmsford
Essex
CM2 6UA
United Kingdom

Draft Report: 8th November 2023
Final Report: 6th December 2023

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 54 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF ONE (1) TEST ARTICLE FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

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

PCR Corp. Study Number: MUSRIP1M

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 07 / 12 / 2023

Jafe Longe
(Project Manager)

Rachel Christian
Rachel Christian (PP)
Date 06 / 12 / 2023

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.

Rob Sherrington
(Quality Assurance)

R.Sherrington
Date 06 / 12 / 2023

TABLE OF CONTENTS

1. KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key Personnel	General Responsibilities
Principal Investigator (PI) Barrie Drewitt PCR Corp 310 S MacDill Ave Suite 100 Tampa FL 33609 USA Tel: +1 813-864-7364	The Principal Investigator (PI) was 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.
Study Supervisor (SS) Andy King PCR Corp 164A Plymouth Grove Ardwick Manchester M13 0AF United Kingdom Tel: +44(0)161 791 1797	The Study Supervisor (SS) was responsible for the conduct of the study on a daily basis.
Project Manager (PM) Rachel Christian PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: +44 (0)1245 934050	The Project Manager (PM) was involved with the study authorisation, compilation of study results and summary report.
Sponsor Contact Dorcas Guo Musment Inc. 191 Main Street Unit 2061 Port Washington Nassau NY 11050 USA	

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 54 healthy volunteers by means of repeated cutaneous occlusive patch applications based on the modified Draize method of Jordan and King (1977)1 to support claims such as "Dermatologically Tested", "Clinically Tested", "Kind to Skin" and "Safe for Skin".

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 inductions 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.

3. TEST MATERIALS

3.1 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	Hicream 24K GOLD EYE MASK	N/A	Use as Supplied

4. STUDY ETHICS

4.1 DECLARATION OF HELSINKI

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013)[2].

4.2 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.

4.3 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)3 in as much as they apply to cosmetic and consumer product testing/research.

5. 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.

6. 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.

7. 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

8. RESULTS

8.1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, located in Manchester between w/c 4th September 2023 and 16th October 2023.

8.2 SUBJECTS

56 male and female subjects were enrolled into the study. 54 subjects completed the study. The age and gender of these subjects is presented in Appendix 2.

8.3 ADVERSE EVENTS, ADVERSE REACTIONS, SUBJECTS NOT COMPLETING THE STUDY AND DEVIATIONS

No adverse events or reactions were reported.

2 subjects withdrew for personal reasons.

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

8.4 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 – Hicream 24K GOLD EYE MASK 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 have demonstrated a low potential for irritation and sensitization.

9. CONCLUSIONS

The test article can be considered as safe for use under the conditions of the study, and claims such as, "Dermatologically Tested", "Clinically Tested", "Kind to Skin" and "Safe for Skin" are substantiated.

APPENDIX 1: INDIVIDUAL RESPONSES

Number	Code	2	3	4	5	6	7	8	9	10	MU	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 A	0 A	0 A	0 A	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 A	0 A	0 A	0 A	0 A	0 A		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	D/O	D/O	D/O	D/O		D/O	D/O
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	0	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 A	0 A	0 A	0 A	0 A		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 A	0 A	0 A		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	0	0	0	0		0	0
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	_	D/O	D/O	D/O	D/O		D/O	D/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	0	0	0	0	0	0		0	0
43	1	0	0	0	0	0	0	0	0	0		0	0
44	1	0	0	0	0	0	0	0 A	0 A	0 A		0	0
45	1	0	0	0	0	0 A	0 A	0 A	0 A	0 A		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 A	0 A		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 A	0 A	0 A	0 A	0 A		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
MEAN		0.00	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	0.00

APPENDIX 2: SUBJECT DEMOGRAPHICS

SUBJECT NUMBER	MALE OR FEMALE	AGE
1	Female	39
2	Female	21
3	Male	28
4	Female	27
5	Female	21
6	Female	35
7	Male	20
8	Male	28
9	Female	20
10	Female	30
11	Female	31
12	Male	27
13	Female	43
14	Male	52
15	Female	42
16	Female	48
17	Female	34
18	Male	45
19	Female	45
20	Female	39
21	Female	54
22	Female	20
23	Male	28
24	Male	27
25	Female	19
26	Male	21
27	Female	28
28	Female	36
29	Female	49
30	Female	51
31	Female	34
32	Male	37
33	Female	28
34	Male	33
35	Female	24
36	Female	29
37	Female	41
38	Male	38
39	Female	26
40	Female	37
41	Female	26
42	Male	29
43	Female	23
44	Female	50

45	Female	34
46	Female	28
47	Male	34
48	Female	24
49	Female	61
50	Female	29
51	Male	46
52	Female	40
53	Male	48
54	Female	45
55	Female	23
56	Male	29

APPENDIX 3: INCI LISTINGS

Test Article 1: Hicream 24K GOLD EYE MASK

AQUA、GLYCERIN、PROPYLENE GLYCOL、CHONDRUS CRISPUS POWDER、GLUCOMANNAN、BUTYLENE GLYCOL、SODIUM HYALURONATE、ALLANTOIN、HYDROXYACETOPHENONE、PHENOXYETHANOL、CHLORPHENESIN、CALCIUM CHLORIDE、POTASSIUM CHLORIDE、DISODIUM ED、CI 77891、CI 77019、XANTHAN GUM、AGAR、CENTELLA ASIATICA EXTRACT、PEG-40 HYDROGENATED CASTOR OIL、PARFUM、POLYGONUM CUSPIDATUM ROOT EXTRACT、SCUTELLARIA BAICALENSIS ROOT EXTRACT、CI 77491、CITRIC ACID、POTASSIUM CITRATE、CAMELLIA SINENSIS LEAF EXTRACT、GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT、CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT、ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT.