SUMMARY REPORT

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 47 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(2FEB2021)

PCR Corp. Study Number: [redacted]

TEST ARTICLE: 4. Lustre

Prepared for: Prepared by:

[redacted]

Draft Report: 12th November 2021
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PCR Corp. Study Number: [redacted]

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)
Date .....1..1.. ./. .1..8.. ./. .2..0..2..1.....

B Drewitt

Michael Gabriel .....
(Project Manager)
11 / 18 / 2021
Date .....

Michael Gabriel

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.

Reece Statham .....

Date ...1..1.. ./. .1..8.. ./. .2..0..2..1.....

R.Statham

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KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key Personnel General Responsibilities	
Principal Investigator (PI) The Principal Investigator (PI) responsible Barrie Drewitt for ensuring sufficient resources were PCR Corp available to conduct the study and was Baypoint Commerce Center responsible for the study design, review of 9600 Koger Blvd N the study protocol, authorization and St Petersburg, FL 33702 summary report. Tel: +1(727) 576 7300	
Study Supervisor (SS) The Study Supervisor (SS) responsible for Shannel Rice the conduct of the study on a daily basis. PCR Corp 310 South MacDill Avenue Tampa Florida 33609, USA Tel: +1 813) 864 7364	
Project Manager (PM) The Project Manager (PM) involved with Michael Gabriel the study authorization, compilation of PCR Corp study results and summary report. Baypoint Commerce Center 9600 Koger Blvd N St Petersburg, FL 33702 Tel: +1(727) 576 7300	
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INTRODUCTION AND OBJECTIVE

The objective of this study was to investigate the irritation and sensitisation potential of cosmetic test articles, in a shared panel of 47 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”.

MATERIALS AND METHODS

1. STUDY DESIGN

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

The test articles were 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.

2. TEST MATERIALS

2.1. TEST ARTICLES

The test articles were supplied by the Sponsor and labelled as follow:

TA#	Test Article Name/Description	ID Code (Batch/Lot #)	Dilution/special handling*
	Lustre		Use as Supplied

3. STUDY ETHICS

3.1. DECLARATION OF HELSINKI

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

3.2. INDEMNITY PROVISION

The Sponsor was 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.

3.3. 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.

4. QUALITY ASSURANCE

The study was conducted according to the Sponsor Authorization, 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.

5. RETENTION OF DATA

All raw data generated by PCR Corp during the course of the study, including the sponsor authorization 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 authorized representative. The study master protocol will be archived and retained indefinitely at PCR Corp.

6. 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

RESULTS

1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, located in Tampa, Florida between 27th September 2021 and 8th November 2021.

2 SUBJECTS

55 male and female subjects were enrolled into the study. 47 subjects completed the study. The age & gender of these subjects is presented in table in Appendix 2.

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

No adverse events or reactions were reported.

8 subjects withdrew for personal reasons.

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

4 ASSESSMENTS

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

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

Test Article 4 Lustre , 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 any of the test articles. These results support the assessment that under the conditions of the study, the test articles have demonstrated a low potential for irritation and sensitization.

CONCLUSIONS

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

APPENDIX 1: INDIVIDUAL RESPONSES

TEST ARTICLE 4 – Lustre

							Subject #Site #23456789			10	11	12	13
121		0	0	0	0	0	0	0	0	0	0	0	0
221		0	0	0	0	0	0	0	0	0	0	0	0
321		0	0	0	0	0	0	0	0	0	0	0	0
421		0	0	0	0	0	0	0	0	0	0	0	0
521		0	0	0	0	0	0	0	0	0	0	0	0
621		0	0	0	0	0	0	0	0	0	0	0	0
721		0	0	0	0	0	0	0	0	0	0	0	0
821		0	0	0	0	0	0	0	0	0	0	0	0
921		0	0	0	0	0	0	0	0	0	0	0	0
	1021	0	0	0	0	0	0	0	0	0	0	0	0
	1121	0	0	0	0	0	0	0	0	0	0	0	0
	1221	D/O	d/o	d/o	d/o	d/o	d/o	d/o	D/O	d/o	d/o	d/o	d/o
	1321	d/o	d/o	d/o	d/o	d/o	d/o	d/o	D/O	d/o	d/o	d/o	0
	1421	0	0	0	0	0	0	0	0	0	0	0	0
	1521	0	0	0	0	0	0	0	0	0	0	0	0
	1621	d/o	d/o	d/o	d/o	d/o	d/o	d/o	D/O	d/o	d/o	d/o	0
	1721	0	0	0	0	0	0	0	0	0	0	0	0
	1821	0	0	0	0	0	0	0	0	0	0	0	0
	1921	0	0	0	0	0	0	0	0	0	0	0	0
	2021	0	0	0	0	0	0	0	0	0	0	0	0
	2121	d/o	d/o	d/o	d/o	d/o	d/o	d/o	D/O	d/o	d/o	d/o	0
	2221	0	0	0	0	0	0	0	0	0	0	0	0
	2321	0	0	0	0	0	0	0	0	0	0	0	0
	2421	0	0	0	0	0	0	0	0	0	0	0	0
	2521	0	0	0	0	0	0	0	0	0	0	0	0
	2621	0	0	0	0	0	0	0	0	0	0	0	0
	2721	0	0	0	0	0	0	0	0	0	0	0	0
	2821	0	0	0	0	0	0	0	0	0	0	0	0
	2921	0	0	0	0	0	0	0	0	0	0	0	0
	3021	0	0	0	0	0	0	0	0	0	0	0	0
	3121	0	0	0	0	0	0	0	0	0	0	0	0
	3221	0	0	0	0	0	0	0	0	0	0	0	0
	3321	0	0	0	0	0	0	0	0	0	0	0	0
	3421	0	0	0	0	0	0	0	0	0	0	0	0
	3521	0	0	0	0	0	0	0	0	0	0	0	0
	3621	0	0	0	0	0	0	0	0	0	0	0	0
	3721	0	0	0	0	0	0	0	0	0	0	0	0
	3821	0	0	0	0	0	0	0	0	0	0	0	0
	3921	0	0	0	0	0	0	0	0	0	0	0	0
	4021	0	0	0	0	0	0	0	0	0	0	0	0
	4121	0	0	0	0	0	0	0	0	0	0	0	0
	4221	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o
	4321	0	0	0	0	0	0	0	0	0	0	0	0
	4421	0	0	0	0	0	0	0	0	0	0	0	0
	4521	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o
	4621	0	0	0	0	0	0	0	0	0	0	0	0
	4721	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o
	4821	0	0	0	0	0	0	0	0	0	0	0	0
	4921	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o	d/o
	5021	0	0	0	0	0	0	0	0	0	0	0	0
	5121	0	0	0	0	0	0	0	0	0	0	0	0
	5221	0	0	0	0	0	0	0	0	0	0	0	0
	5321	0	0	0	0	0	0	0	0	0	0	0	0
	5421	0	0	0	0	0	0	0	0	0	0	0	0
	5521	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX 2: SUBJECT DEMOGRAPHICS

Subject/ Rando #	Age	Gender	Subject Rando #	Age	Gender
01	56	Female	41	32	Female
02	68	Female	42	42	Female
03	41	Female	43	40	Female
04	31	Female	44	28	Male
05	36	Female	45	32	Male
06	39	Female	46	55	Male
07	56	Female	47	43	Male
08	57	Male	48	30	Female
09	31	Female	49	28	Male
10	62	Female	50	32	Female
11	61	Female	51	22	Female
12	56	Female	52	21	Female
13	23	Male	53	21	Female
14	22	Female	54	23	Male
15	52	Female	55	21	Female
16	31	Female			
17	56	Female			
18	50	Female			
19	63	Male			
20	67	Female			
21	29	Female			
22	46	Female			
23	41	Female			
24	36	Female			
25	46	Male			
26	61	Male			
27	65	Female			
28	33	Female			
29	40	Female			
30	58	Male			
31	71	Female			
32	50	Female			
33	46	Female			
34	22	Male			
35	47	Male			
36	64	Female			
37	66	Female			
38	56	Female			
39	26	Male			
40	36	Male			

APPENDIX 3:

INCI LISTINGS

Test Article 4: Lustre

WATER (AQUA)
PROPANEDIOL
C15-19 ALKANE
1,2-HEXANEDIOL
GLYCERIN
PYRUS MALUS (APPLE) FRUIT EXTRACT
BETAINE
XYLITYLGLUCOSIDE
SODIUM POLYACRYLATE
ANHYDROXYLITOL
ARACHIDYL ALCOHOL
SILICA
BEHENYL ALCOHOL
XYLITOL
POLYACRYLATE CROSSPOLYMER-6
ARACHIDYL GLUCOSIDE
TOCOPHEROL
SODIUM PHYTATE
CITRIC ACID
PIPERONYL GLUCOSIDE
HABERLEA RHODOPENSIS LEAF EXTRACT
PENTYLENE GLYCOL
SODIUM ACETYLATED HYALURONATE
SODIUM HYALURONATE
SODIUM HYALURONATE CROSSPOLYMER
HYDROLYZED SODIUM HYALURONATE
ETHYLHEXYLGLYCERIN
GLUCOSE