



ECOWORKS

ECOWORKS LAUNDRY DETERGENT (ALPHA FORMULATION)  
**Derma Consult GmbH Report**

## Expertise

Examination of the Product

**“Ecoworks Laundry Alpha”**

formulation code: SCLLD/GC 005/10/23

Concentration: 1,0% in water

by Human Patch Test (Cosmetic Trial)

Sponsor

Performing Laboratory  
**Derma Consult GmbH**  
Brunnenstr. 61  
53347 Alfter  
Germany

## Study Details

Type of study.....: Determination of irritating effects to the skin with an occlusive patch test.  
Study Period.....: December 2023  
Study Director.....: Dr. med. H. Prieur  
Test subjects.....: 50 (18-66 years; sex distribution non-standardized)  
30 normal healthy, 5 eczema, 1 allergy and 14 subjects with sensitive skin  
Test site.....: Back  
Concentration.....: 1,0% in water  
Controls.....: SDS (1% in water), water


## Summary Results

All participants completed the study. Under the test conditions, SDS (1% in water) caused positive reactions in 15 subjects. The negative control water showed no reactions. None of the subjects showed any reaction to the test product. On the basis of the test results and under the test conditions, the product


**“Ecoworks Laundry Alpha“**

is to be classified as 'harmless' as regards the possibility of skin irritation.

Signature:

  
Dr. med. H. Prieur  
Dermatologist - Allergist

Signature:

  
Dr. J. Nissen  
Pharmacist - M.D.R.A.

## Methodology

### Introduction

The epicutaneous patch test allows us to assess the primary skin irritation potential of cosmetic-finished products and raw materials.

### Description

All the work described in this expertise was conducted considering the guidelines by COLIPA (Walker A.P. et al: Test Guidelines for Assessment of Skin Compatibility of Cosmetic Finished Products in Man. Food and Chemical Toxicology 34, 1996, 651-660; COSMETICS EUROPE: Product test guidelines for the assessment of human skin compatibility 1997).

Because it was a study with humans, it was carried out taking into account the principle requirements of the Declaration of Helsinki (1964) and subsequent revisions.

Experiments were carried out on 50 volunteers (30 normal healthy subjects, 5 eczema patients, 1 allergy patients, 14 subjects with sensitive skin) between the ages of 18 to 66. Sex distribution was not standardized. The volunteers were clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They gave their written informed consent before participating in the study.

Participants could withdraw from the study at any time without giving reason. During the test period, the subjects refrained from using other substances on the test areas. Drop-outs were replaced and their data discarded.

### Inclusion criteria

- informed volunteers
- age ≥ 18 years

### Exclusion criteria

- pregnant or lactating women
- blemishes or marks (tattoos, sunburn) which interfere with scoring
- any skin disease that may interfere with the aim of the study

### Procedure

The product was applied in a concentration as outlined above in square test-chambers (allergEAZE® clear Patch Test Chambers; SmartPractice®, Phoenix, AZ) to the backs of the panellists for a period of 48 hours. Proper adherence of the test patches was assured by the inclusion of sodium dodecyl sulphate (SDS) in one concentration (1%) as positive control. Water was used as a negative control.

The treatment sites were assessed for the presence of irritation by a trained evaluator using a 5 point visual scoring scale at 48 h (30 min after patch removal) and 72 h after patch application.

**Scoring scale**

**Erythema** 0: no E., 1: slight E., 2: significant E., 3: pronounced E., 4: strong E.  
**Fissure** 0: no F., 1: minimal F., 2: significantly perceptible F., 3: pronounced F., 4: ulceration  
**Scaling** 0: no Sc., 1: minimal Sc., 2: moderate Sc., 3: significant Sc., 4: closed scale crust

**Results**

The test results outlining the data for erythema, scaling and fissure formation on a per subject base for the test product are attached in tabulated form.

**Literature**

*Magnus Lindberg and Mihaly Matura:*  
 "Patch Testing" in  
 J. D. Johansen, P.J. Frosch, J.-P. Lepoittevin (Eds.),  
Contact Dermatitis 5<sup>th</sup> Edition  
 Springer-Verlag, Berlin Heidelberg, Germany (2011), pp. 439-464

*J.-M. Lachapelle, H. I. Maibach:*  
 "Patch Testing and Prick Testing - A practical Guide  
 Official Publication of the ICDRG"  
 Third Edition  
 Springer-Verlag, Berlin Heidelberg, Germany (2012)

**Appendix:** test protocol

No.	Type	after 48 h			after 72 h		
		E	F	S	E	F	S
1	S	0	0	0	0	0	0
2	S	0	0	0	0	0	0
3		0	0	0	0	0	0
4	S	0	0	0	0	0	0
5	S	0	0	0	0	0	0
6	E	0	0	0	0	0	0
7	E	0	0	0	0	0	0
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11	S	0	0	0	0	0	0
12		0	0	0	0	0	0
13		0	0	0	0	0	0
14	S	0	0	0	0	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17	E	0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20		0	0	0	0	0	0
21	S	0	0	0	0	0	0
22		0	0	0	0	0	0
23	S	0	0	0	0	0	0
24		0	0	0	0	0	0
25		0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	0	0	0	0	0	0
28	E	0	0	0	0	0	0
29		0	0	0	0	0	0
30		0	0	0	0	0	0
31		0	0	0	0	0	0
32		0	0	0	0	0	0
33	S	0	0	0	0	0	0
34		0	0	0	0	0	0
35		0	0	0	0	0	0
36	S	0	0	0	0	0	0
37		0	0	0	0	0	0
38		0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
41	E	0	0	0	0	0	0
42		0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	A	0	0	0	0	0	0
46		0	0	0	0	0	0
47		0	0	0	0	0	0
48		0	0	0	0	0	0
49	S	0	0	0	0	0	0
50		0	0	0	0	0	0
SUM		0,0	0,0	0,0	0,0	0,0	0,0

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4  
 Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4  
 Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4

S: subjects with sensitive skin  
 E: patients with eczema  
 A: patients with allergy

No.	Type	after 48 h			after 72 h		
		E	F	S	E	F	S
1	S	0	0	0	0	0	0
2	S	2	0	0	2	0	0
3		0	0	0	0	0	0
4	S	0	0	0	0	0	0
5	S	1	0	0	1	0	0
6	E	1	0	0	0	0	0
7	E	2	0	2	2	0	1
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	1	0	0	1	0	0
11	S	0	0	0	0	0	0
12		0	0	0	0	0	0
13		0	0	0	0	0	0
14	S	1	0	0	1	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17	E	1	0	1	1	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20		0	0	0	0	0	0
21	S	0	0	0	0	0	0
22		0	0	0	0	0	0
23	S	0	0	0	0	0	0
24		0	0	0	0	0	0
25		0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	0	0	0	0	0	0
28	E	1	0	1	1	0	1
29		0	0	0	0	0	0
30		1	0	0	1	0	0
31		0	0	0	0	0	0
32		0	0	0	0	0	0
33	S	1	0	0	1	0	0
34		0	0	0	0	0	0
35		0	0	0	0	0	0
36	S	2	0	1	2	0	1
37		0	0	0	0	0	0
38		0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
41	E	1	0	0	1	0	0
42		0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	A	1	0	0	0	0	0
46		0	0	0	0	0	0
47		0	0	0	0	0	0
48		0	0	0	0	0	0
49	S	1	0	0	1	0	0
50		1	0	1	1	0	1
SUM		0,36	0,0	0,12	0,32	0,0	0,08

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4  
 Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4  
 Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4

S: subjects with sensitive skin  
 E: patients with eczema  
 A: patients with allergy

No.	Type	after 48 h			after 72 h		
		E	F	S	E	F	S
1	S	0	0	0	0	0	0
2	S	0	0	0	0	0	0
3		0	0	0	0	0	0
4	S	0	0	0	0	0	0
5	S	0	0	0	0	0	0
6	E	0	0	0	0	0	0
7	E	0	0	0	0	0	0
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11	S	0	0	0	0	0	0
12		0	0	0	0	0	0
13		0	0	0	0	0	0
14	S	0	0	0	0	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17	E	0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20		0	0	0	0	0	0
21	S	0	0	0	0	0	0
22		0	0	0	0	0	0
23	S	0	0	0	0	0	0
24		0	0	0	0	0	0
25		0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	0	0	0	0	0	0
28	E	0	0	0	0	0	0
29		0	0	0	0	0	0
30		0	0	0	0	0	0
31		0	0	0	0	0	0
32		0	0	0	0	0	0
33	S	0	0	0	0	0	0
34		0	0	0	0	0	0
35		0	0	0	0	0	0
36	S	0	0	0	0	0	0
37		0	0	0	0	0	0
38		0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
41	E	0	0	0	0	0	0
42		0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	A	0	0	0	0	0	0
46		0	0	0	0	0	0
47		0	0	0	0	0	0
48		0	0	0	0	0	0
49	S	0	0	0	0	0	0
50		0	0	0	0	0	0
SUM		0,0	0,0	0,0	0,0	0,0	0,0

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4  
 Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4  
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S: subjects with sensitive skin  
 E: patients with eczema  
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ECOWORKS LAUNDRY DETERGENT (ALPHA FORMULATION)  
**PCR Corp Report**



## SUMMARY REPORT

**A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 53 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: **KRCRIP2M**

**TEST ARTICLES 1: Ecoworks Laundry Alpha (SCLLD/GC 005/10/23)**

**Confidentiality Statement:**

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

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

## Prepared by:

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

Draft Report: 29<sup>th</sup> January 2024

Final Report: 27<sup>th</sup> February 2024

**A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 53 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: **KRCRIP2M**

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: 28 / 02 / 2024

Charlie Gould  
(Project Manager)

*C Gould*

Date: 28 / 02 / 2024

Dr. Geetha Kugan, MRCP, DCH, FRCPCH  
(Consulting Paediatrician)

*Geetha Kugan*

Date: 28 / 02 / 2024

**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.

*R Sherrington*

Bryan Baker  
(Quality Assurance)

Date: 28 / 02 / 2024

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## KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key Personnel	General Responsibilities
<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, authorization and summary report.
<b>Study Supervisor (SS)</b> Andrew King PCR Corp 164A Plymouth Grove Manchester M13 0AF United Kingdom  Tel: 44(0)161 791 1797	The Study Supervisor (SS) responsible for the conduct of the study on a daily basis.
<b>Consulting Paediatrician</b> Dr. Geetha Kugan, MRCP, DCH, FRCPCH	The Consulting Paediatrician has reviewed the study results and concurs with the study result conclusions.
<b>Project Manager (PM)</b> Charlie Gould Princeton Consumer Research 8 Richmond Road Dukes Park Chelmsford CM2 6UA United Kingdom  Tel: +44(0)1245 934050	The Project Manager (PM) involved with the study authorization, compilation of study results and summary report.

## 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 53 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 "Dermatologically Tested", "Clinically Tested", "Clinically Proven", "Kind to Skin", "Safe for Skin", "Mild for Skin", "Suitable for Eczema prone skin", "Paediatrician Approved", and "Suitable for Newborns".

## MATERIALS AND METHODS

### 1. STUDY DESIGN

The study was conducted single blind, at a single center 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.

### 2. TEST MATERIALS

#### 2.1. TEST ARTICLES

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

TA#	Test Article Name/Description	ID Code (Batch/Lot #)	Dilution/special handling*
1	Ecoworks Laundry Alpha	(SCLLD/GC 005/10/23)	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)<sup>2</sup>.

#### 3.2. 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.

#### 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)<sup>3</sup> 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





## APPENDIX 2: SUBJECT DEMOGRAPHICS

SUBJECT NUMBER	MALE OR FEMALE	AGE	SKIN TYPE
1	Female	27	Eczema
2	Female	40	Eczema
3	Female	18	Normal
4	Female	22	Eczema
5	Male	34	Normal
6	Female	36	Normal
7	Female	20	Eczema
8	Male	19	Eczema
9	Female	20	Normal
10	Male	21	Eczema
11	Male	34	Normal
12	Female	26	Normal
13	Female	37	Eczema
14	Female	25	Eczema
15	Female	18	Normal
16	Female	37	Eczema
17	Male	24	Eczema
18	Female	26	Normal
19	Female	27	Normal
20	Male	18	Normal
21	Male	29	Eczema
22	Male	40	Eczema
23	Female	42	Normal
24	Male	20	Eczema
25	Female	26	Normal
26	Male	40	Eczema
27	Male	22	Normal
28	Female	21	Eczema
29	Male	19	Normal
30	Female	28	Eczema
31	Female	37	Eczema
32	Female	43	Normal
33	Female	19	Eczema
34	Female	22	Normal
35	Male	46	Eczema
36	Female	33	Normal
37	Female	28	Normal
38	Male	27	Eczema
39	Female	29	Eczema
40	Male	23	Normal
41	Male	29	Eczema
42	Female	62	Eczema
43	Female	59	Normal
44	Female	26	Eczema
45	Female	32	Normal
46	Female	24	Normal
47	Male	52	Eczema
48	Female	48	Eczema
49	Female	45	Normal
50	Male	40	Eczema
51	Female	49	Normal
52	Male	49	Eczema
53	Female	27	Normal
54	Female	35	Eczema
55	Male	42	Normal
56	Female	28	Normal

## APPENDIX 3: INCI LISTINGS

Test Article 1: Ecoworks Laundry Alpha (SCLLD/GC 005/10/23)**Product Name:** Ecoworks Laundry Alpha**Code:** SCLLD/GC 005/10/23