

**REPORT FROM DERMATOLOGICAL
TEST
PATCH TEST METHOD****MEMBER COMPANY**
POLISH ASSOCIATION OF COSMETIC
AND DETERGENT INDUSTRY **PACDI**

Version: 01/27.02.2025

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1. GENERAL INFORMATION

Date of report	25.11.2025
Sample number / test number	14/10/25/D/11
Information given by the Principal	Sample name
	Identification number given by Principal (series / production date / internal number)
	Product type
	Product composition / INCI
	Principal / Responsible person
Beginning of research	14.10.2025
Completion of research	22.10.2025
Comments on sample state	None
Volunteers group	10 volunteers
Skin type	normal



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2. BASIS FOR RESEARCH IMPLEMENTATION

- Order form and test samples delivered by Principal
- Confirmation of microbiological purity / microbiological insensitivity

The Principal is responsible for compliance with the declared quality composition of the samples sent for testing.

3. PURPOSE OF RESEARCH

Product evaluation in terms of irritating and sensitizing properties.

4. SCOPE OF RESEARCH

4.1. LEGAL BASE OF RESEARCH

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997”.
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964 - 2013).
- The Act on Cosmetic Products, October 4, 2018, Journal of Laws No. 2018 item 2227.
- Test procedure by SKINLAB P.S.A.: PO-08 Research Implementation.
- Instruction by SKINLAB P.S.A.: I02/PO-08 Dermatological test – patch test.
- Instruction by SKINLAB P.S.A.: I04/PO-08 Scheme for assessing skin reactions - product classification.

5. VOLUNTEERS SELECTION

5.1. INCLUSION CRITERIA IN ACCORDANCE WITH LEGAL STANDARDS

- Current European and Polish law
- Cosmetics Europe- The Personal Care Association
- Declaration of Helsinki (1964-2013)
- Test procedure by SKINLAB P.S.A.: PO-08 Research Implementation
- Instruction by SKINLAB P.S.A.: I01/PO-08 Volunteers qualification for the study

5.2. EXCLUSION CRITERIA

- Use of antibiotics
- Pregnancy/breastfeeding
- Chemotherapy/radiotherapy
- Fever
- Infection (e.g. Cold)
- Use of anti-allergic drugs/ointments
- Skin with lesions
- Persons under 18 years of age



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6. INFORMED CONSENT OF THE VOLUNTEERS

All volunteers selected for the study met the requirements for inclusion in the study and signed consent to voluntary participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. During the entire study, the volunteers were under the constant care of a dermatologist.

7. METHODS OF RESEARCH

The test was performed in accordance with the research procedure of SKINLAB P.S.A. (PO-08 Research implementation) under the supervision of a dermatologist. The research model is the skin test according to Jadassohn-Bloch modified by Rudzki. The test consisted in a single application of the product to a selected area of the skin, and then observing the condition of the skin at intervals. The recording of the results and the classification of the product is made on the basis of the point classification (0-4) of the skin reaction (I04 / PO-08). Qualification, sample application and readings take place at SKINLAB P.S.A. in Cracow.

8. RESULTS

8.1. VOLUNTEERS IDENTIFICATION

8.1.1. READINGS FROM THE TEST - POINT CLASSIFICATION

VOLUNTEER IDENTIFICATION NUMBER	SEX F – female M – male	AGE	SKIN TYPE N – normal S – sensitive	RESULT	
				AFTER 48 h	
				Erythema	Edema/ Swelling
1	M	27	N	0	0
2	F	24	N	0	0
3	F	24	N	0	0
4	F	23	N	0	0
5	F	21	N	0	0
6	F	42	N	0	0
7	F	68	N	0	0
8	F	62	N	0	0
9	F	45	N	0	0
10	F	47	N	0	0

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8.2. IRRITATION INDEX

The average irritation index is calculated from the sum of the scores for erythema and edema. Based on the irritation index, the product is classified according to the scale.

AVERAGE IRRITATION INDEX (x_{sr})	PRODUCT CLASSIFICATION
$x_{\text{sr}} < 0,5$	non-irritating
$0,5 < x_{\text{sr}} < 2,0$	slightly irritating
$2,0 < x_{\text{sr}} < 5,0$	moderately irritating
$5,0 \leq x_{\text{sr}}$	strongly irritating

Average irritation index for tested product: $x_{\text{sr}} = 0$, where $x_{\text{sr}} = \frac{\text{sum of the scores}}{\text{volunteers number}}$

9. CONCLUSION

A dermatological study conducted on volunteers who were not allergic to any of the ingredients of the tested product "**PediZone Intense Repair Foot Care Cream**" confirms that the tested product is **WELL TOLERATED BY THE SKIN**, as it did not show any irritating or allergenic properties. The product can be classified as **NON-IRRITATING**.

The study authorises the responsible person to place the logo of the SKINLAB P.S.A. specialist research laboratory on the label of the product "**PediZone Intense Repair Foot Care Cream**" and to use the following statement: "**Dermatologically tested by the independent research and consulting laboratory SKINLAB P.S.A.**".

10. RESULTS AUTHORIZATION

Report authorised by	Aleksandra Dutka R&D Coordinator
Report approved by	Doctor of medicine DERMATOLOGIST AND VENEROLOGIST KR 5562935

----- END OF THE REPORT -----