Státní zdravotní ústav

PUELLAvone s.r.o.
Rovníková 1457/7
040 12 Košice
Slovak Republic

Your ref.: 2/2025
from .: 6. 2. 2025
Our ref. : **SZÚ/02146/2025; 53-187-25; EX 250174**
Handled by : RNDr. Hana Bendová, Ph.D.
Tel.: 2 6708 2321
E-mail: hana.bendova@szu.cz
Date: 12. 3. 2025

EXPERT OPINION on the skin compatibility test in humans.

SUBJECT OF THE REQUEST:

Regarding your request dated 06.02.2025 for the skin compatibility test in humans, we inform you:

SUBMITTED SAMPLES:

1. PUELLA White Laundry Gel (ID 3274)

Applicant:

PUELLAvone s.r.o.

Rovníková 1457/7

040 12 Košice

Slovak Republic

SUBMITTED DOCUMENTATION:

No documentation was submitted.

PERFORMED TEST:

The skin compatibility test in humans was conducted according to the Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, COLIPA, Brussels, 1997. COLIPA = The European Cosmetic, Toiletry and Perfumery Association.

The submitted samples were used up during the mentioned examination.

EXPERT ASSESSMENT:

The test was conducted at Testing Laboratories No. 1206, accredited by the Slovak Institute for Accreditation (SIA), Center for Toxicology and Health Safety.

CONCLUSION:

PUELLA White Laundry Gel (ID 3274):

Under the test conditions, no reactions such as erythema, edema, or scaling were observed in the exposed subjects at any evaluation interval.

Based on the results, it can be concluded that the tested sample does not have skin irritant potential under the test conditions.

The product packaging may include the claim "DERMATOLOGICALLY TESTED."

RNDr. Hana Bendová, Ph.D.
vedoucí
Centrum toxikologie a zdravotní bezpečnosti

STÁTNÍ ZDRAVOTNÍ ÚSTAV
Centrum toxikologie
a zdravotní bezpečnosti
Šrobárova 49/48
100 00 Praha 10

(Signature: RNDr. Hana Bendová, Ph.D., Head, Center for Toxicology and Health Safety)

ANNEXES:

Protocol of the skin compatibility test in humans, SZÚ/02146/2025, 53-187-25

PROTOCOL OF THE SKIN COMPATIBILITY TEST IN HUMANS

Testing Facility: National Reference Center for Cosmetics, Center for Toxicology and Health Safety, State Health Institute, Šrobárova 49/48, 100 00 Prague 10, Testing Laboratory No. 1206, accredited by SIA.

Test Date: March 24 – March 31, 2025
Protocol Number: SZÚ/02146/2025; 53-187-25
Test Conducted by: RNDr. Hana Bendová, Ph.D.
Dermatologist: MUDr. Petra Squerzi

The test was conducted according to the Skin Compatibility Test in Humans (Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, COLIPA, Brussels 1997, COLIPA = The European Cosmetic, Toiletry and Perfumery Association).

Objective of the test: to determine the skin compatibility of the tested material.

TEST REPORT

TESTED SAMPLE (labelled TS)

TS 1: PUELLA laundry gel for white laundry (ID 3274)

Applicant:
PUELLA Avone s.r.o.
Rovníková 1457/7
040 12 Košice
Slovak Republic

SAMPLE PREPARATION
Repeated Closed Test
TS 1: *The sample was applied as a 1% aqueous solution in a volume of 0.1 ml for each application.*

Solvent Control (SC)
Distilled water applied in a volume of 0.1 ml for each application.

TEST SUBJECTS - PERSONS

The selection of human volunteers and the testing procedure are governed by the principles established in the Declaration of Helsinki — WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects (1964, revised 2013) and the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016). The study was conducted with the approval of the Ethics Committee of the Slovak Public Health Authority.
Participation was entirely voluntary. All volunteers met the inclusion criteria for the study and completed a special questionnaire for this purpose. All study documentation is confidential. Fifteen subjects with sensitive skin participated in the test.

GROUP OF TEST SUBJECTS

Test Subject Number	Initials	Age	Gender
1	UR	62	F
2	JL	63	F
3	SL	56	F
4	OD	68	F
5	PD	63	F
6	ŘM	49	F
7	JZ	53	F
8	TJ	61	F
9	VA	59	F
10	PM	62	F
11	PJ	34	M
12	HI	46	F
13	VK	61	F
14	JT	26	F
15	BO	32	M

- **TEST METHODOLOGY**
- The study included:
- Repeated closed test (epicutaneous test on the upper arm)

Repeated Closed Patch Test

Test materials were applied under semi-occlusion on the upper arm. The exposure time was 24 hours on the first day, and 6 hours each day from the second to the fifth day. Residues of the tested substance were removed by rinsing and gentle wiping. Readings were performed on the eighth day after the first application and before each subsequent application. Reaction assessments were carried out according to the Skin Reaction Classification System.

Semi-occlusive dressing: Curatest (Lohman/Rauscher, Germany)

SKIN REACTION CLASSIFICATION SYSTEM

Reaction	Numerical Rating
ERYTHEMA – REDDENING:	
No erythema	0
Very slight erythema, barely perceptible	0,5
Weak redness, dotted and diffuse	1
Moderate uniform redness	2
Strong uniform redness	3
Flaming redness	4
DRYNESS – SCALING:	
No scaling	0
Dry skin without scaling; appearance smooth and taut	0,5
Fine, slight scaling	1
Moderate scaling	2
Severe scaling with large skin flakes	3
EDEMA:	
no edema	-
edema present	+

RESULTS

The reaction results are provided in Annex No. 1.

ASSESSMENT OF RESULTS

Under the test conditions, no reactions such as erythema, edema, or scaling were observed in the exposed subjects at any evaluation interval.

Based on the results, it can be concluded that the tested sample does not have skin irritant potential under the test conditions.

The product packaging may include the claim "DERMATOLOGICALLY TESTED."

Annex No. 1 to Protocol No. SZÚ/02146/2025; 53-187-25

TS 1

Reading time / Skin reaction

Test subject No.	Before 2nd application			Before 3rd application			Before 4th application			Before 5th application			Eighth day after 1st application		
	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema
1	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-

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Test subject No.	Before 2nd application			Before 3rd application			Before 4th application			Before 5th application			Eighth day after 1st application		
	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema	Erythema	Dryness	Edema
1	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
2	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
3	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
4	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
5	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
6	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
7	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
8	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
9	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
10	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
11	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
12	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
13	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
14	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-
15	0	0	-	0	0	-	0	0	-	0	0	-	0	0	-

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