

REPORT No. 714542/24/INT/S

Sponsor:		Investigational product (according to declaration of the Sponsor) R24-34395; R24112636 - PROLOM ANTI-AGE FACE SERUM, 30ml (ID NUMBER: DS170502)
SP Laboratorija A.D., 21220 BECEJ, INDUSTRIJSKA 3		
Sample reception date:	14.11.2024	
Start of study:	03.12.2024	
End of study:	06.12.2024	
Report date:	09.12.2024	Sample status: no objections Sample received from the Sponsor

**DERMATOLOGICAL TEST - PRESENCE OF AN ALLERGIC
REACTION/CONTACT ECZEMA. IN VIVO SKIN IRRITATION METHOD -
SEMI-OPEN TEST (25 SUBJECTS WITH ALLERGOLOGICAL HISTORY,
25 SUBJECTS WITHOUT ALLERGOLOGICAL HISTORY)**

REPORT No. 714542/24/INT/S**THE STUDY IS COMPLIANT WITH:**

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on Cosmetic Products.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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REPORT No. 714542/24/INT/S**1. BASIS OF THE STUDY**

The test sample was delivered by the Client.

The qualitative composition of the product was delivered by the Client.

The results of microbiological purity of the product provided by the Client (or the Client's declaration concerning microbiological purity) do not apply to low microbiological risk products.

The Client is responsible for compliance with the declared qualitative composition and microbiological purity of the product sample sent for testing.

2. OBJECT OF THE STUDY

Parameter	Description
Intended use	Cosmetic
Packaging	Replacement packaging containing the name and sample number for testing

3. QUALITATIVE COMPOSITION OF THE PRODUCT

The qualitative composition was delivered to the Laboratory by the Client before the start of the study.

4. PURPOSE OF THE STUDY

The purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

REPORT No. 714542/24/INT/S**5. DESCRIPTION OF VOLUNTEERS**

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive history of allergies. The selection of the group included the criteria of inclusion and exclusion. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations or changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

6. TESTING METHODOLOGY

The preparation in an appropriate concentration is applied onto filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area with the use of a sticking patch. At the same time, in order to guarantee objective results of the study and to exclude possible reading errors connected with dermal irritations, two control samples (control sample called "blind" and control sample containing water) are used. The dermatologist removes the patch 48 hours after the application and examines the skin reaction 30 minutes after the removal. 72 hours after the application, the dermatologist examines the skin again for a reaction. If irritations appear or persist 72 hours after the application, an additional examination takes place after 96 hours. While determining the skin reaction, the dermatologist assesses the irritating and sensitising effects of the tested product. The study results may be influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

*Dermatological test - Presence of an allergic reaction/contact eczema. In vivo skin irritation method - semi-open and closed test PB-561 ed. 3 of 15.01.2024

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7. EVALUATION PARAMETERS

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	Classification point
No erythema	0
Light erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	Classification point
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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8. RESULTS
8.1. CHARACTERISTICS OF VOLUNTEERS
Table 1

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	MOK.PA	03.12.2024	24	F	II
2	BOC.AL	03.12.2024	46	F	II
3	WOZ.MA	03.12.2024	26	F	II
4	ZAW.AG	03.12.2024	42	F	II
5	WEN.MO	03.12.2024	27	F	II
6	ROK.BA	03.12.2024	62	F	II
7	GAS.ZE	03.12.2024	55	F	II
8	KLI.JA	03.12.2024	56	M	II
9	JAW.LU	03.12.2024	51	F	II
10	KUB.KL	03.12.2024	48	F	II
11	GAN.AG	03.12.2024	27	F	II
12	DAW.NA	03.12.2024	25	F	II
13	BIE.IZ	03.12.2024	36	F	II
14	ADA.AN	03.12.2024	40	F	II
15	GOL.DA	03.12.2024	21	M	II
16	WOJ.JU	03.12.2024	25	F	II
17	FAN.AL	03.12.2024	27	F	II
18	KRZ.EW	03.12.2024	38	F	II
19	ROS.WI	03.12.2024	48	F	II
20	ZAM.PA	03.12.2024	33	F	II
21	JUR.ED	03.12.2024	40	F	II
22	UFN.DO	03.12.2024	24	F	II
23	DOB.MI	03.12.2024	65	M	II
24	KOT.AN	03.12.2024	64	M	II
25	DIE.BE	03.12.2024	50	F	II
			Min	21	No. F phototype I
			Max	65	4
			Average	40	No. M phototype II
				21	25
					phototype III
					0
					phototype IV
					0

Table 1. Characteristics of volunteers with negative history of allergies

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Table 2

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	CIE.MA	03.12.2024	63	F	II
2	PIO.AN	03.12.2024	52	F	II
3	ZAL.IZ	03.12.2024	46	F	II
4	WEN.EL	03.12.2024	37	F	II
5	SZR.MA	03.12.2024	49	F	II
6	MAZ.HA	03.12.2024	21	F	II
7	SZY.MA	03.12.2024	53	F	II
8	KWI.BO	03.12.2024	69	F	II
9	SOS.AG	03.12.2024	36	F	II
10	GAN.MA	03.12.2024	60	F	II
11	ROM.KA	03.12.2024	50	F	II
12	PIA.DA	03.12.2024	60	F	II
13	MAN.MA	03.12.2024	49	F	II
14	STR.MA	03.12.2024	38	F	II
15	ZYL.AN	03.12.2024	64	F	II
16	BAR.KA	03.12.2024	45	F	II
17	SAD.MA	03.12.2024	27	F	II
18	KIE.OL	03.12.2024	44	F	II
19	TRO.MA	03.12.2024	45	F	II
20	SRE.DO	03.12.2024	52	F	II
21	DRO.KR	03.12.2024	61	F	II
22	ROZ.AG	03.12.2024	42	F	II
23	WEN.JU	03.12.2024	23	F	II
24	WIE.MO	03.12.2024	44	F	II
25	BOV.TE	03.12.2024	55	F	II
		Min	21	No. F	phototype I
		Max	69	25	0
		Average	47	No. M	phototype II
				0	25
					phototype III
					0
					phototype IV
					0

Table 2. Characteristics of volunteers with positive history of allergies

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8.2. TABLE OF SKIN RESPONSE
Table 3

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Table 3. Results for volunteers with negative history of allergies

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Table 4

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Table 4. Results for volunteers with positive history of allergies

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9. CALCULATED VALUES

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index (X_{av}).

	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
The sum of negative reaction (the sum of classification points)	0.00	0.00	0.00	0.00	Examination skipped	
X _{av}	0.00					

10. INTERPRETATION

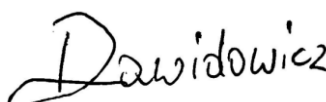
The average irritation index (X_{av}) was calculated. The product was then classified according to the following table:

Average irritation index (x_{av})	Class
$X_{av} < 0.50$	Non irritating
$0.50 \leq X_{av} < 2.00$	Slightly irritating
$2.00 \leq X_{av} < 5.00$	Moderately irritating
$5.00 \leq X_{av}$	Highly irritating

REPORT No. 714542/24/INT/S**11. CONCLUSION**

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergies/atopy (sensitive skin). The study allows to conclude that product **R24-34395; R24112636 - PROLOM ANTI-AGE FACE SERUM, 30ml (ID NUMBER: DS170502)** used by volunteers, who didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as **NON IRRITATING**.

REPORT No. 714542/24/INT/S**12. SIGNATURES**

PROJECT MANAGER	Sign and date:  09.12.2024
TECHNICIAN	Sign and date:  09.12.2024
QUALITY ASSURANCE AUDITOR	Sign and date:  09.12.2024
DERMATOLOGIST	Sign and date:  09.12.2024 Registered N° 2880077

Attention: The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland

The results relate to the analysed samples only.

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*Accredited study

THE END OF THE REPORT