HAMILTON

AB 079

REPORT No. 250870/25/GDA

Sponsor:		Investigational product (according to declaration of the Sponsor)
Lively Roasters d.o.o. **10000 Zagreb, Vrsarska 2**		**1539/25** **Phytomar Sophia Serum** 250825/25/ZAD
Sample reception date:	15.04.2025	
Start of study:	22.04.2025	
End of study:	25.04.2025	
Report date:	28.04.2025	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)

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TESTING LABORATORY
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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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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	Serum
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.

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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	Begining of the study	Age	Sex	Phototype
1	GAN.AG	22.04.2025	27	F	II
2	DAW.NA	22.04.2025	26	F	II
3	ADA.AN	22.04.2025	41	F	II
4	GOL.DA	22.04.2025	22	M	II
5	BIE.IZ	22.04.2025	36	F	II
6	KRZ.EW	22.04.2025	38	F	II
7	ZAM.PA	22.04.2025	34	F	II
8	ROS.WI	22.04.2025	48	F	II
9	JAN.AG	22.04.2025	37	F	II
10	JUR.ED	22.04.2025	41	F	II
11	SME.BO	22.04.2025	63	F	II
12	CHO.AG	22.04.2025	30	F	II
13	NIE.MA	22.04.2025	53	F	II
14	AUG.AG	22.04.2025	38	F	II
15	POR.AL	22.04.2025	65	F	II
16	KRU.MA	22.04.2025	61	F	II
17	WRO.AL	22.04.2025	49	F	II
18	LUK.JE	22.04.2025	54	M	II
19	GAW.AN	22.04.2025	50	F	II
20	SWI.EW	22.04.2025	65	F	II
21	OZO.AN	22.04.2025	66	F	II
22	SEP.JA	22.04.2025	43	M	II
23	GLO.AN	22.04.2025	42	F	II
24	HAJ.DA	22.04.2025	22	M	II
25	FAN.AL	22.04.2025	27	F	II
		Min	22	**No. F**	**phototype I**
		Max	66	21	0
		Average	43	**No. M**	**phototype II**
				4	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	Begining of the study	Age	Sex	Phototype
1	SAD.MA	22.04.2025	28	F	II
2	MIL.KA	22.04.2025	32	F	II
3	STA.KA	22.04.2025	25	F	II
4	CIE.MA	22.04.2025	64	F	II
5	KWI.BO	22.04.2025	69	F	II
6	SOS.AG	22.04.2025	36	F	II
7	ZYL.AN	22.04.2025	64	F	II
8	ROK.GR	22.04.2025	49	F	II
9	CHR.PA	22.04.2025	37	F	II
10	WEN.MO	22.04.2025	27	F	II
11	ZIE.RO	22.04.2025	26	F	II
12	WOZ.MA	22.04.2025	26	F	II
13	LIP.MO	22.04.2025	30	F	II
14	JAC.AL	22.04.2025	20	F	II
15	MOK.PA	22.04.2025	24	F	II
16	WOD.KA	22.04.2025	36	F	II
17	BOC.AL	22.04.2025	46	F	II
18	ROD.MA	22.04.2025	20	F	II
19	WIE.MO	22.04.2025	45	F	II
20	WEN.EL	22.04.2025	37	F	II
21	GAN.MA	22.04.2025	60	F	II
22	SKU.CA	22.04.2025	19	F	II
23	JAG.MA	22.04.2025	64	F	II
24	MAR.AN	22.04.2025	36	F	II
25	WEN.JU	22.04.2025	24	F	II
		Min	19	**No. F**	**phototype I**
		Max	69	25	0
		Average	38	**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 (xav)	Class
$\mathbf{X_{av}} < 0.50$	Non irritating
$0.50 \leq \mathbf{X_{av}} < 2.00$	Slightly irritating
$2.00 \leq \mathbf{X_{av}} < 5.00$	Moderately irritating
$5.00 \leq \mathbf{X_{av}}$	Highly irritating

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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 **1539/25 Phytomar Sophia Serum** 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**.

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12. SIGNATURES

DERMATOLOGY AND APPLICATIONS SECTION MANAGER	Sign and date:  28.04.2025
SENIOR TECHNICIAN	Sign and date:  28.04.2025
QUALITY ASSURANCE AUDITOR	Sign and date:  28.04.2025
DERMATOLOGIST	Sign and date:  28.04.2025 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.

Authorized by: Anna Adamska, Senior Specialist for Cosmetic Products Research

The test report bears the certified electronic seal of J.S. Hamilton Poland Sp. z o.o.

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

The results relate to the analysed samples only.

*Accredited study

THE END OF THE REPORT

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