

**REPORT OF ANALYSIS No. L613/23/JSHR**

Client: <b>Camco Ltd., 4006 Plovdiv, 112 Tsarigradsko Shose Blvd.</b>		Sample description ( <i>according to declaration of the Client</i> ) SYNERGY FACE SERUM AYRA Lot/Batch: CC0001 Production date: 04.01.2023 Expiration date: 01.2026 Sampling date: 04.01.2023 Sampling quantity: 5X30 ML Sample temperature: 20°C Reception hour: 12:30 Responsible for sampling: IVO DRAMOV Sample condition with no objections
Sample received on:	06.01.2023	
Report issued on:	27.01.2023	

**Dermatological test SEMI-OPEN TEST EXPANDED**

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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 (previously COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997

Cosmetics Europe The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008

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### 1. BASIS OF THE STUDY

Test sample delivered by the Client.

The qualitative composition of the product delivered by the Client.

The results of microbiological purity of the product provided by the Client (or declaration from the Client about microbiological purity) does 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
Appearance	Dense liquid
Color	Transparent
Fragrance	Characteristic for raw materials (or fragrance composition)
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 allergy history. 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 and 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 the 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. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations two control samples (control sample called "blind" and control sample with water) are used. The purpose of this study is to exclude possible reading errors connected with dermal irritations. The results of the study are presented in section 10 of this report. The dermatologist removes the patch 48h after the application and examines the skin response 30 minutes after removal. 72h after the application, the dermatologist examines the skin again for a response. If irritations appear or persist 72h after the application, an additional examination takes place after 96 hours. Determining the response of the skin, 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.

### 7. DATE OF THE STUDY

24.01.2023 – 27.01.2023

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**REPORT OF ANALYSIS No. L613/23/JSHR**
**8. EVALUATION PARAMETERS**

<b>EVALUATION PARAMETERS OF SKIN REACTION</b>	
<b>Erythema</b>	<b>Classification point</b>
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
<b>Edema</b>	<b>Classification point</b>
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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**9. RESULTS**
**9.1. CHARACTERISTICS OF VOLUNTEERS**
**Table 1**

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	ZAT.BA	24.01.2023	44	F	II	
2	KLI.JA	24.01.2023	54	F	II	
3	SER.NA	24.01.2023	26	F	II	
4	ZAK.JO	24.01.2023	68	F	II	
5	GAS.ZE	24.01.2023	53	F	II	
6	GUR.ED	24.01.2023	48	F	II	
7	BEH.NA	24.01.2023	24	F	II	
8	KAS.VA	24.01.2023	67	F	II	
9	KUB.AL	24.01.2023	62	F	II	
10	WIE.MA	24.01.2023	25	F	II	
11	ROS.WI	24.01.2023	46	F	II	
12	JAC.AN	24.01.2023	39	F	II	
13	GRA.WI	24.01.2023	24	F	II	
14	MAC.PA	24.01.2023	29	F	II	
15	ROS.PA	24.01.2023	18	F	II	
16	FLO.MA	24.01.2023	25	F	II	
17	NOW.EW	24.01.2023	68	F	II	
18	RYD.WI	24.01.2023	63	F	II	
19	BAB.WI	24.01.2023	66	F	II	
20	PAC.NA	24.01.2023	23	F	II	
21	ZAM.PA	24.01.2023	32	F	II	
22	DIE.BE	24.01.2023	48	F	II	
23	MIC.BA	24.01.2023	55	F	II	
24	AUG.AG	24.01.2023	36	F	II	
25	RUS.MA	24.01.2023	52	F	II	
			<b>Min</b>	18	<b>No. F</b>	<b>phototype I</b>
			<b>Max</b>	68	25	0
			<b>Average</b>	44	<b>No. M</b>	<b>phototype II</b>
					0	25
						<b>phototype III</b>
						0
						<b>phototype IV</b>
						0

**Table 1. Characteristics of volunteers with a negative history of allergy**

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**Table 2**

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	RAD.MA	24.01.2023	50	F	II	
2	MIK.NA	24.01.2023	25	F	II	
3	KUL.SY	24.01.2023	25	F	II	
4	PIA.DA	24.01.2023	58	F	II	
5	BOV.TE	24.01.2023	53	F	II	
6	PIO.AN	24.01.2023	50	F	II	
7	ARB.AL	24.01.2023	21	F	II	
8	SZR.MA	24.01.2023	47	F	II	
9	PIA.ID	24.01.2023	20	F	II	
10	PIO.EL	24.01.2023	52	F	II	
11	BRZ.JU	24.01.2023	20	F	II	
12	MAC.MA	24.01.2023	62	F	II	
13	MAR.KA	24.01.2023	61	F	II	
14	ROM.DO	24.01.2023	46	F	II	
15	WLO.AG	24.01.2023	36	F	II	
16	DER.OL	24.01.2023	45	F	II	
17	GAN.MA	24.01.2023	58	F	II	
18	POD.JA	24.01.2023	68	F	II	
19	PAW.MA	24.01.2023	21	F	II	
20	SEL.GR	24.01.2023	45	F	II	
21	KAL.OL	24.01.2023	23	F	II	
22	LIS.DA	24.01.2023	36	F	II	
23	RAD.MA	24.01.2023	57	F	II	
24	ARB.LU	24.01.2023	45	F	II	
25	CIE.MA	24.01.2023	35	F	II	
			<b>Min</b>	20	<b>No. F</b>	<b>phototype I</b>
			<b>Max</b>	68	25	0
			<b>Average</b>	42	<b>No. M</b>	<b>phototype II</b>
					0	25
						<b>phototype III</b>
						0
						<b>phototype IV</b>
						0

Table 2. Characteristics of volunteers with a positive history of allergy

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## REPORT OF ANALYSIS No. L613/23/JSHR

### 9.2. 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 a negative history of allergy**

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**REPORT OF ANALYSIS No. L613/23/JSHR**
**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 a positive history of allergy**

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### 10. 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					

### 11. 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
$X_{av} < 0.50$	Not 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

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### **12. CONCLUSION**

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers positive history of allergy/atopy (sensitive skin). The study allows to conclude that product SYNERGY FACE SERUM AYRA used by volunteers, that 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 NOT IRRITATING.

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**REPORT OF ANALYSIS No. L613/23/JSHR****13. SIGNATURES**

<b>Project Manager Assistant</b>	<b>Paulina Maciszka</b>	
<b>Dermatologist - venereologist</b>	<b>Karolina Osiecka (2487308)</b>	
<b>Project Manager</b>	<b>Iwona Świniańska</b>	

The Client is responsible for conformity with the declared quality composition as well as microbiological purity of the delivered samples.  
Attention: The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

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