

SUPPLEMENT 6

-RESULTS OF DERMATOLOGICAL TESTS

REPORT OF ANALYSIS No. 291668/20/JSHS

Client: GALEX, proizvodnja in promet s farmaceutskimi in drugimi proizvodi d.o.o., 9000 Murska Sobota, Tišinska ulica 29 g		Sample description (<i>according to declaration of the Client</i>) Flinoa Gelenkwohk (massage oil for joint pain) 30 ml
Sample received on:	19.06.2020	
Report issued on:	03.07.2020	

Dermatological test SEMI-OPEN TEST EXPANDED

Prepared by: Kinga Roman, Senior Technician

Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)
Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)

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

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REPORT OF ANALYSIS No. 291668/20/JSHS**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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REPORT OF ANALYSIS No. 291668/20/JSHS**LIST OF CONTENTS**

1. Basis of the study
2. Object of the study
3. Qualitative composition of the product
4. Purpose of the study
5. Description of volunteers
6. Testing methodology
7. Date of the study
8. Evaluation parameters
9. Results
 - 9.1. Characteristics of volunteers
 - 9.2. Table of skin response
10. Calculated values
11. Interpretation
12. Conclusion
13. Signatures

Prepared by: Kinga Roman, Senior Technician

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Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)

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

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REPORT OF ANALYSIS No. 291668/20/JSHS**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	Liquid
Color	Yellow
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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Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)

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REPORT OF ANALYSIS No. 291668/20/JSHS**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

30.06.2020 – 03.07.2020

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

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8. 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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REPORT OF ANALYSIS No. 291668/20/JSHS
9. RESULTS
9.1. CHARACTERISTICS OF VOLUNTEERS
Table 1

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	WIE.MA	30.06.2020	50	F	II	
2	CHR.AN	30.06.2020	55	F	II	
3	WOL.ZB	30.06.2020	51	M	II	
4	WOL.EW	30.06.2020	47	F	II	
5	ZEN.ZO	30.06.2020	69	F	II	
6	KRO.DO	30.06.2020	49	F	II	
7	PIS.KA	30.06.2020	57	F	II	
8	KOL.KR	30.06.2020	62	F	II	
9	ZMU.EL	30.06.2020	61	F	II	
10	ZMU.MI	30.06.2020	63	F	II	
11	WIE.ZO	30.06.2020	65	F	II	
12	WLO.TE	30.06.2020	48	F	II	
13	PED.TE	30.06.2020	68	F	II	
14	OWC.ED	30.06.2020	50	F	II	
15	JUC.ZUZ	30.06.2020	28	F	II	
16	BUT.AN	30.06.2020	52	F	II	
17	CHY.EW	30.06.2020	68	F	II	
18	KAR.EL	30.06.2020	49	F	II	
19	LUT.EW	30.06.2020	57	F	II	
20	PIE.EL	30.06.2020	56	F	II	
21	SID.MA	30.06.2020	59	F	II	
22	GAR.JU	30.06.2020	47	F	II	
23	BEC.EL	30.06.2020	54	F	II	
24	JER.DA	30.06.2020	53	F	II	
25	STE.KA	30.06.2020	52	F	II	
			Min	28	No. F	phototype I
			Max	69	24	0
			Average	55	No. M	phototype II
					1	25
						phototype III
						0
						phototype IV
						0

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

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 Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)
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REPORT OF ANALYSIS No. 291668/20/JSHS
Table 2

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	KOL.TO	30.06.2020	55	M	II	
2	ZAL.IZ	30.06.2020	41	F	II	
3	NIT.AN	30.06.2020	45	M	II	
4	SZY.MA	30.06.2020	48	F	II	
5	DUD.IR	30.06.2020	63	F	II	
6	DAS.EW	30.06.2020	67	F	II	
7	BER.AN	30.06.2020	49	F	II	
8	GRA.AL	30.06.2020	44	F	II	
9	GRA.MA	30.06.2020	68	F	II	
10	OGI.AL	30.06.2020	54	F	II	
11	CZA.HA	30.06.2020	65	F	II	
12	KUR.MA	30.06.2020	48	F	II	
13	SEK.EL	30.06.2020	67	F	II	
14	MAZ.AG	30.06.2020	19	F	II	
15	POR.MO	30.06.2020	23	F	II	
16	ARB.AL	30.06.2020	19	F	II	
17	WOJ.SE	30.06.2020	65	F	II	
18	WIE.SL	30.06.2020	52	M	II	
19	MAT.MA	30.06.2020	64	F	II	
20	OKU.AG	30.06.2020	48	F	II	
21	ROZ.AG	30.06.2020	37	F	II	
22	TAR.AG	30.06.2020	55	F	II	
23	BRU.AN	30.06.2020	25	F	II	
24	PIO.EL	30.06.2020	49	F	II	
25	JUN.AG	30.06.2020	42	F	II	
			Min	19	No. F	phototype I
			Max	68	22	0
			Average	48	No. M	phototype II
					3	25
						phototype III
						0
						phototype IV
						0

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

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REPORT OF ANALYSIS No. 291668/20/JSHS
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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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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REPORT OF ANALYSIS No. 291668/20/JSHS**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 Flinoa Gelenkwohk (massage oil for joint pain) 30 ml 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. 291668/20/JSHS**13. SIGNATURES**

Senior Technician	Kinga Roman	
Dermatologist - venereologist	Karolina Osiecka (2487308)	
Cosmetic Laboratory Manager	Marta Rosińska	

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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