REPORT OF ANALYSIS No. 251113/20/JSHS

Client: **IOS, inštitut za okoljevarstvo in senzorje, proizvodnja, trgovina in storitve, d.o.o., 2000 Maribor, Beloruska ulica 7**		Sample description *(according to declaration of the Client)* Stay Safe, razkužilo za roke
Sample received on:	28.05.2020	
Report issued on:	05.06.2020	

Dermatological test OPEN TEST

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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	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 (25 people) were healthy, with negative 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 to the skin on the forearm in the area of 3x3 cm. Reading the response of the skin was performed 15 minutes, 30 minutes, 1 hour, and 24 hours after the test application. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations one control samples (control sample with water) are carried out. 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. If irritations appear or persist 24h after the application, an additional examination takes place after 48 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

02.06.2020 – 05.06.2020

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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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9. RESULTS

9.1. CHARACTERISTICS OF VOLUNTEERS

Table 1

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	WYS.ZA	02.06.2020	41	F	II
2	KUR.KL	02.06.2020	24	F	II
3	BIE.GR	02.06.2020	60	F	II
4	DIE.TO	02.06.2020	49	M	II
5	CIE.MA	02.06.2020	59	F	II
6	KAR.DA	02.06.2020	42	M	II
7	BZD.RE	02.06.2020	60	F	II
8	KAC.AN	02.06.2020	45	F	II
9	PRZ.MA	02.06.2020	59	F	II
10	TOM.EL	02.06.2020	69	F	II
11	SIE.AG	02.06.2020	42	F	II
12	KAL.EW	02.06.2020	59	F	II
13	KUR.AN	02.06.2020	46	F	II
14	PAL.MA	02.06.2020	34	F	II
15	CIE.TE	02.06.2020	67	F	II
16	SUC.EW	02.06.2020	55	F	II
17	KRA.AG	02.06.2020	42	F	II
18	SMI.MA	02.06.2020	30	F	II
19	BOC.KI	02.06.2020	26	F	II
20	CHR.EL	02.06.2020	63	F	II
21	WAN.MA	02.06.2020	60	F	II
22	PIO.MI	02.06.2020	60	F	II
23	ZWO.JO	02.06.2020	63	F	II
24	DIE.DA	02.06.2020	19	M	II
25	BIE.AL	02.06.2020	38	F	II
		Min	19	**No. F**	**phototype I**
		Max	69	22	0
		Average	48	**No. M**	**phototype II**
				3	25
					phototype III
					0
					phototype IV
					0

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

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9.2. TABLE OF SKIN RESPONSE

Table 2

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
2	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
3	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
5	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
6	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
7	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
8	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
9	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
10	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
11	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
12	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
13	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
14	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
15	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
16	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
17	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
18	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
19	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
21	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
22	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
23	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
24	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
25	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	

Table 2. Results for volunteers with a negative 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 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
The sum of negative reaction (the sume of classification points)	**Erythema**	**Edema**	**Erythema**	**Edema**	**Erythema**	**Edema**	**Erythema**	**Edema**	**Erythema**	**Edema**
	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	Examination skipped	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 (xav)	Class
$\mathbf{X_{av}} < 0.50$	Not 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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12. CONCLUSION

The patch test study was performed under dermatological control on a group of 25 volunteers. The study allows to conclude that product Stay Safe, razkužilo za roke 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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13. SIGNATURES

Technician	**Paulina Maciszka**	
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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