REPORT OF ANALYSIS No. 119428/18/JSHR

Client		Sample description *(according to declaration of the Client)*
Daraveli Elisavet & Co. – Beautylab 22 Davaki str., Pefki, 151 21 Athens		**C 05MILK30PH SUNSCREEN MILK SPF 30**
Sample received:	19.03.2018	
Analysis completed:	17.05.2018	
Report dated:	21.05.2018	

IN VIVO DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) AND OF THE WATER RESISTANCE
FINAL REPORT
(COMPLEMENT OF PRELIMINARY ASSESSMENT NO. 119427/18/JSHR)

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SCOPE OF TEST COMPLIANT WITH:

- Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of 30 November 2009 on cosmetic products.
- EN ISO 24444:2010/PN-EN ISO 24444:2011 - Cosmetics – Sun Protection test methods – In vivo determination of the sun protection factor (SPF).
- Recommendation No. 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto.
- COLIPA guidelines (December, 2005) : „Guidelines for evaluating Sun products water resistance".

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CONTENT OF THE REPORT:

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1. THE BASIS OF THE STUDY

- Test samples delivered by the Client.
- The qualitative composition of the product delivered by the Client.
- The result of microbiology purity of the product delivered by the Client (Report of analysis no.: MBT 16125).
- Negative results of the dermatological test (occlusive patch test) of the product delivered by the Client (Report of analysis no.: 18 24 00200).
- Declared a sun protection factor: 30.

2. SUBJECT OF TEST

Parameter	Description
Appearance	Emulsion
Color	Creamy
Fragrance	Characteristic for used fragrance composition
Packaging	Repackaging covered with a label containing the name of the product

Picture 1: Sample no. 119428/18/JSHR - subject of study.

3. QUALITATIVE COMPOSITION OF THE PRODUCT

Aqua, Parfum, Aloe Barbadensis Leaf Juice Powder, Glycerin, Xanthan Gum, Magnesium Aluminum Silicate, Sodium Hydroxide, Disodium EDTA, Butyl Hydroxy Toluene, Benzyl Alcohol & Dehydroacetic Acid, Sodium Dehydroacetate, Ethylhexylglycerin, Glyceryl Stearate & PEG-100 Stearate, Octyl Palmitate, Cyclopentasiloxane, Dimethicone, Cetearyl Alcohol & Dicetyl Phosphate & Ceteth-10 Phosphate, C12-15 Alkyl Benzoate, Arachis Hypogaea Oil & Daucus

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Carota Sativa Extract & Isopropyl Myristate & Betacarotene & Tocopherol, Sorbitan Monostearate, Tocopheryl Acetate, Retinyl Palmitate, Panthenol, Allantoin, Octylmethoxy Cinnamate, Benzophenone-3, Octocrylene, Hydrolyzed Wheat Protein/PVP Crosspolymer, Butyl Methoxydibenzoylmethane, VP/Eicosene Copolymer, Titanium Dioxide (nano) & Isohexadecane & Triethylhexanoin & Aluminium Stearate & Polyhydroxystearic Acid & Alumina, Titanium Dioxide (nano) & Oleth-10 & Isodeceth-6 & Aluminium Stearate & Alumina & Dimethicone & Propylene Glycol & Diazolidinyl Urea.

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

4. PURPOSE OF THE TEST

Confirmation / exclusion declared by the Manufacturer the Sun Protection Factor level and water resistance.

5. SAMPLES AND TESTING CONDITIONS

Upon arrival, all products are registered on the HAMILTON LIMS System and kept at room temperature (unless otherwise requested). The test is performed in an air-conditioned room, with the room temperature maintained at 22 ± 4°C and the relative humidity 50 ± 10%.

6. INCLUSION CRITERIA

Healthy volunteers,
Subject having given her/his informed, written consent,
Subject that is willing to cooperate and aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could have been expected,
Age between 18 and 60,
Type: Caucasian,
Phototype: I to III,
Untanned skin on the test area.

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7. NON-INCLUSION CRITERIA

Children and persons below the age of consent or >60 years,
Pregnant or lactating women,
Persons using medication with photo-sensitizing potential,
Persons using anti-inflammatory medication,
Persons with dermatological conditions,
Persons with a history of abnormal response to the sun,
Persons accustomed to using tanning beds,
Persons having had sun exposure on the back area in the previous four weeks prior to SPF testing,
Persons having marks, blemishes or nevi or presenting existing sun damage in the test area,
Persons having excessive hair in the area of the test.

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8. TESTING EQUIPMENT

UV source:	Xenon lamp: Solar Light type Multiport 601
	Spectrum: 290 - 400 nm
	Power of the lamp: 300 W.
	Elimination of IR and visible radiation: UG11 (1mm) and dichroic mirror.
	Radiated surface: Six holes (diameter 8 mm).
UV Light Radiometer:	Solar Light Co. DCS 2.0.
Detector:	Solar Light Co. Erythema detector PMA2108.LLG.
Bath:	For water immersion test.

9. LABORATORY STAFF

The application of the product and visual skin assessment of the responses are made by technically qualified and trained persons.

10.DESCRIPTION OF METHODOLOGY

The matter is to compare the Sun Protection Factor of the product applied at 2 ± 0,05 mg/cm² obtained after 2 immersions of 20 minutes in a bath of water at 29 ± 2°C, to that obtained without immersion.

The Sun Protection Factor is the ratio of the Minimal Erythemal Dose obtained in presence of the product (MEDp) to the Minimal Erythemal Dose obtained without the product (MEDu).

$$SPF = MEDp/MEDu$$

The Minimal Erythemal Dose is defined as the quantity of energy necessary to produce the first perceptible unambiguous redness reaction with clearly defined borders, evaluated 16 to 24 hours after exposure to a solar simulator, with 6 increasing doses of UV (12% progression).

The study must be carried out on at least 10, and not more than 20 subjects and must satisfy the statistical criterion on the SPF (95% CI < 17% Average SPF) and on the water resistance (WR% - d ≥ 50%).

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11.SPF REFERENCE STANDARD

The method is controlled by the use of one of three reference sunscreen formulations to verify the test procedure (P2, P3, P7). At least one standard product must be used per test. The mean SPF and the acceptance limits for the used reference sunscreen formulations are:

Reference Sunscreen Formulation	Mean SPF	Range (±SD)	Acceptance limits (mean + 2SD)	
			Lower limit	Upper limit
P2	16,1	1,2	13,7	18,5

12.PRODUCT LABELING METHOD

The following range of sun protection factors for each category and the respective labeling is recommended (in accordance with 2006/647/CE):

Labelled category	Labelled sun protection factor	Measured sun protection factor
"Low protection"	"6"	6-9,9
	"10"	10-14,9
"Medium protection"	"15"	15-19,9
	"20"	20-24,9
	"25"	25-29,9
"High protection"	"30"	30-49,9
	"50"	50-59,9
"Very high protection"	"50+"	60≤

13.DATE OF PERFORMANCE OF THE STUDY

119427/18/JSHR: 11.04.2018-18.04.2018
119428/18/JSHR: 14.05.2018-17.05.2018

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14.TEST RESULTS

VOLUNTEERS				RESULTS							
No.	Age	Sex	Phototype	MEDu	MEDs	MEDp	MEDpi	SPFs	SPFi p	SPFi pi	% WR Retention
				mJ/cm^2							
1	36	W	III	36,00	612,00	1116,00	570,00	17,00	31,00	15,83	51,08
2	29	W	II	24,00	415,00	768,00	416,00	17,29	32,00	17,33	54,17
3	26	W	II	32,00	544,00	992,00	566,72	17,00	31,00	17,71	57,13
4	53	W	I	32,00	560,00	992,00	506,00	17,50	31,00	15,81	51,01
5	47	W	I	26,00	448,00	806,00	412,00	17,23	31,00	15,85	51,12
6	32	M	II	36,00	576,00	1080,00	617,12	16,00	30,00	17,14	57,14
7	31	W	III	32,00	576,00	992,00	567,84	18,00	31,00	17,75	57,24
8	47	W	III	38,00	680,00	1178,00	601,00	17,89	31,00	15,82	51,02
9	23	W	II	36,00	576,00	1080,00	621,60	16,00	30,00	17,27	57,56
10	58	W	II	38,00	627,00	1140,00	651,84	16,50	30,00	17,15	57,18
Average value								17,0	30,8	16,8	54,5
Standard deviation								0,7	0,6	0,8	3,08
cn								0,5	0,5	0,6	2,20
Cln(100%)								2,9	1,5	3,6	4,05

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MEDu: the Minimal Erythema Dose (MED) for unprotected skin.
MEDs: the Minimal Erythema Dose (MED) for protected skin by standard sunscreen.
MEDp: the Minimal Erythema Dose (MED) for protected skin by tested sunscreen without immersion.
MEDpi: the Minimal Erythema Dose (MED) for protected skin by tested sunscreen after immersion.

SPF s: MEDs/MEDu
SPFi p: MEDp/MEDu
SPFi pi: MEDpi/MEDu

15.CONCLUSION

Product « **C 05MILK30PH SUNSCREEN MILK SPF 30** »:

- has an average SPF of **30,8.**
- could support the claim «**Water resistant**» because the value [Mean %WRR] is greater than 50% of the SPF without immersion.
  - **a.** mean SPF value: **30,8.**
  - **b.** standard deviation: 0,6.
  - **c.** 95%CI confidence interval: from 30,00 to 32,00.
  - **d.** SPF value to be used in labelling (according to 2006/647/CE): **30. (high protection).**
  - **e.** mean SPF value after immersion: 16,8.
  - **f.** standard deviation: 0,8.
  - **g.** 95%CI confidence interval: from 15,81 to 17,75.
  - **h.** % WR Retention: 54,5.

16.SIGNATURES

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