

**REPORT OF ANALYSIS No. 119422/18/JSHR**

Client <b>Daraveli Elisavet &amp; Co. – Beautylab</b> <b>22 Davaki str., Pefki,</b> <b>151 21 Athens</b>		Sample description ( <i>according to declaration of the Client</i> )  <b>C 05OIL30PH, SUNSCREEN OIL SPF30</b>
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. 119421/18/JSHR)**

Authorised by: **Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)**  
**Karolina Osiecka, Dermatologist, 2487308**

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

The results relate to the analysed samples only.

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**REPORT OF ANALYSIS No. 119422/18/JSHR****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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## REPORT OF ANALYSIS No. 119422/18/JSHR

### 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 16289).
- Negative results of the dermatological test (semi-occlusive patch test) of the product made in J.S. Hamilton (Report of analysis no.: 119419/18/JSHR).
- Declared a sun protection factor: 30.

### 2. SUBJECT OF TEST

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



Picture 1: Sample no. 119422/18/JSHR - subject of study.

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**REPORT OF ANALYSIS No. 119422/18/JSHR****3. QUALITATIVE COMPOSITION OF THE PRODUCT**

Parfum, Helianthus Annuus Seed Oil & Alkanna Tinctoria Extract & Calendula Officinalis Extract & Elaeis Guinnensis Fruit Extract, Butyl Hydroxy Toluene, CI. 26100, Paraffinum Liquidum, Sorbitan Sesquioleate, Arachis Hypogaea Oil & Daucus Carota Sativa Extract & Isopropyl Myristate & Betacarotene & Tocopherol, Tocopheryl Acetate, Retinyl Palmitate, Octylmethoxy Cinnamate, Benzophenone-3, Butyl Methoxydibenzoylmethane, Octyl Palmitate, Octocrylene.

The Client is responsible for compliance with the declared qualitative composition of the product and microbiological purity of sent samples for testing.
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**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  $22 \pm 4^{\circ}\text{C}$  and the relative humidity  $50 \pm 10\%$ .

**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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**REPORT OF ANALYSIS No. 119422/18/JSHR****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  $2 \pm 0,05 \text{ mg/cm}^2$  obtained after 2 immersions of 20 minutes in a bath of water at  $29 \pm 2^\circ\text{C}$ , to that obtained without immersion.

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

$$\text{SPF} = \text{MEDp}/\text{MEDu}$$

The Minimal Erythema 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  $\geq$  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 ( $\pm$ SD)	Acceptance limits (mean + 2SD)	
			Lower limit	Upper limit
P3	15,7	1,0	13,7	17,7

### 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 $\leq$

### 13. DATE OF PERFORMANCE OF THE STUDY

119421/18/JSHR: 11.04.2018-18.04.2018

119422/18/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
1	36	W	III	32,00	480,00	1110,04	566,72	15,00	34,72	17,71	59,11
2	29	W	II	38,00	520,60	1276,80	651,81	13,70	33,60	17,15	57,24
3	26	W	II	28,00	420,00	840,00	429,00	15,00	30,00	15,32	51,00
4	53	W	I	39,00	534,30	1209,00	617,00	13,70	31,00	15,82	51,00
5	47	W	I	28,00	392,00	868,00	443,00	14,00	31,00	15,82	51,08
6	32	M	II	47,00	789,00	1457,00	744,00	16,79	31,00	15,83	51,05
7	31	W	III	24,00	329,00	744,00	380,00	13,71	31,00	15,83	54,93
8	47	W	III	26,00	416,00	873,60	445,76	16,00	33,60	17,14	51,05
9	23	W	II	36,00	576,00	1209,60	617,12	16,00	33,60	17,14	57,24
10	58	W	II	30,00	456,00	1041,60	532,00	15,20	34,72	17,73	57,18
Average value								14,9	32,4	16,6	51,0
Standard deviation								1,1	1,8	0,9	0,02
cn								0,8	1,3	0,6	0,02
Cln(100%)								5,4	3,9	3,9	0,03

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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 05OIL30PH, SUNSCREEN OIL SPF30** »:

- has an average SPF of **32,4**.
- could support the claim «**Water resistant**» because the value [Mean %WRR] is greater than 50% of the SPF without immersion.
  - a. mean SPF value: **32,4**
  - b. standard deviation: 1,8.
  - c. 95%CI confidence interval: from 30,00 to 34,72.
  - d. SPF value to be used in labelling (according to 2006/647/CE): **30. (high protection)**.
  - e. mean SPF value after immersion: 16,6.
  - f. standard deviation: 0,9.
  - g. 95%CI confidence interval: from 15,32 to 17,73.
  - h. % WR Retention: 51,0.

**16. SIGNATURES**

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