HELIOSCIENCE
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DETERMINATION *IN VIVO* OF THE SUN PROTECTION FACTOR (ISO 24444:2019) AND *IN VIVO WATER RESISTANCE* *(ISO 16217:2020 ISO 18861:2020)*

Report n°	HE00063-2301
Customer	[redacted]
Sample	P0949-2 Cream SPF30 perfum adult
Batch n°	N/A
Date	06/02/23

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1. STUDY SUMMARY

1.1. Title

DETERMINATION *IN VIVO* OF THE SUN PROTECTION FACTOR (ISO 24444:2019) AND *IN VIVO WATER RESISTANCE (ISO 16217:2020 ISO 18861:2020)*

1.2. Information Tested product

Information provided by the Customer

- Product name : **P0949-2 Cream SPF30 perfum adult**
- Batch : **N/A**
- Expected SPF: **30**
- Study number: HE00063-2301
- The tested cosmetic product conforms to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.
- The tested cosmetic product was evaluated for its safety of use on human volunteers.
- Qualitative INCI formula: Filed

1.3. Experimental conditions

1.3.1. Ambient conditions

All the study procedures were carried out in a temperate room (20-26°C).

1.3.2. UV Source

The source of UV radiation used was obtained from a Multiport 601-300W Solar simulator (Solar® Light Co. Inc.). The spectral quality complies with required acceptance limits.

1.3.3. Monitoring of the UV output

The dose of UV radiation applied was adjusted with a model PMA 2100 radiometer (Solar® Light Co. Inc.) equipped with a Erythema PMA 2103 detector (Solar® Light Co. Inc.).

1.3.4. Incremental progression of UV dose

The geometric progression factor applied was 1.15

1.3.5. Application area and amount of product applied

The site of application was situated in the intrascapular region of the back of the volunteers in an area of 50cm^2. The product-treated area was 0.50 cm^2. The quantity of the product applied is 2.00 mg/cm^2 ± 0.05 mg/cm^2. The quantity of the product to be applied was measured using an analytic balance (KERN AU 160-4NM, PBI INTERNATIONAL). The product was weighed inside on a syringe. A finger cot in latex was used for product spreading.

1.3.6. Immersion equipment

The spa-pool (Jacuzzi with water jets to circulate water and water temperature at 30 ± 2°C) should be furnished with a means of continuous water circulation which does not direct water onto the test areas and avoiding contact between any test site and any part of immersion equipment

1.3.7. Place of investigation

Products are tested by our partner laboratories and reports are realized by Helioscience, Cité de la Cosmétique, 2 , rue Odette Jasse 13015 Marseille

1.3.8. UV Standard

The method is controlled by the use of reference sunscreen formulation P2 to verify the test procedure. The mean SPF and the acceptance limits for the used reference sunscreen formulation are presented below.

Additional subjects may be added as necessary to achieve means for the reference standards that are within the acceptance range. The mean SPF and the acceptance limits for the used reference sunscreen formulations are:

Reference sunscreen formulation P2	Medium	Acceptance limits (Medium value ±2SD)	
		Lower limit	Upper limit
SPF	16,0	13,7	18,5

Reference sunscreen formulation P2 (Immersion time 40min)	Medium	Standard Deviation	Acceptance limits (Medium value ±2SD)	
			Lower limit	Upper limit
SPF	11,5	1,7	9,0	15,0
WR%	68,1	10,9	50,0	85,0

2. STUDY DESIGN: SPF AND WR DETERMINATION

2.1. Ethical requirements

All of the study procedures are carried out in compliance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments.

2.2. Test subjects

2.2.1. Selection of test subjects

The subjects participating to the test are selected by a trained scientist or technician (and by the dermatologist in case of new subjects) according to the inclusion and not inclusion criteria here reported.

2.2.1.1. Inclusion criteria

- Male and female healthy subjects
- Age: between 18 and 70 years
- Type: Caucasian
- Skin type: I, II and III (Fitzpatrick classification)
- WI Subjects who have not involved in any sun test since less than two months
- Subjects who have not sun exposure on the back area for at least two months prior to the study
- Absence of sunburn, suntan, scars, or active dermal lesions on the areas of the back selected for the test purposes 121 Test area must be uniform in colour, without nevi, blemishes or solar lentigo and without hairs
- Subjects aware of the test procedure and having signed an informed consent form.

2.2.1.2. Not inclusion criteria

- Subjects who do not fit the inclusion criteria
- Pregnant or breastfeeding women
- Past history of allergy, photoallergic, phototoxic, or other abnormal responses to sun exposure
- Past history of allergies or sensitivity to cosmetic products, toiletries, sunscreens and/or topical drugs
- Known allergy to latex
- Subjects with dermatological problems on the test area
- Subjects having used self tanning products on the back in the previous month after the date of the study
- Subjects accustomed to using tanning beds
- Subjects taking medication with photosensitizing potential, drugs and/or dietary supplements able to induce skin colouring, corticoids, currently or during the month before the study
- Subjects taking anti-histaminic or anti-inflammatory drugs, currently or within the week before the study

2.3. Study area

The back is the chosen anatomical region for the study. The individual sites is delineated within the region between the scapula line and the waist. Skeletal protrusions and extreme areas of curvature are avoided.

2.3.1. Product application site

The area for a product application site is 0.50 cm^2. The product application site is delineated with a skin marker using a template made from non-absorbent material.

2.4. Product application

2.4.1. Amount of product applied

The amount of test product and reference sunscreen formulation applied to the skin before spreading is 2.00 mg/cm^2 ± 0.05 mg/cm^2. The sensitivity of the used balance is 0.0001 g. Care is taken to prevent evaporative loss of volatile components when the product is being weighed and before application to the skin. It is important that the total quantity of weighed product is transferred to the product application site. A method of weighing by loss is used.

2.4.2. Drying time

Exposure of the test site to the sequence of UV doses shall start 15 to 30 minutes after the application of the product. Any extraneous exposure of the test sites to UV light (artificial or natural) should be avoided during this period and for a period of 24 hours before the exposures as well as 24 hours after exposure.

2.4.3. Water immersion conditions

Test product is applied to the test area (back) designated for sweat induction according to the current International Standard ISO 24444:2019'Cosmetics- Sun protection test methods - In vivo determination of the sun protection factor (SPF), 15 to 30 minutes drying time must elapse after application of the test product to the skin and before immersion in water.

The volunteer is then immersed in the immersion equipment for 20 minutes ensuring complete immersion of the test sites under the water and avoiding contact between any test site and any part of the immersion equipment The Volunteer exits the immersion and the area tested is allowed to air dry for 15 minutes. The volunteer is then immersed in the immersion equipment for 20 minutes ensuring complete immersion of the test sites under the water and avoiding contact between any test site and any part of the immersion equipment. The Volunteer exits the immersion and the area tested is allowed to air-dry for 15 minutes.

After the skin is completely dry, the SPF of the product applied to the test sites and immersed in water is then determined according to the ISO 24444:2019

2.5. Ambient condition

Product application, UV exposures and MED assessment are carried out in stable ambient conditions, with the room temperature maintained between 20 and 26°C.

2.6. Exposure to UV radiation

2.6.1 Source and quality of UV radiation

The source of UV radiation is a Xenon arc solar simulator. The UV solar simulator emits a continuous spectrum with no gaps or extreme peaks of emission in the UV region. The output from the UV solar simulator is stable, uniform across the whole output beam and suitably filtered to create a spectral quality that complies with the required acceptance limits of the method. Furthermore, the radiometric proportion of the UVAII (320-340 nm) irradiance is equal or exceed 20% of the total UV irradiance while the radiometric proportion of the UVAI (340-400) region is equal or exceed 60% of the total UV irradiance.

2.7. Product removal

After UV exposure, the tested product and the reference sunscreen formulation may be removed gently using a cotton pad with a mild lotion (make up remover for example).

2.8. MED assessment

The MED is assessed visually 20 ± 4 hours after UV exposure. Visual assessment should be performed in sufficient and uniform illumination (al least 450 lux are recommended). The observer's eyesight should have been checked for normal colour vision. A yearly check of acuity vision is recommended. It is recommended that erythemal responses should be observed in a "blind manner": the observer of erythemal responses on any subjects should not be the same persons as performed product application and UV exposure, nor should be aware of the study design (randomisation of sites and UV doses) on that subject.

2.9. Calculation of the sun protection factor and statistics

2.9.1. Calculation of the sun protection factor

The sun protection factor of each product on each subjects (individual SPF, SPFI) is calculate as:

$$SPF = MEDpl/MEDul$$

The sun protection factor of the tested product is then calculated as the arithmetical mean of all the valid results, expressed to one decimal point:

2.9.2. 95% confidence interval

The 95% confidence interval (95%C1) for the mean SPF is expressed as:

$$95\%CI = SPF \pm c$$

Where c is calculated as:

$$c = t * s/\sqrt{n}$$

The percentange 95% confidence interval is then:

$$CI[\%] = 100 * C/SPF$$

Where:
s = the standard error of the mean
n = total number of valid results
t = is the value from the "two-sided" student-t distribution table and with degrees of freedom v = (n-1)

2.9.3. Calculation of the individual percentage water resistance retention

The individual percentage water resistance retention value shall be for each subjects according to the formula below :

$$\%WR = ((SPFw - 1)/(SPFi - 1)) * 100$$

where :

SPFw = individual wet SPF after water immersion

SPFI = individual static SPF

2.9.4. 90% unilateral confidence interval

The 90% unilateral confidence interval for the mean %WR is :

$$90\%CI = (\%WR - d)$$

Where d is :

$$d = (t * s/\sqrt{n})$$

Where:
s = the standard error of the mean
n = total number of valid results
tu= is the value from the "one-sided" Student-t distribution table at a probability level p=0,10 and with degrees of freedom v = (n-1)

3. CONCLUSION AND RESULTS

Based on the results obtained in the experimental conditions elsewhere described in this report it is possible to maintain that the product **P0949-2 Cream SPF30 perfum adult,** batch n° **N/A** submitted to the evaluation of the sun protection factor (SPF) according to the ISO 24444:2019 Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF), has the following SPF:

31,9± 2,4

(mean ± c)

On the basis on the results obtained in the experimental conditions elsewhere described in this report it is possible to maintain that the product submitted to the evaluation of the resistance water retention according to *in vivo water resistance standard (ISO 16217:2020 ISO 18861:2020)* (is than higher than 50%):

50,5% > 50%

(Mean %WR-d)

Therefore according to the COLIPA guidelines (Guidelines for evaluating sun product water resistance, COLIPA, December 2005, the sample **P0949-2 Cream SPF30 perfum adult,** batch n° **N/A** can be classified has :

Labeled category : **HIGH PROTECTION SPF 30**

Claim ; **Water resistant**

Validation of the test : **COMPLIANT**

Reference sunscreen formulation	Medium SPF	Acceptance limits (Medium value ±2SD)		SPF RESULT	%WR-d	COMPLIANCE
		Lower limit	Upper limit			
P2	16,0	13,7	18,5	17,3±1,6	76,0	COMPLIANT

Marseille, 06/02/23

Jean Claude HUBAUD
President

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SPF TEST RESULT TABLE

Product code	P0949-2 Cream SPF30 perfum adult							Batch	N/A
Study number	HE00063-2301							Expected SPF	30
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)								
Subj. No	**SUBJECTS SPF**							**RESULTS**	
	Exposure date	Subj. code	ITA°	MEDu		MEDp		SPFi	
				Sec	(J/m²)	Sec	(J/m²)		
1	28/12/2022	ANCA58	56,7	30	282	897	8465	30,0	
2	28/12/2022	ELTO58	36,9	49	461	1467	13838	30,0	
3	29/12/2022	LUBO60	40,2	45	427	1357	12805	30,0	
4	29/12/2022	MAFI50	38,4	47	445	1415	13351	30,0	
5	30/12/2022	MIMO57	50,1	35	291	1065	10046	34,5	
6	30/01/2023	MIDI41	58,1	29	271	863	8143	30,0	
7	30/01/2023	CLMA56	57,7	29	208	873	8239	39,7	
8	31/01/2023	ANBE50	55,2	31	255	933	8799	34,5	
9	01/02/2023	SEBA40	46,0	39	323	1181	9685	30,0	
10	01/02/2023	FEME48	45,4	40	376	1197	11293	30,0	

Mean SPF	31,9
s	3,3
c	2,4
CI (%)	7,5
CI (%) ≤ 17%	Complies
n (n° subjects)	10

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WR TEST RESULT TABLE

Product code	P0949-2 Cream SPF30 perfum adult	Batch	N/A
Study number	HE00063-2301	Expected SPF	30
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)		

Subj. No	SUBJECTS WR							RESULTS	
	Subj. code	MEDu Wet		MEDp Wet		SPFi Wet	%WRRi		
		Sec	(J/m²)	Sec	(J/m²)				
1	ANCA58	30	213	449	3680	17,3	56,0		
2	ELTO58	49	349	733	6017	17,3	56,0		
3	LUBO60	45	427	679	6403	15,0	48,3		
4	MAFI50	47	387	708	5805	15,0	48,3		
5	MIMO57	35	291	532	5023	17,3	48,5		
6	MIDI41	29	236	432	4071	17,3	56,0		
7	CLMA56	29	208	437	4119	19,8	48,7		
8	ANBE50	31	222	466	4400	19,8	56,2		
9	SEBA40	39	281	590	4211	15,0	48,3		
10	FEME48	40	285	599	4910	17,3	56,0		

Mean %WR	52,2
s	4,0
90% CI	1,7
%WR-D	50,5
n (n° subjects)	10

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SPF STANDARD TEST RESULT TABLE

Product code	REFERENCE SUNSCREEN FORMULATION P2 (High SPF reference formula)								Batch	N/A
Study number	HE00063-2301								Expected SPF	16
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)									
Subj. No	SUBJECTS SPF								RESULTS	
	Exposure date	Subj. code	ITA°	MEDu		MEDp		SPFi		
				Sec	(J/m²)	Sec	(J/m²)			
1	03/11/2022	SANBO40	35,5	50	313,2	808	6627,9	21,2		
2	03/11/2022	LALU52	31,7	50	340,6	796	7208,0	21,2		
3	08/11/2022	ALMA35	60,7	27	220,4	430	3526,2	16,0		
4	08/11/2022	SAMA28	53,9	32	264,0	515	4224,8	16,0		
5	10/11/2022	MAFE50	56,9	27	244,2	432	3907,0	16,0		
6	10/11/2022	FRGO65	42,0	39	355,9	629	5693,9	16,0		
7	06/12/2022	GICO52	32,3	54	386,2	866	7105,3	18,4		
8	06/12/2022	MARO48	48,1	34	306,4	542	4902,7	16,0		
9	12/12/2022	MIVE52	54,0	29	263,6	466	4217,9	16,0		
10	12/12/2022	MILE46	30,8	56	459,1	896	7346,4	16,0		

Mean SPF	17,3
s	2,2
c	1,6
CI (%)	9,0
CI (%) ≤ 17%	Complies
n (n° subjects)	10

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WR TEST RESULT TABLE

Product code	REFERENCE SUNSCREEN FORMULATION P2 (High SPF reference formula)							Batch	N/A
Study number	HE00063-2301							Expected SPF	16
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)								
Subj. No	SUBJECTS VWR							RESULTS	
	Subj. code	MEDu Wet		MEDp Wet		SPFi Wet	%WRRi		
		Sec	(J/m²)	Sec	(J/m²)				
1	SANBO40	50	313,2	808	5011,6	16,0	74,4		
2	LALU52	50	289,5	796	4632,8	16,0	74,4		
3	ALMA35	27	166,6	430	2266,4	13,6	84,0		
4	SAMA28	32	199,7	515	2715,4	13,6	84,0		
5	MAFE50	27	212,3	432	2511,1	11,8	72,2		
6	FRGO65	39	309,5	629	3659,6	11,8	72,2		
7	GICO52	54	335,8	866	4566,7	13,6	72,4		
8	MARO48	34	231,7	542	3151,1	13,6	84,0		
9	MIVE52	29	199,3	466	2710,9	13,6	84,0		
10	MILE46	56	347,2	896	4721,7	13,6	84,0		
								Mean %WR	78,6
								s	5,8
								90% CI	2,5
								%WR-D	76,0
								n (n° subjects)	10

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16. UNI EN ISO 16217- 2020- Cosmetics- Sun protection tests methods – Water resistance – Water immersion procedure for determining water resistance

5. INCI List

Composition (please report all active ingredients in the formulation)