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DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) ACCORDING TO ISO 24444:2019 STANDARD

Report n°	HE00201-2201
Sample	DAS BOEP SONNENCREME FAMILIE SPF 30
Date	20/01/22

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Tables of contents

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1. STUDY SUMMARY

1.1. Title

DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) ACCORDING TO ISO 24444:2019 STANDARD — Sun protection test methods — *In vivo* determination of the sun protection factor (SPF).

1.2. Information Tested product

Information provided by the Customer

- Product name : **DAS BOEP SONNENCREME FAMILIE SPF 30**
- Batch n° : **N/A**
- Code : HE00201-2201
- Expected SPF: **30**
- 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: Annex A

1.3. Experimental conditions

1.3.1. Ambient conditions

All the study procedures were carried out in a temperate room (19-22°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.).

1.3.3.1. Incremental progression of UV dose

The geometric progression factor applied was 1.25

1.3.4. Application area and amount of product applied

The product-treated area was 0.50 cm^2. The quantity of the product applied is 100 mg (2 mg x 50 cm^{-2}= 100 mg/cm^2). The quantity of the product to be applied was measured using an analytic balance (KERN AU 160-4NM, PBI INTERNATIONALI. The product was weighed inside on a syringe. A finger cot in latex was used for product spreading.

1.3.5. 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

1.3.6. UV Standard

The method is controlled by the use of one of five reference sunscreen formulations to verify the test procedure (P2, P3, P5, P6 or P8). Only one SPF reference standard sunscreen shall be required on each subject (if reference standard P5, P6 and P8 are used on subject an inferior standard P2 or P3 are not required) . The choice of the standard to be used takes place in the following ways:

- SPF Claim ≤24: P2 or P3 reference standard (all subjects);
- SPF ≥25 but less than SPF 50: P5 or P6 reference standard (on at least 5 subjects) and P2 or P3 on remaining subjects;
- SPF ≥50: P8 reference standard (on at least 5 subjects) and P2 or P3 on the remaining subjects.

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	Medium SPF	Acceptance limits (Medium value ±2SD)	
		Lower limit	Upper limit
P2	16,0	13,7	18,5
P3	15,7	13,7	17,7
P5	30,6	23,7	37,4
P6	43,0	31,0	54,9
P8	63,1	43,9	82,3

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2. STUDY DESIGN: SPF 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 $mg \bullet cm^{-2}$ ± 2.5% (0.05 mg). 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.

2.5. Ambient condition

Product application, UV exposures and MED assessment are carried out in stable ambient conditions, with the room temperature maintained between 19°C and 22°C.

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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.

2.6.2 Incremental progression of UV dose

For the unprotected site, the quantity of the total UV dose range is established using the subject's provisional MEDu or estimated MEDu. 6 sub-sites centred on the provisional/estimated MEDu shall be exposed with incremental UV doses using a recommended geometric progression of 1.25. Other geometric progression of less than 1.25 may be used but should be consistent throughout the test.

For the product-protected site, the UV doses delivered are defined by the expected MEDp which is the multiple of the expected SPF of the test product and the provisional MEDu for the subject. 6 sub-sites centred on the provisional/estimated MEDu shall be exposed with incremental UV doses using a recommended geometric progression of 1.25. Other geometric progression may be used (e.g. 1.2, 1.15, 1.12). A maximum geometric progression of 1.15 shall be used for expected SPF >25. Smaller geometric progression (e.g. 1.12) may be used but should be consistent throughout the test.

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:

$$SPF = MEDpi/MEDui$$

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:
SEM =the standard error of the mean
n = total number of valid results
t = is the value from the "two-sided" student-t distribution table at a probability level p=0,05 and with degrees of freedom v = (n-1)

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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 **DAS BOEP SONNENCREME FAMILIE SPF 30,** 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:

30,2± 1,8

(mean ± c)

Therefore according to the 'EC Recommandation 22/09/2006n 2006/647/CE on the efficacy of sunscreen products and the claims made for them', the sample **DAS BOEP SONNENCREME FAMILIE SPF 30,** batch n° **N/A** can be classified has **:**

Labeled category : **HIGH PROTECTION SPF 30**

Validation of the test : **COMPLIANT**

Reference sunscreen formulation	Medium SPF	Acceptance limits (Medium value ±2SD)		RESULT	COMPLIANCE
		Lower limit	Upper limit		
P8	63,1	43,9	82,3	57,6±3,6	COMPLIANT

Marseille, 20/01/22

Jean Claude HUBAUD
President

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SPF TEST RESULT TABLE

Product code	DAS BOEP SONNENCREME FAMILIE SPF 30							Batch	N/A
Study number	HE00201-2201							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°	sec	MEDu (J/m2)	sec	MEDp (J/m2)	SPFi	
1	09/12/2021	ALAG45	52,2	34	317,2	1013	9514,7	30,0	
2	15/12/2021	PATA52	58,1	29	236,2	868	7086,6	30,0	
3	15/12/2021	MIDI50	55,7	31	252,1	926	8697,5	34,5	
4	15/12/2021	FRMA22	22,9	66	471,5	1992	14144,9	30,0	
5	16/12/2021	FARO60	54,3	32	300,3	959	9009,6	30,0	
6	16/12/2021	ANCO55	49,2	36	298,0	1095	7773,4	26,1	
7	17/01/2022	ROBI60	48,9	37	345,2	1103	10355,4	30,0	
8	17/01/2022	SIGI40	59,8	28	259,7	829	5890,2	22,7	
9	17/01/2022	GICA50	51,6	34	280,5	1030	9676,8	34,5	
10	17/01/2022	DECU33	38,7	47	334,4	1413	11537,6	34,5	

Mean SPF	30,1
s	3,8
c	1,8
CI (%)	5,9
CI (%) s 17%	Complies
n (n° subjects)	10

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SPF TEST RESULT TABLE									
Product code	REFERENCE SUNSCREEN FORMULATION P8 (High SPF reference formula)						Batch	/	
Study number	HE00201-2201						Expected SPF	63	
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)								
Subj. No	**SUBJECTS SPF**							**RESULTS**	
	Exposure Date	Subj. code	ITA°	sec	MEDu (J/m2)	sec	MEDp (J/m2)	SPFi	
1	09/12/2021	ALAG45	52,2	34	317,2	2127	15108,4	47,6	
2	15/12/2021	PATA52	58,1	29	236,2	1822	12940,7	54,8	
3	15/12/2021	MIDI50	55,7	31	252,1	1945	15882,4	63,0	
4	15/12/2021	FRMA22	22,9	66	471,5	4183	29704,4	63,0	
5	16/12/2021	FARO60	54,3	32	300,3	2014	14306,4	47,6	
6	16/12/2021	ANCO55	49,2	36	298,0	2299	18772,7	63,0	
7	17/01/2022	ROBI60	48,9	37	345,2	2315	18909,9	54,8	
8	17/01/2022	SIGI40	59,8	28	259,7	1742	14224,9	54,8	
9	17/01/2022	GICA50	51,6	34	280,5	2164	15365,9	54,8	
10	17/01/2022	DECU33	38,7	47	334,4	2967	24229,0	72,5	

Mean SPF	57,6
s	7,7
c	3,6
CI (%)	6,29
CI (%) ≤ 17%	Complies
n (n° subjects)	10

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6. Department of health and human services, FDA, USA: Sunscreen drug products tor over-the counter human use; Final monograph, Federai Register. 64/98, 27686-27693, May, 21,1999
7. lnternational sun prote ction factor (SPF) test method CFFA SA, Colipa, JCIA, CTFA, 2006,(a CDROM showing products application procedure is included in the guidelines)
8. ISO/TR 26369 Cosmetics - Sun prote ction test methods - Review and evaluation of methods to assess the photoprotection of sun protection products ICH Guidelines tor Good Clinical Practice
9. Guidelines for monitoring UV radiation sources Colipa, March 2007

10. Declaration of Helsinki - ethical principles for medic al research involving human subjects adopted by the 18th wma general assembly, Helsinki, Finland, June 196 4, and consecutive amendments
(last amendment: 59th WMA general assembly, Seoul, October 2008)
11. UNI EN ISO 24444:2011- Cosmetics - Sun Protection test methods - In vivo determination of the sun protection Factor (SPF)
12. UNI EN ISO 24444:2019- Cosmetics - Sun Protection test methods - In vivo determination of the sun protection Factor (SPF)
13. UNI EN ISO 24442:2011- Cosmetics- Sun protection test methods- In vivo determination of sunscreen UVA protection

14. Colipa Guidelines for Evaluating Sun Product Water Resistance, December 2005

15. Commission recommendation of 22 September 2006 n. 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto

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Annex A : INCI Formula

(Das boep Sonnencreme Familie SPF 30)

aqua, zinc oxide, caprylic/capric triglyceride, dicaprylyl ether, glyceryl stearate, glycerin, cetearyl alcohol, brassica campestris/aleurites fordi oil copolymer, polyhydroxystearic acid, sorbitan caprylate, silybum marianum ethyl ester, cocos nucifera oil*, tocopherol, pongamia pinnata seed extract, sodium stearoyl lactylate, sodium polyphosphate, xanthan gum, parfum, benzyl alcohol, limonene

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