

DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) ACCORDING TO ISO 24444:2010 STANDARD

(Cosmetics — Sun protection test methods — *In vivo* determination of
the sun protection factor (SPF))

Report n°	HE0026-19-01
Sample	Boep Sonnenbasalm SPF 30 Charge: P803695
Date	25/01/2019

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1. STUDY SUMMARY

1.1. Title

DETERMINATION OF THE SUN PROTECTION FACTOR (SPF) ACCORDING TO ISO 24444:2010 STANDARD — Sun protection test methods — *In vivo* determination of the sun protection factor (SPF).

'Cosmetics - Sun protection test methods - *In vivo* determination of the sun protection factor (SPF)

1.2. Tested product

Information provided by the Customer

- Product name: **Boep Sonnenbasalm SPF 30**
- 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: Filed

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.).

1.3.4. Incremental progression of UV dose

The geometric progression factor applied was 1.25

1.3.5. Application area and amount of product applied

The product-treated area was 50 cm². The quantity of the product applied is 100 mg (2 mg x 50 cm²= 100 mg/cm²). 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.

1.3.6. 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

1.3.7. UV Standard

As reference UV standard, standard P2 COLIPA was used as described by the method

Reference	Mean SPF	Lower/ Upper limit
P2	16.2	13.7 / 18.5

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 (see figure 1a). Skeletal protrusions and extreme areas of curvature are avoided.

2.3.1. Product application site

The area for a product application site is 50 cm². 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 ± 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 and 22°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 (at 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 erythral responses should be observed in a "blind manner": the observer of erythral 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:

$$SPF = MED_{pi} / MED_{ui}$$

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%CI) for the mean SPF is expressed as:

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

Where c is calculated as:

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

The percentage 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 and with degrees of freedom $v = (n-1)$

CONCLUSION

Based on the results obtained in the experimental conditions elsewhere described in this report it is possible to maintain that the product **Boep Sonnenbasalm SPF 30** submitted to the evaluation of the sun protection factor (SPF) according to the ISO 24444:2010 Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF), has the following SPF:

$$31,3 \pm 0,90$$

(mean \pm c)

Marseille, 25 January 2019

SPF TEST RESULT TABLE

Product code	Boep Sonnenbasalm SPF 30						Batch	P803695	
Study number	HE0026-19-01						Expected SPF	30	
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)								
Subj. No	SUBJECTS				SUBJECTS SPF			RESULTS	
	Subj. code	Gender	ITA°	Phototype	MEDu (mJ/cm2)	MEDp (mJ/cm2)	SPFi		
1	ALOJ0891	M	58	I	21,0	645	30,7		
2	LYTA0120	F	49	II	33,2	968	29,2		
3	DAM00686	M	29	III	60,0	1842,0	30,7		
4	MOLE1035	M	56	I	29,6	974	32,9		
5	JUPA0968	F	35	III	42,3	1345	31,8		
6	ITSA0884	F	42	II	43,1	1402	32,5		
7	PEAL0897	F	46	II	27,9	864	31,0		
8	JHRO0927	M	44	II	35,6	1053	29,6		
9	PASA1055	M	43	II	29,7	964	32,5		
10	ROJO0585	M	56	I	35,3	1123	31,8		
								Mean SPF	31,3
								s	1,26
								c	0,90
								CI (%)	2,88
								CI (%) s 17%	Complies
								n (n° subjects)	10

SPF TEST RESULT TABLE

Product code	REFERENCE SUNSCREEN FORMULATION P2 (High SPF reference formula)						Batch	/	
Study number	HE0026-19-01						Expected SPF	16	
UV Source	Solar Light MuMoon solar simulator model 601 - 300W (Solar Llgth Co. Inc)								
Subj. No	SUBJECTS				SUBJECTS SPF			RESULTS	
	Subj. code	Gender	ITA°	Phototype	MEDu (mJ/cm2)	MEDp (mJ/cm2)	SPFi		
1	ALOJ0891	M	58	I	21,0	354	16,9		
2	LYTA0120	F	49	II	33,2	390,5	11,8		
3	DAM00686	M	29	III	60,0	823,5	13,7		
4	MOLE1035	M	56	I	29,6	547,0	18,5		
5	JUPA0968	F	35	III	42,3	633,2	15,0		
6	ITSA0884	F	42	II	43,1	532,6	12,4		
7	PEAL0897	F	46	II	27,9	454,0	16,3		
8	JHRO0927	M	44	II	35,6	584,1	16,4		
9	PASA1055	M	43	II	29,7	502,4	16,9		
10	ROJO0585	M	56	I	35,3	514,7	14,6		
								Mean SPF	15,2
								s	2,15
								c	1,53
								CI (%)	6,24
								CI (%) s 17%	Complies
								n (n° subjects)	10