Farcoderm
TESTED WELLNESS

tested by Farcoderm

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)

INOXDERM 2012 S.L.

ONCOSMETICS CREMA DE DÍA
Crema multiacción con protección solar alta SPF 50 y un suave toque de color

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COMPLIFE GROUP

Fully paid-up share capital € 100.000 - Tax Code and VAT No. IT 03893350961
Certified Quality Management System UNI EN ISO 9001:2008 13659

UNI EN ISO 9001:2008 CERTIQUALITY SISTEMA DI GESTIONE QUALITÀ CERTIFICATO
CERTIQUALITY È MEMBRO DELLA FEDERAZIONE CISQ IQNet

KEY PERSONNEL

Customer

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Study Director

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Degree in Medicine and Surgery, Specialist in Dermatology and Venereology
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SECTION 1 - STUDY SUMMARY

1.1. Title

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).

1.2. Tested product

1.2.1. Information provided by the Customer

☒ Product name: **ONCOSMETICS CREMA DE DÍA. Crema multiacción con protección solar alta SPF 50 y un suave toque de color.**

☒ Expected SPF: **50**

The tested cosmetic products do not contain any substance which is forbidden by EEC regulations regarding the use of cosmetic and personal hygiene products; the preservatives contained in their formula are in the list of accepted ingredients published by EEC and are used in a concentration provided for by the law. The use of all substances that are subject to concentration limits conforms to the limits and instructions published in the respective appendices of EEC regulation 76/768.

☒ Tested cosmetic products were evaluated for their 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 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 PMA2100 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 product-treated area was 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 ALJ 160-4NM, PBI INTERNATIONAL). The product was weighed inside on a syringe. A finger cot in latex was used for product spreading.

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SECTION 2 - STUDY DESIGN

2.1. Title

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).

2.2. Aim

The study is aimed to evaluate the protective effectiveness of a sunscreen product towards the damage caused by UVB radiation.

2.3. Study design

The study is carried out according to the single-blinded protocol with randomisation of the application sites. The randomisation scheme of the application sites of the product and of the standard product is filed by the study director.

2.4. Ethical requirements

The study is carried out in accordante with the following ethical requirements

2.4.1. All the subjects participating in the study are healthy volunteers of at least 18 years old.
2.4.2. All of the subjects participating in the study are selected with the supervision of a dermatologist according to inclusion/not inclusion criteria.
2.4.3. All of the subjects participating in the study are informed of the aim and the design of the study.
2.4.4. All of the subjects participating in the study are informed of the possible risk involved in the study execution.
2.4.5. All of the subjects participating in the study give their informed consent signed at the beginning of the study.
2.4.6. Before volunteer exposure to the tested product, all relevant safety information about the product itself and each ingredient were collected and evaluated.
2.4.7. 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.
2.4.8. All of the precautions are taken in consideration in order to avoid excessive skin reactions.
2.4.9. If any unexpected/adverse skin reaction occurs, medical investigating specialist evaluates the severity of the reaction (reporting it in the volunteer's data collecting sheet) and proceeds with appropriate therapy.
2.4.10. To protect the subjects, exposure to UV rays is started with a lower SPF value and then increased progressively.

2.5. Test subjects

2.5.1. 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.

2.5.1.1. Inclusion criteria

- ☑ Male and female healthy subjects
- ☑ Age: between 18 and 70 years
- ☑ Type: Caucasian
- ☑ Skin type: I, II and III (Fitzpatrick classification)
- ☑ 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
- ☑ 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

2.5.1.2. 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

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2.5.2. Frequency of participation in the study

Since a sufficient interval after a previous test is needed in order to allow for reversal of skin tanning resulting from that previous test, a test site that has been exposed to UV is not used in a subsequent test until not less than two months have elapsed and the site is clear.

2.5.3. Number of subjects

A minimum of ten and a maximum of twenty valid results shall be recorded, as follows:

- ☐ a minimum of 10 valid results is only sufficient if the 95% confidence interval of the mean SPF is within ± 17% of the mean SPF;
- ☐ if the above statistical criterion is not met with the valid results from 10 subjects, the number of subjects is increased stepwise from 10 until the statistical criterion is met, up to a maximum of 25 subjects and a maximum of 20 valid results.

2.6. Study area

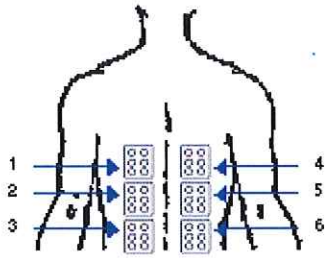
The back is the chosen anatomical region for the study. The individual sites is delineated within the region between the scapula line and the waist (see figure 1a). Skeletal protrusions and extreme areas of curvature are avoided.

2.6.1. Product application site

The area for a product application site is 50 cm^2. The product application site is delineated with a skin marker using a template made from non-absorbent material.

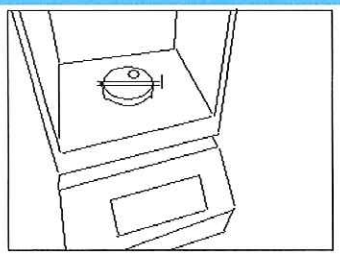
Figure 1

a)



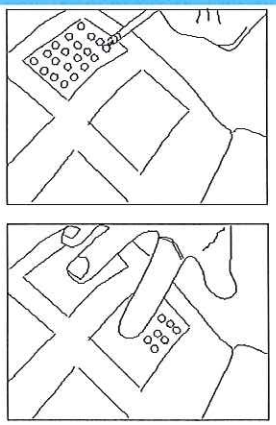
Anatomic site: Back
Area: 50 cm^2
Distance between each site: at least 1 cm

b)



1. firstly, weigh the finger cot and the dispenser used for the delivery of the product to be tested to the application site and zero the balance;
2. weigh the right quantity of product to be tested and take note of the weight;
3. after product application, weigh the dispenser used for the delivery of the product and the finger cot (if used).

c)



30 droplets of product are applied in the application site.

firstly, spread the product with circular movements;
then, with up to down movements;
and finally, with left to rigth movements.

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2.7. Products application

2.7.1. 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 (see figure 1b) is used.

2.7.2. Mode of delivery: lotions, liquids, milks, creams and sprays

To aid uniform coverage, droplets (approximately 30) of the product are deposited with a syringe/pipette (see figure 1c), then spread over the whole test site with light pressure (see figure 1c), using a finger cot. Spreading time is in the range of 20 to 50 seconds depending on the surface and ease of spreading of the product. Liquid type products consisting of two layers must be shaken strongly before weighing in order to ensure a homogenous dispersion.

2.7.3. Mode of delivery: Powders

In the case of powder products, aliquots of powder are transferred to the skin in a grid-like manner, using a spatula or finger. The accumulated powder is tapped and then spread over the whole test site using a finger with or without a finger cot. Alternatively, the tip of a pre-loaded cosmetic applicator puff may be used instead of a finger. In this case, it is important to verify that 2 mg/cm^2 of test powder product remains on the skin after spreading, by weighing the powder remaining on the tip of the applicator puff. Purified water or another suitable solvent that has no UV protection properties may be applied before the powder application to help the sample adhere to the application site. Subjects should be in the prone position to prevent the samples from falling off the surface.

2.7.4. 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.

2.8. SPF reference sunscreen formulations

A reference sunscreen formulation is to be used as a methodological control to verify the test procedure.
The reference sunscreen formulation is selected based on the expected SPF value of the product to be tested as follows:

- Expected SPF below SPF 20 - any of the following reference sunscreen formulation shall be used: P2, P3 o P7.
- Expected SPF equal to or greater SPF 20 - any of the following reference sunscreen formulation shall be used: P2 or P3.

If a high SPF reference sunscreen formulation is used there is no necessity to also include the low SPF reference formulation in the test even though there may be low SPF test products. In the following paragraphs are described the reference sunscreen formulation that shall be used in a SPF test.

2.8.1. P2 Reference sunscreen formulation

The P2 reference sunscreen formulation (proposed by CTFA) is a fluid emulsion containing 7.0% Ethylhexyl Dymethyl PABA and 3.0% Benzophenone-3. The mean SPF value is 16.1 with a lower limit (-2SE) of 13.7 and an upper limit of 18.5 (+2SE).

2.8.2. P3 Reference sunscreen formulation

The P3 reference sunscreen formulation (proposed by COLIPA, reference formula C202/101) is an emulsion containing 2.78% Phenylbenzimidazole Sulfonic acid, 3.0% EthylHexyl Methoxycinnamateand and 0.5% Butyl Methoxydibenzoylmethane. The mean SPF value is 15.7 with a lower limit (-2SE) of 13.7 and an upper limit of 17.7 (+2SE).

2.8.3. P7 Reference sunscreen formulation

The P7 reference sunscreen formulation (reference sunscreen formulation of FDA method) is a lotion containing 8.0% Homosalate. The mean SPF value is 4.4 with a lower limit (-2SE) of 4.0 and an upper limit of 4.8 (+2SE).

2.9. 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.

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2.10. Exposure to UV radiation

2.10.1 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.

2.10.2. Incremental progression of UV dose

The incremental UV dose is centred on the provisional MEDu (determined up to 1 week before the study) with a geometric progression of 1.25 or 1.15 based on the expected SPF value, as follow:

- Expected SPF below SPF 25 - use a recommended geometric progression of 1.25;
- Expected SPF greater to SPF 25 - use a maximum recommended geometric progression of 1.15 (or lower).

2.11. 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).

2.12. 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.

2.13. Data rejection criteria

Test data shall be rejected when 20 ± 4 hours after UV exposure:

- the exposure series on a subjects fails to elicit an erythema response on any sub-site;
- the erythema responses within an exposure series are randomly absent;
- all sub-sites in the exposure series show an erythemal response.

When one or more of the above criteria:

- applies to the exposure on unprotected skin or to the sunscreen reference formulation exposure sites, then all the data for all tested products must be rejected;
- to a product to be tested treated exposure series, then all data for that product on that subject must be rejected.

If data has to be rejected on more than 5 subjects, than the whole test must be rejected.

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2.14. Calculation of the sun protection factor and statistics

2.14.1. Calculation of the sun protection factor

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

$$SPFi = \frac{MED_{pi}}{MED_{ui}} \quad [1]$$

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:

$$\left(\sum_{1}^{n} SPFi\right)/n \quad [2]$$

2.14.2. 95% confidence interval

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

$$95\%CI = SPF \pm c \quad [3]$$

Where c is calculated as:

$$t \cdot \frac{\sqrt{\dfrac{\sum_{1}^{n}(SPF_i^2) - \dfrac{\sum_{1}^{n} SPF_i^2}{n}}{(n-1)}}}{\sqrt{n}} = t \cdot \frac{s}{\sqrt{n}} = t \cdot SEM \quad [4]$$

The percentange 95% confidence interval is then:

$$CI[\%] = 100 \cdot \frac{c}{SPF} \quad [5]$$

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)

2.15 Attachments

Attachment 1. Results: tested product
Attachment 2. Results: reference sunscreen formulation

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CONCLUSION

Based on the results obtained in the experimental conditions elsewhere described in this report it is possible to maintain that the product **ONCOSMETICS CREMA DE DÍA. Crema multiacción solar alta SPF 50 y un suave toque de color,** 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:

55.3 ± 2.6

(mean ± c)

According to the European Commission 2006/647/CE recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, the sun protection factor provided by the product belong to the category:

« HIGH PROTECTION»

San Martino Siccomario, Dicember, 16th 2015

Experimenter

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SPF TEST RESULT TABLE

Farcoderm TESTED WELLNESS

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Product code:	ONCOSMETICS CREMA DE DíA. Crema multiacción con protección solar alta SPF 50 y un suave toque de color	Expected SPF:	50
UV Source:	Solar Light Multiport solar simulator model 601 - 300W (Solar Ligth Co. Inc)		

	TEST		SUBJECTS					RESULTS					CONCLUSION:	
Subj. No.	Technician name	MED Assessor name	Subject code	Photo type	MEDu ($mJxcm^{-2}$)	MEDp ($mJxcm^{-2}$)	SPFi	SPFn'	$s_{n'}$	$c_{n'}$	$CI_{n'}$[%] ($100_{cn'}/SPF_{n'}$)	n	$CI_{n'}$[%] ≤ 17%	COMMENTS
01	dr. Scilironi	dr. Cestone	M0218O	II	26,2	1506,5	57,5	---	---					none
02	dr. Scilironi	dr. Cestone	C1167R	III	31,3	1799,8	57,5	57,5	0,0					none
03	dr. Scilironi	dr. Cestone	D1174B	III	39,1	2248,3	57,5	57,5	0,0					none
04	dr. Scilironi	dr. Cestone	P1562L	II	24,1	1205,0	50,0	55,6	3,8					none
05	dr. Scilironi	dr. Cestone	M1721L	II	21,0	1207,5	57,5	56,0	3,4					none
06	dr. Sciumè	dr. Cestone	A1462R	III	27,3	1569,8	57,5	56,3	3,1					none
07	dr. Sciumè	dr. Cestone	B3145S	III	34,0	1955,0	57,5	56,4	2,8					none
08	dr. Sciumè	dr. Cestone	F2070C	I	16,4	820,0	50,0	55,6	3,5					none
09	dr. Sciumè	dr. Cestone	R1784M	III	30,5	1525,0	50,0	55,0	3,8					none
10	dr. Sciumè	dr. Cestone	T3150B	III	27,3	1569,8	57,5	**55,3**	3,6	**2,6**	4,7%	1	Complies	none
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														

FINAL RESULT: **Mean SPF= 55,3** **s= 3,6** **c= 2,6** **95% CI: from: 52,7 to: 57,8 (n=10)**

For display purposes values are rounded to the first decimal place. All calculation are done using the original values.

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SPF TEST RESULT TABLE

Farcoderm TESTED WELLNESS

Laboratory: Farcoderm srl - Via Angelini, 21
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Product code:	REFERENCE SUNSCREEN FORMULATION P2 (High SPF reference formula)	Expected SPF:	16
UV Source:	Solar Light Multiport solar simulator model 601 - 300W (Solar Ligth Co. Inc)		

	TEST		SUBJECTS					RESULTS					CONCLUSION:	
Subj. No.	Technician name	MED Assessor name	Subject code	Photo type	MEDu ($mJxcm^{-2}$)	MEDp ($mJxcm^{-2}$)	SPFi	SPFn'	$s_{n'}$	$c_{n'}$	$CI_{n'}$[%] ($100_{cn'}/SPF_{n'}$)	n	$CI_{n'}$[%] ≤ 17%	COMMENTS
01	dr. Scilironi	dr. Cestone	M0218O	II	26,2	419,2	16,0	---	---					none
02	dr. Scilironi	dr. Cestone	C1167R	III	31,3	435,5	13,9	15,0	1,5					none
03	dr. Scilironi	dr. Cestone	D1174B	III	39,1	625,6	16,0	15,3	1,2					none
04	dr. Scilironi	dr. Cestone	P1562L	II	24,1	385,6	16,0	15,5	1,0					none
05	dr. Scilironi	dr. Cestone	M1721L	II	21,0	386,4	18,4	16,1	1,6					none
06	dr. Sciumè	dr. Cestone	A1462R	III	27,3	502,3	18,4	16,5	1,7					none
07	dr. Sciumè	dr. Cestone	B3145S	III	34,0	625,6	18,4	16,7	1,7					none
08	dr. Sciumè	dr. Cestone	F2070C	I	16,4	262,4	16,0	16,6	1,6					none
09	dr. Sciumè	dr. Cestone	R1784M	III	30,5	488,0	16,0	16,6	1,5					none
10	dr. Sciumè	dr. Cestone	T3150B	III	27,3	436,8	16,0	**16,5**	1,5	**1,0**	6,3%	1	Complies	none
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														

FINAL RESULT: **Mean SPF= 16,5** **s= 1,5** **c= 1,0** **95% CI: from: 15,5 to: 17,6 (n=10)**

For display purposes values are rounded to the first decimal place. All calculation are done using the original values.

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