INTERNAL STUDY CODE: VV_SUN-SPF/10SPF50+A_1034_24_002
Study Report - Version No. 2

COSMETIC PRODUCT SUN PROTECTION FACTOR DETERMINATION IN HUMANS

ACCORDING TO STANDARD ISO 24444:2019

Reception date: **June 05th, 2024**	**Experimental phase end date:** **July 12th, 2024**
Experimental phase start date: **June 13th, 2024**	**Report date:** **August 30th, 2024**

SPONSOR	KRAES ApS Peder Skrams gade 29, st. (baggården), Århus N Tel: (+45)20513320

Testing Facility	ZURKO RESEARCH S.L. Avenida de la Osa Mayor 4, 28023, Madrid (España). Tel: (+34) 91.521.15.88
Technical team	Head of solar department: Naiara Linaza Reyna. Solar department technical team: Verónica Serrano Moreno, Verónica Hellín Gutiérrez,María Fernanda Molina Fossati and Beatriz De La Morena Cabanillas.

Information provided by the client:

Tested product	Name: KRAES SOLCREME 30 Reference: 382C Batch: 00062025 Predicted SPF: 30

Zurko Research S.L. is not responsible for the data provided by the sponsor, included in this table.

Reference products	Reference product P2: Predicted SPF: 16,1 (acceptance range 13,7-18,5), reference/batch:10/23. Reference product P5: Predicted SPF 30,6 (acceptance range 23,7-37,4), reference/batch: 6/24. Reference product P8: Predicted SPF: 63,1 (acceptance range 43,9-82,3), reference/batch: 5/24.

REPORT TABLE OF CONTENTS

1. ABSTRACT

Volunteers	**Number of volunteers at the start: 11.** **Gender: both.** **Age: 18-70.** **ITAº: >28º.** **Number of volunteers at completion: 11.**
Experiment area	Back.
Application	Duration: 20”-50”.
Test execution	13/06/2024 – 12/07/2024
Study parameters	Sun Protection factor determination.
Study design	Day 0: measurement and determination of the volunteer's ITAº. Application and irradiation of products and unprotected area. Day 1: reading of erythemal responses at 20±4 h after irradiation.
Assessment	Minimal Erythema Dose assessment

Results

According to the international standard ISO 24444:2019 and based on resulting data, the tested product, **KRAES SOLCREME 30**, reference **382C (batch 00062025),** has the following characteristics:

- **The average sun protection factor is 40,1.**
- **The standard deviation is 3,7.**
- **The c is 2,7.**
- **The 95% CI is [42,77;37,43].**
- **The 17% of the average SPF is [46,92;33,28].**

2. OBJECTIVE AND PRINCIPLE OF THE STUDY

This study was conducted in accordance with Zurko Research's general conditions established for the execution of human tests (Structure and Content of Clinical Study Reports from ICH Harmonized Tripartite Guideline; Guideline for good clinical practice E6 (R2) of June 14th, 2017, EMA/CHMP/ICH/135/1995 of May 1st1996, European Parliament and Council Guideline 2001/20/EC - May 1st2001). The principles of the current version of the Declaration of Helsinki (2013 review) have also been taken into account.

The purpose of this study is to determine the Sun Protection Factor (hereinafter SPF) of a cosmetic product according to the International Standard ISO 24444:2019.

The SPF was quantified by means of a Minimal Erythema Dose (hereafter MED) assessment using a solar simulator consisting of a xenon arc lamp.

Skin MED is defined as the amount of energy required to produce the first noticeable and unambiguous reddening reaction with clear and distinct edges, covering more than 50% of the exposed area assessed between 16 and 24 hours after exposure to the solar simulator.

The product individual SPF factor (SPFi) is the ratio between the MED on skin protected with the product (MEDp) and the MED on unprotected skin (MEDu) of the same subject.

The SPF of the tested product is the arithmetic average of all valid SPFi values from each volunteer.

3. VOLUNTEERS

3.1. Ethical aspects

Each volunteer participating in the study has been previously informed about the test type and procedures, and has signed an informed consent form prior to the study's start. Original informed consents were stored in Zurko Research.

3.2. Number of volunteers

The number of subjects recruited is **11**. The minimum number of valid SPFi results is 10 in order to meet the statistical criterion (95% CI of the average SPF within ± 17% average SPF) according to ISO Standard 24444:2019 while the maximum number of valid SPFi results is 20.

During the study conduct, one volunteer's data (V1) were considered invalid due to the absence of erythemal response in any subsite in MEDP, and no dropouts were recorded. Therefore, the SPF of the tested product was determined in 10 volunteers.

Volunteers were assigned a number from 1 to n, according to the arrival sequence. Details are available in Annex I.

3.3. Specific inclusion and exclusion criteria:

Specific inclusion criteria for this study were as follows:

- Age: 18-70.
- Gender: both.
- >28 ITAº value.
- Normal preliminary clinical assessment.
- No dermatological lesions or marks in the experimental area (marks, pigmentation, erythema, moles, etc.).
- Affiliation to a social security program or being a beneficiary of a third-party membership.
- Acceptance of protocol restrictions.
- Signing of the informed consent form to participate in the study.

The specific exclusion criteria for this study were as follows:

  - Non-acceptance of the conditions of article L 209-17 of Law 20/12/88 related to:
  - The prohibition to participate in several biomedical research trials simultaneously without a direct personal benefit.
- The exclusion period during which the subject cannot participate in any other biomedical trial that has no direct personal benefit.
- Volunteers who refuse to sign the informed consent form.
- Volunteers who have undergone organ removal or transplantation; volunteers who have suffered from brain trauma with prolonged loss of consciousness in the last 5 years or ongoing after-effects.
- Pregnant or breastfeeding volunteers or women during a period of sexual activity without medical contraceptive treatment.
- Volunteers who have the following:
  - A cardiovascular, digestive, neurological, psychiatric, genital, urinary, hematologic or endocrine progressive alteration.
  - Immunodeficiency.
  - A previous history of intolerance to medications, cosmetics, medical devices, household products, industrial products and clothing, specially made of latex, nickel or aluminium.
  - A previous history of allergies, photosensitivity or phototoxicity.
  - Progressive skin alteration. Progressive fever process.
  - Metabolic photodermatitis: porphyria, tryptophan metabolism disorders.
- Volunteers who are treated with phototoxic or photosensitive substances or who have ceased any of these treatments during the 15 days prior to the start of the trial.

- Volunteers who are treated with antibiotics, antihistamines, anti-inflammatory drugs, corticosteroids or beta-blockers or whose treatment has finished during the 15 days prior to the start of the trial.
- Volunteers who have undergone treatments with topical retinoids (applied on the back) during the 6 months prior to the trial.
- Volunteers with a previous clinical history of abnormal response to the sun (polymorphic light eruptions, etc.).
- Volunteers using UV booths currently or 8 weeks prior to the study.
- Volunteers who exposed their skin to the sun or were under treatment in heliotherapy sessions during the 8 weeks prior to the start of the trial.
- Volunteers with sun damage in the experiment area.
- Volunteers who have participated in this type or similar studies 8 weeks before or who still have marks on the study area.
- Volunteers who have applied cosmetic or pharmaceutical products to relevant areas 48 hours prior to the start of the trial.
- Volunteers with excessive hair in the trial area.
- Volunteers with skeletal protrusions and extremely curved areas in the experiment area.

All volunteers met the inclusion and exclusion criteria.

4. MATERIAL AND EQUIPMENT

- **UV radiation source**

The UV radiation source was a Solar Light type multi-port 601-300W, WG320 Filter (1.25 mm), Xenon lamp whose spectrum ranges from 290 to 400 nm.
To eliminate IR and visible radiation, it is equipped with a UG11 filter (mm) and dichroic mirror.
The lamp power is 300W.
Its multi-port feature can irradiate 6 areas of 8 mm diameter in each area.
System for the determination of the Minimal Erythema Dose (MED): The UV flux of each optical fibres is determined by the technician in charge of the study to obtain a geometric progression (the progression was kept constant throughout the entire trial).

- **Skin-Colorimeter® CL 400**

Instrument for skin colorimetric measurements.

- **UV light radiometer**

Brand: Solar Light Co. PMA2100 and DCS-2.
Detector: Solar Light Co. PMA2108 erythema detector. LLG.

- **Accuracy scale**

Brand and model: KERN ABT100 5NM. Serial number: WB21G0132. Accuracy: 0.01 mg.

- **Reference product**

It is a cosmetic product with a known SPF to verify the study procedure.

- **Wood Lamp, 9 W**

Instrument for skin and product homogeneity verification.

5. METHODOLOGY

5.1. Environmental conditions

Throughout the procedure, conditions were controlled and the room temperature was always kept between 20ºC and 26ºC.

5.2. Product application characteristics

Type of product: emulsion.
Product preparation: the product is well-homogenized before application.
Product application: with latex fingercot.
Quantity applied: 2.00±0.05 mg/cm^2.

5.3. Data rejection criteria

According to ISO 24444:2019 test data should be rejected under the following circumstances.

- A: No erythemal response for any exposed subsites.
- B: Erythemal response for all exposed subsites.
- C: Erythema response(s) is (are) randomly absent or illogical sequence.
- D: No-compliance of the subject (protocol deviation).
- E: Technical failure (protocol deviation).

If the data had to be rejected in more than 5 subjects for the reasons A (reference standard), B (tested product/reference standard) or C (tested product/reference standard), the test should be NULL.

6. RESULTS

Annex II. Results.

The results obtained in the laboratory and reported in this report correspond to the sample analysed in the laboratory.

7. CONCLUSIONS

The purpose of this study was to determine the SPF of the cosmetic product in humans according to the International Standard ISO 24444:2019.
According to ISO 24444:2019, the test shall be considered valid if the SPF results obtained with the reference product P2 are between 13.7 – 18.5 (theoretical SPF 16.1) / with the reference product P5, between 23.7 – 34.7 (theoretical SPF 30.6) / with the reference product P8, between 43.9 – 82.6 (theoretical SPF 63.1). A minimum of 10 valid SPFi results must also be obtained, with a maximum of 5 invalid results, and 95%CI of the SPF of the tested product must be within ±17% SPF of the same product.
If data are not within these limits, the test is invalid and shall be repeated.

The average SPF of the reference product P2 obtained was **16,1**, for P5 it was **29,9** , for P8 it was **70,0**, and the 95%CI of the SPF of the evaluated product is within ±17% SPF.
These data validate the trial procedure

According to the international standard ISO 24444:2019 and based on the data obtained, it can be stated that **the average sun protection factor value** of the tested product **KRAES SOLCREME 30**, reference **382C (batch 00062025), is 40,1**, and 95%CI of the SPF is within ±17% SPF of the same product.

8. MODIFICACIONS

Version	Description	Date
01	**Realization of the report**	**July 15th, 2024**
02	**Replace the digital signatures with handwritten signatures**	**August 30th, 2024**

The new report versions replace the previous one.

9. DEVIATIONS

If the protocol is not followed and the deviation resulting from the breach is minor, the technician or researcher in charge of the test shall warn the volunteer about the importance of following test instructions. If the volunteer's breach persists or if the deviation from the protocol is greater, the volunteer shall be excluded from the test for breach of the protocol.
There were no deviations or noncompliance with the protocol recorded during the study.

10. CONSERVATION OF DOCUMENTATION AND SAMPLES

The study documentation will be stored at Zurko Research facilities.
The test documents will be stored for 10 years.
The tested product will be stored in the Zurko Research sample library for 1 year. After this time, it will be disposed of by the usual waste management procedure for this type of product.

11. BIBLIOGRAPHIC REFERENCES

1. The SCCS´S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation.
2. ISO 24444:2019. Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF).

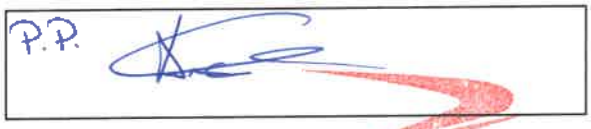
12. SIGNATURES

The undersigned declare that this study has been carried out based on the principles of Good Clinical Practice (Structure and content of clinical study reports from ICH Harmonized Tripartite Guideline Topic E3; Guideline for good clinical practice E6(R2) of June 14th 2017; Regulation (EU) No 536/2014 of the European Parliament and of the council of 16 April 2014).

-The results reported accurately and completely reflect the test data.

Specialized Technician: Beatriz de la Morena Cabanillas. I, the undersigned, declare that this study has been carried out under my responsibility.

Lead Researcher: Naiara Linaza Reyna. I, the undersigned, declare that this study has been reviewed under my responsibility.



Zurko bioresearch
CIF: B84273911

ANNEXES

Annex I. Volunteer information

Nº	SUBJECT CODE	AGE	GENDER
1	V1	31	F
2	V2	26	F
3	V3	47	F
4	V4	40	F
5	V5	19	F
6	V6	34	F
7	V7	26	M
8	V8	69	F
9	V9	19	F
10	V10	18	F
11	V11	23	F

Annex II. Results

Tested product description: EMULSION SPF30															Dose progression: 1,15
Test						Sim	Test subjects								
Nº	Date of exposure	Applied by	Irradiated by	Read by		Sim EE (máx) W/m² eff.	Subject code	Skin ITAº	MEDu Time (s)	MEDu J/m² eff.	MEDp Time (s)	MEDp J/m² eff.	SPFi	Valid/ Not valid	Comments
1	13/06/2024	VHG	VHG	MMF	NLR	9,6	V1	49,1	36	344	1071		-	Not valid	Absence of erythemal response in any subsite in MEDp
2	26/06/2024	BMC	BMC	NLR	VSM	9,1	V2	56,2	31	286	1257	11440	40,0	Valid	
3	27/06/2024	VSM	VSM	NLR	BMC	8,4	V3	40,9	50	420	2002	14640	34,9	Valid	
4	27/06/2024	MMF	MMF	VSM	BMC	9,6	V4	35,4	50	477	1984	19080	40,0	Valid	
5	27/06/2024	VHG	VHG	VSM	BMC	9,1	V5	47,3	39	359	1579	14360	40,0	Valid	
6	27/06/2024	VHG	VHG	VSM	BMC	9,6	V6	38,0	47	391	1869	18000	46,0	Valid	
7	04/07/2024	VHG	VHG	MMF	NLR	8,4	V7	34,2	58	426	2335	19600	46,0	Valid	
8	08/07/2024	VSM	VSM	BMC	NLR	8,1	V8	54,6	37	298	1482	11920	40,0	Valid	
9	11/07/2024	BMC	BMC	NLR	VSM	9,6	V9	42,2	42	408	1694	16320	40,0	Valid	
10	11/07/2024	VSM	VSM	BMC	NLR	9,1	V10	44,5	42	385	1694	15400	40,0	Valid	
11	11/07/2024	BMC	BMC	NLR	VSM	9,1	V11	48,0	39	354	1555	12320	34,8	Valid	

SPF	**40,1**
s	**3,7**
c	**2,7**
17% SPFs	**6,8%**
CI (%)	**6,7%**

Tested product description: Reference Products											Dose progression: 1,15																
Test						Sim	Test subjects																				
Nº	Date of exposure	Applied by	Irradiated by	Read by		Sim EE (máx) W/m² eff.	Subject code	Skin ITAº	MEDu Time (s)	MEDu J/m² eff.	Reference pattern 1 P2	Time (s)	J/m² eff.	SPFi	Valid/ Not valid	Reference pattern 1 P5	Time (s)	J/m² eff.	SPFi	Valid/ Not valid	Reference pattern 1 P8	Time (s)	J/m2 eff.	SPFi	Valid/ Not valid	Comments
1	13/06/2024	VHG	VHG	MMF	NLR	9,6	V1	49,1	36	344	-	-	-	-	-	-	-	-	-	-	P8	2499	24080	70,0	Valid	
2	26/06/2024	BMC	BMC	NLR	VSM	9,1	V2	56,2	31	286	-	-	-	-	-	-	-	-	-	-	P8	2200	20020	70,0	Valid	
3	27/06/2024	VSM	VSM	NLR	BMC	8,4	V3	40,9	50	420	-	-	-	-	-	P5	1532	11200	26,7	Valid	-	-	-	-	-	
4	27/06/2024	MMF	MMF	VSM	BMC	9,6	V4	35,4	50	477	P2	799	7680	16,1	Valid	-	-	-	-	-	-	-	-	-	-	
5	27/06/2024	VHG	VHG	VSM	BMC	9,1	V5	47,3	39	359	-	-	-	-	-	P5	1208	10985	30,6	Valid	-	-	-	-	-	
6	27/06/2024	VHG	VHG	VSM	BMC	9,6	V6	38,0	47	391	-	-	-	-	-	P5	1430	10404	26,6	Valid	-	-	-	-	-	
7	04/07/2024	VHG	VHG	MMF	NLR	8,4	V7	34,2	58	426	-	-	-	-	-	P5	1786	14994	35,2	Valid	-	-	-	-	-	
8	08/07/2024	VSM	VSM	BMC	NLR	8,1	V8	54,6	37	298	-	-	-	-	-	-	-	-	-	-	P8	2594	20860	70,0	Valid	
9	11/07/2024	BMC	BMC	NLR	VSM	9,6	V9	42,2	42	408	-	-	-	-	-	P5	1296	12485	30,6	Valid	-	-	-	-	-	
10	11/07/2024	VSM	VSM	BMC	NLR	9,1	V10	44,5	42	385	-	-	-	-	-	-	-	-	-	-	P8	2904	26950	70,0	Valid	
11	11/07/2024	BMC	BMC	NLR	VSM	9,1	V11	48,0	39	354	P2	625	5699	16,1	Valid	-	-	-	-	-	-	-	-	-	-	
											P2 SPF			16,1		**P5 SPF**			29,9		**P8 SPF**			70,0		

Annex III. UV irradiation source characterization

Solar Light Multiport 601-300W v2.5 with ref. 26338, complies with the % RCEE according to the calibration certificate of an external supplier dated 07.04.2024, valid until 07.04.2025.

Solar Light Multiport 601-300W v2.5 with ref. 27612, complies with the % RCEE according to the calibration certificate of an external supplier dated 07.04.2024, valid until 07.04.2025.

Solar Light Multiport 601-300W v2.5 with ref. 20413, complies with the % RCEE according to the calibration certificate of an external supplier dated 07.04.2024, valid until 07.04.2025.

Solar Light Multiport 601-300W v2.5 with ref. 12711, complies with the % RCEE according to the calibration certificate of an external supplier dated 07.04.2024, valid until 07.04.2025.

Measurements done and report issued by:	Report ordered by:	Customer:
Dr. José Aguilera Arjona Laboratorio de Fotobiología Dermatológica Centro de Investigaciones Medico-Sanitarias Departamento de Medicina y Dermatología Facultad de Medicina Universidad de Málaga Campus Universitario de Teatinos s/n 29071-Málaga	PROYECTOS Y APLICACIONES DE LASER Y ELECTRÓNICA PALESA-LASER Technology S.L. c/ Mestre J. Jambert, 8 080348 Cabrils – Barcelona – Spain	ZURKO Research S.A. Avda de la Osa Mayor, 4 28023 Madrid SPF Test Lab Manager Attn: Naiara Linaza
Date: 07/04/2024	SPECTRORADIOMETRIC TEST RESULTS UMA-26338-ZF0353	SIMULATOR # (33) s/n 26338

1.- EQUIPMENT under test:

Solar Simulator mod. Multiport 601 v2.5 – s/n 26338 with installed Xe lamp s/n ZF0353
Power Supply mod. XPS-300 s/n 26245

Associated Radiometric and UV Bio and UVA test measurement equipment on this simulator:

Radiometer DCS-2	Sensor UV bio PMA-2108	Sensor UVA PMA-2118	Sensor Irradiance Full spectrum PMA-2158	Sensor Quadrant PMA-2174
s/n 26315	s/n 20938	s/n 26046	s/n 23029	s/n 24618

2.- Test equipment used for Simulator Validation, Sensor Intercalibration and Protocol/Test Methode : as per Doc. UMA-080423

3.- STATUS OF COMPLIANCY against Industry Standars

The compliancy of the device under test against the requirements of various test procedures is summarized in Table 1. Further details and values are given in the following sections of this report.

Table 1: Status of Compliance of the Simulator under test to various Test Methods considering the current installed lamp and filter setting of the output radiation.

LAMP s/n	FILTER POSITION	TEST METHOD		
		In-Vivo SPF (ISO 24444:2019)	In-Vivo SPF (FDA 2011)	In-Vivo UVA (ISO 24442:2012)
ZF0353		COMPLIANCE STATUS		
	UVA	Irrelevant	Irrelevant	PASS
	UVA + UVB	PASS	PASS	Irrelevant

Note:
In-vivo SPF and UVA specifications consider an irradiance limitation of 1600 W/m2 to comply with the ISO requirements (1500W/m2 in case of FDA), therefore, it may be necessary to slightly/partially close the occulters of each LLG output .

Measurements done and report issued by:	Report ordered by:	Customer:
Dr. José Agulleiro Arjona Laboratorio de Fotobiología Dermatológica Centro de Investigaciones Médico-Sanitarias Departamento de Medicina y Dermatología Facultad de Medicina Universidad de Málaga Campus Universitario de Teatinos s/n 29071-Málaga	PROYECTOS Y APLICACIONES DE LASER Y ELECTRÓNICA PALESA-LASER Technology S.L. c/ Mestre J. Jambert, 8 080348 Cabrils – Barcelona – Spain	ZURKO Research S.A. Avda de la Osa Mayor, 4 28023 Madrid SPF Test Lab Manager Attn: Naiara Linaza
Date: 07/04/2024	SPECTRORADIOMETRIC TEST RESULTS UMA-27612-ZF0354	SIMULATOR # (39) s/n 27612

1.- EQUIPMENT under test:

Solar Simulator mod. Multiport 601 v2.5 – s/n 27612 with installed Xe lamp s/n ZF0354
Power Supply mod. XPS-300 s/n 27680

Associated Radiometric and UV Bio and UVA test measurement equipment on this simulator:

Radiometer DCS-2	Sensor UV bio PMA-2108	Sensor UVA PMA-2118	Sensor Irradiance Full spectrum PMA-2158	Sensor Quadrant PMA-2174
s/n 27510	s/n 27716	s/n 27843	s/n 23029	s/n 24618

2.- Test equipment used for Simulator Validation, Sensor Intercalibration and Protocol/Test Methode : as per Doc. UMA-080423

3.- STATUS OF COMPLIANCY against Industry Standars

The compliancy of the device under test against the requirements of various test procedures is summarized in Table 1. Further details and values are given in the following sections of this report.

Table 1: Status of Compliance of the Simulator under test to various Test Methods considering the current installed lamp and filter setting of the output radiation.

LAMP s/n	FILTER POSITION	TEST METHOD		
		In-Vivo SPF (ISO 24444:2019)	In-Vivo SPF (FDA 2011)	In-Vivo UVA (ISO 24442:2012)
ZF0354		COMPLIANCE STATUS		
	UVA	Irrelevant	Irrelevant	PASS
	UVA + UVB	PASS	PASS	Irrelevant

Note:
In-vivo SPF and UVA specifications consider an irradiance limitation of 1600 W/m2 to comply with the ISO requirements (1500W/m2 in case of FDA), therefore, it may be necessary to slightly/partially close the occulters of each LLG output .

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Date: 07/04/2024	SPECTRORADIOMETRIC TEST RESULTS UMA-20413-ZF0352	SIMULATOR # (40) s/n 20413

1,- EQUIPMENT under test:

Solar Simulator mod, Multiport 601 v2,5 – s/n 20413 with installed Xe lamp s/n ZF0352
Power Supply mod, XPS-300 s/n 12751

Associated Radiometric and UV Bio and UVA test measurement equipment on this simulator:

Radiometer PMA-2100	Sensor UV bio PMA-2108	Sensor UVA PMA-2118	Sensor Irradiance Full spectrum PMA-2158	Sensor Quadrant PMA-2174
s/n 19893	s/n 13488	s/n 10840	s/n 23029	s/n 24618

2,- Test equipment used for Simulator Validation, Sensor Intercalibration and Protocol/Test Methode : as per Doc, UMA-080423

3,- STATUS OF COMPLIANCY against Industry Standars

The compliancy of the device under test against the requirements of various test procedures is summarized in Table 1, Further details and values are given in the following sections of this report,

Table 1: Status of Compliance of the Simulator under test to various Test Methods considering the current installed lamp and filter setting of the output radiation,

LAMP s/n	FILTER POSITION	TEST METHOD		
		In-Vivo SPF (ISO 24444:2019)	In-Vivo SPF (FDA 2011)	In-Vivo UVA (ISO 24442:2012)
ZF0352		COMPLIANCE STATUS		
	UVA	Irrelevant	Irrelevant	PASS
	UVA + UVB	PASS	PASS	Irrelevant

Note:
In-vivo SPF and UVA specifications consider an irradiance limitation of 1600 W/m2 to comply with the ISO requirements (1500W/m2 in case of FDA), therefore, it may be necessary to slightly/partially close the occulters of each LLG output ,

Measurements done and report issued by:	Report ordered by:	Customer:
Dr. José Aguilera Arjona Laboratorio de Fotobiología Dermatológica Centro de Investigaciones Médico-Sanitarias Departamento de Medicina y Dermatología Facultad de Medicina Universidad de Málaga Campus Universitario de Teatinos s/n 29071-Málaga	laserhechnology PROYECTOS Y APLICACIONES DE LASER Y ELECTRÓNICA PALESA-LASER Technology S,L. c/ Mestre J, Jambert, 8 080348 Cabrils – Barcelona – Spain	ZURKO Research S,A, Avda de la Osa Mayor, 4 28023 Madrid SPF Test Lab Manager Attn: Naiara Linaza
Date: 07/04/2024	SPECTRORADIOMETRIC TEST RESULTS UMA-12711-XB1299	SIMULATOR # (67) s/n 12711

1,- EQUIPMENT under test:

Solar Simulator mod, Multiport 601 v2,5 – s/n 12711 with installed Xe lamp s/n XB1299
Power Supply mod, XPS-300 s/n 21437

Associated Radiometric and UV Bio and UVA test measurement equipment on this simulator:

Radiometer DCS-2	Sensor UV bio PMA-2108	Sensor UVA PMA-2118	Sensor Irradiance Full spectrum PMA-2158	Sensor Quadrant PMA-2174
s/n 22802	s/n 20960	s/n 21002	s/n 23029	s/n 24618

2,- Test equipment used for Simulator Validation, Sensor Intercalibration and Protocol/Test Methode : as per Doc, UMA-080423

3,- STATUS OF COMPLIANCY against Industry Standars

The compliancy of the device under test against the requirements of various test procedures is summarized in Table 1, Further details and values are given in the following sections of this report,

Table 1: Status of Compliance of the Simulator under test to various Test Methods considering the current installed lamp and filter setting of the output radiation,

LAMP s/n	FILTER POSITION	TEST METHOD		
		In-Vivo SPF (ISO 24444:2019)	In-Vivo SPF (FDA 2011)	In-Vivo UVA (ISO 24442:2012)
XB1299		COMPLIANCE STATUS		
	UVA	Irrelevant	Irrelevant	PASS
	UVA + UVB	PASS	PASS	Irrelevant

Note:
In-vivo SPF and UVA specifications consider an irradiance limitation of 1600 W/m2 to comply with the ISO requirements (1500W/m2 in case of FDA), therefore, it may be necessary to slightly/partially close the occulters of each LLG output ,

Annex IV. Certificates of Standard sunscreens.

LabAnalysis
HIGH QUALITY CONTROLS

Date: July 11th, 2023 Prot. 86/23

ANALYSIS REPORT

P2 HIGH SPF STANDARD

(I) GENERAL DATA

Sample	P2 HIGH SPF STANDARD – Batch n° 10/23
Date of Analysis	June 19th, 2023
Expiry Date	June 19th, 2025 (stored at not more than 20°C in a vessel protected from light)

(II) PHYSICAL-CHEMICAL DATA

Physical-chemical data	Detected data	ISO/DIS 24444 acceptability limits
Appearance	Homogeneous creamy emulsion	White-yellowish fluid emulsion
Colour	White-yellowish	
Odour	Characteristic	-
pH-value (directly)	8.3	8.0±0.5
Density (20°C)	0.960 [g/cm^3]	0.970±0.05 [g/cm^3]
Viscosity (20°C) (Brookfield RVT; Helipath T-B; time of assessment: 60 sec) 10 rpm	21200 [cps]	19000-33000 [cps]

(III) ANALYTICAL DATA (Content)

Analyte	Detected [% w/w]	Expected: Theoretical±5%** [% w/w]	Standard coefficient of variation % [≤ 2.5%**]
Ethylhexyl Dimethyl PABA*	6.72	7.00±0.35	0.06
Benzophenone-3*	2.86	3.00±0.15	0.08

*HPLC **ISO/DIS 24444

Dr Nicola Lionetti

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LabAnalysis LIFE SCIENCE

MONADERM

Date: April 29th, 2024

Prot. 82/24

ANALYSIS REPORT

P5 SPF 30 REFERENCE STANDARD

(I) GENERAL DATA

Sample	P5 SPF 30 REFERENCE STANDARD – Batch n° 6/24
Date of Manufacture	March 25th, 2024
Expiry Date	March 25th, 2025

(II) PHYSICAL-CHEMICAL DATA

Physical-chemical data	Detected data	ISO 24444:2019/Amd1:2022 acceptability limits
Appearance	Homogeneous smooth cream	White/slightly off-white smooth lotion
Colour	Slightly off-white	
Odour	Characteristic	Characteristic
pH-value (directly)	5.3	5.5±0.5
Density	1.00 [g/cm³]	1.00 ± 0.05 [g/cm³]
Viscosity (Brookfield LV with Helipath, spindle F) 10 rpm	75000 [cps]	77000 ± 10% [cps]

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MONADERM

Date: April 4th, 2024 Prot. 70/24

ANALYSIS REPORT

P8 SPF 63 REFERENCE STANDARD

(I) GENERAL DATA

Sample	P8 SPF 63 REFERENCE STANDARD – Batch n° 5/24
Date of Analysis	March 11th, 2024
Expiry Date	March 11th, 2025

(II) PHYSICAL-CHEMICAL DATA

Physical-chemical data	Detected data	ISO 24444:2019/Amd1:2022 acceptability limits
Appearance	Homogeneous creamy emulsion	White cream
Colour	White	
Odour	Characteristic	-
pH-value (directly)	7.1	7.1±0.3
Density	1.00 [g/cm³]	0.97 to 1 [g/cm³]
Viscosity (Brookfield DVIII Ultra; Spindle RV-5) 10 rpm	12000 [cps]	12000-15000 [cps]

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