INTERNAL STUDY CODE: VV_SUN-WR/10SPF30-A_420_24_001

Study Report - Version No. 1

DETERMINATION OF THE SUN PROTECTION FACTOR AND WATER RESISTANCE OF A COSMETIC PRODUCT IN HUMANS

ACCORDING TO STANDARD: ISO 24444:2019, ISO 16217:2020, ISO 18861:2020

Reception date: **May 20th, 2024**	**Experimental phase end date:** **June 21st, 2024**
Experimental phase start date: **May 27th, 2024**	**Report date:** **June 25th, 2024**

SPONSOR	**DERMAPHARM** Europavej 10, 8890 Fårup, Denmark Tel: (+45) 87 82 84 04

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: SUN LOTION SPF30 Reference: 40501418 Batch: 2400804 Predicted SPF: 30

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

Reference product	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. Reference product WR (P2): Predicted SPFwr: 12,0. (acceptance range 9,0-15,0), reference/batch: 10/23.

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1. ABSTRACT

Volunteers	**Number of volunteers at the start: 10.** **Gender: both.** **Age: 18-70.** **ITAº: >28º.** **Number of volunteers at completion: 10.**
Experiment area	Back.
Application	Duration: 20”-50”.
Test execution	27/05/2024 – 21/06/2024
Study parameters	Sun Protection factor and Water-Resistant 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. Performed the water resistance test (40min). Day 2: reading of erythemal responses of water subsites at 20±4 h after irradiation.
Assessment	Minimal Erythema Dose assessment.

Results

According to the international standard ISO 24444:2019, 18861:2020 and 16217:2020 and based on resulting data, the tested product, **SUN LOTION SPF30**, reference **40501418, has the following characteristics:**

- **The average sun protection factor is 30,2.**
- **The s is 4,3.**
- **The c is 3,1.**
- **The 95% CI is [33,26; 27,14].**
- **The 17% of the average SPF is [35,33; 25,07].**
- **WR-d value is 52,6%.**

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 trials (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 1st 1996, European Parliament and Council Guideline 2001/20/EC - May 1st 2001). The principles of the current version of the Declaration of Helsinki (2013 review) have also been taken into account.

This study aims to determine the Sun Protection Factor (hereinafter SPF) according to International ISO Standard 24444:2019 and the water resistance according to International Standards ISO 16217:2020 and 18861:2020 of a cosmetic product.

The quantification of the SPF (before and after the water-resistance test) was calculated by assessing the Minimum Erythema Dose (hereinafter MED) using a solar simulator made up 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 individual static SPF factor (SPFis) of the product is the ratio between the MED on skin protected by the product (MEDisp) and the MED on unprotected skin (MEDisu) of the same subject without passing the water-resistance test.

The tested product SPF is the result of the arithmetic mean of all valid SPFis values of each volunteer.

The SPF factor after the individual water resistance study (SPFiwr) of the product is the ratio between the MED on skin protected by the product after the water-resistance test (MEDiwrp) and the MED on unprotected skin after the water-resistance test (MEDiwru) on the same subject.

The SPFwr of the tested product is the arithmetic mean of all valid SPFiwr values of each volunteer.

The percentage of individual water resistance (%WRi) is calculated with the following formula:

$$\%\mathrm{WRi} = \frac{(\mathrm{SPFiwr} - 1)}{(\mathrm{SPFis} - 1)} \times 100$$

The product water resistance percentage, %WR, is the arithmetic mean of all valid %WRi values of each volunteer.

A product can be considered to be "Water Resistant" if the lower one-sided 90% confidence bound (%WR-d) is greater than or equal to 50% and the SPF 95% confidence interval is within ±17% of the SPF.

3. VOLUNTEERS

3.1. Ethical aspects

Each volunteer participating in the study has been previously informed about the trial 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

10 subjects were recruited. The minimum number of valid SPFis results to meet the statistical criterion (95% CI of mean SPF within ± 17% of SPF) according to ISO Standard 24444:2019 is 10 and the maximum number of valid SPF results is 20.

Prior to immersion in water, no volunteer data were considered invalid and no dropouts were recorded. After immersion in water, no volunteer data were considered invalid and no dropouts were recorded. Therefore, the SPF of the tested product was calculated in 5 volunteers, and the value of [%WR-d] was calculated 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, hematology 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 aluminum.
  - 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 allows for irradiating, in each area, 6 areas of 8 mm diameter.
System for the determination of the Minimum Erythema Dose (MED): The UV flux of each optical fiber 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 usual SPF, which allows for verifying the study procedure.

- **Hydromassage tub for water immersion testing**

Brand: Jacuzzi, with a capacity of 250 l.
All the characteristics of bathtubs comply with the requirements established according to ISO 16217:2020.

- **Wood lamps, 9 W**

Instrument for skin and product homogeneity verification.

5. METHODOLOGY

5.1. Environmental conditions

Throughout the entire procedure, conditions were controlled and the ambient temperature was kept between 20° C and 26° C.

During the water-resistance phase, the room temperature was kept between 20° C and 26° C, and the water temperature, between 28° C and 32° C.

Drinking water with a pH between 6.5 and 7.5 and a conductivity of ≥500mS was used in the study.

The linear water flow was measured before each subject entered the bathtub and was found to be between 0.02 and 0.05 m/s.

5.2. Product application characteristics

Type of product: emulsion.

Product preparation: the product is well shaken- 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 Standard 24444:2019, test data must 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).

In the event that data must be rejected in more than 5 subjects for reasons A, B or C, 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 analyzed in the laboratory.

7. CONCLUSIONS

The purpose of this study was to determine the cosmetic product SPF in humans according to the International ISO Standard 24444:2019.
According to ISO 24444:2019, the trial 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 do not comply with the above, the test is invalid and must be repeated.

The average SPF of the reference product P2 obtained was **16,1**, for P8 it was **80,9**, for P5 it was **31,4**, and the 95%CI of the SPF of the evaluated product is within ±17% SPF**.**
According to ISO Standards 16217:2020 and 18861:2020, the test is considered valid if SPFwr results obtained in the P2 reference product are between 9.0 and 15.0 (theoretical SPFwr 12.0). The average SPFwr of the P2 reference product was **13,3.**
These data validate the test procedure.

According to international ISO Standards 24444:2019, 18861:2020 and 16217:2020 and based on obtained data, the product tested, **SUN LOTION SPF30**, of reference **40501418**, **has an average sun protection factor value of 30,2.** Besides, 95%CI of the SPF is within ±17% SPF of that product.
The [%WR-d] value is 53,5% so it can be claimed that the product is water-resistant.

8. MODIFICATIONS

Version	Description	Date
01	**Realization of the report**	**June 25th, 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 trial shall warn the volunteer of the importance of following trial instructions. If the volunteer's breach persists or if the deviation from the protocol is greater, the volunteer shall be excluded from the trial 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).
3. ISO 16217:2020. Cosmetics - Sun protection test methods - Water immersion procedure for determining water resistance.
4. ISO 18861:2020. Cosmetics - Sun protection test methods - Percentage of water resistance.

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 trial data.

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

DE LA MORENA CABANILLAS BEATRIZ - 05290720F

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Leading researcher: Naiara Linaza Reyna. I, the undersigned, declare that this study has been reviewed under my liability.

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ANNEXES

Annex I. Volunteer information

Nº	SUBJECT CODE	AGE	GENDER
1	V1	32	M
2	V2	43	M
3	V3	38	M
4	V4	30	M
5	V5	32	M
6	V6	62	F
7	V7	36	F
8	V8	26	F
9	V9	52	F
10	V10	64	M

Annex II. Results

Tested product description: EMULSION SPF 30													Dose progression: 1,15		
Trial						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	27/05/2024	VSM	VSM	NLR	BMC	10,9	V1	36,0	43	471	1302	10680	22,7	Valid	
2	05/06/2024	VSM	VSM	NLR	BMC	10,0	V2	40,5	43	425	1277	11070	26,0	Valid	
3	05/06/2024	VHG	VHG	MMF	NLR	10,0	V3	50,5	33	251	997	8640	34,4	Valid	
4	05/06/2024	VHG	VHG	MMF	NLR	9,6	V4	41,1	43	363	1302	12540	34,5	Valid	
5	10/06/2024	BMC	BMC	NLR	VSM	9,6	V5	35,5	49	414	1483	10800	26,1	Valid	
6	17/06/2024	MMF	MMF	NLR	VHG	9,6	V6	49,6	35	339	1057	10170	30,0	Valid	
7	17/06/2024	MMF	MMF	NLR	VHG	9,6	V7	51,0	34	285	1022	9840	34,5	Valid	
8	19/06/2024	VSM	VSM	NLR	BMC	9,6	V8	38,6	46	444	1383	13320	30,0	Valid	
9	19/06/2024	VSM	VSM	BMC	NLR	9,1	V9	61,5	27	248	818	7440	30,0	Valid	
10	19/06/2024	VHG	VHG	MMF	NLR	9,1	V10	42,3	45	307	1340	10590	34,5	Valid	

SPF	30,2
s	4,3
c	3,1
17% SPFs	5,1%
CI (%)	10,1%

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	MEDu		Reference pattern 1				Valid/ Not valid	Reference pattern 1				Valid/ Not valid	Reference pattern 1				Valid/ Not valid	Comments
								ITAº	Time (s)	J/m² eff.	P2	Time (s)	J/m² eff.	SPFi		P5	Time (s)	J/m² eff.	SPFi		P8	Time (s)	J/m2 eff.	SPFi		
1	27/05/2024	VSM	VSM	NLR	BMC	10,9	V1	36,0	43	471	-	-	-	-	-	-	-	-	-	-	P8	3038	32970	70,0	Valid	
2	05/06/2024	VSM	VSM	NLR	BMC	10,0	V2	40,5	43	425	-	-	-	-	-	P5	1302	13005	30,6	Valid	-	-	-	-	-	
3	05/06/2024	VHG	VHG	MMF	NLR	10,0	V3	50,5	33	251	-	-	-	-	-	-	-	-	-	-	P8	2096	23170	92,3	Valid	
4	05/06/2024	VHG	VHG	MMF	NLR	9,6	V4	41,1	43	363	-	-	-	-	-	P5	1328	12791	35,2	Valid	-	-	-	-	-	
5	10/06/2024	BMC	BMC	NLR	VSM	9,6	V5	35,5	49	414	-	-	-	-	-	P5	1512	11016	26,6	Valid	-	-	-	-	-	
6	17/06/2024	MMF	MMF	NLR	VHG	9,6	V6	49,6	35	339	-	-	-	-	-	P5	1079	10373	30,6	Valid	-	-	-	-	-	
7	17/06/2024	MMF	MMF	NLR	VHG	9,6	V7	51,0	34	285	-	-	-	-	-	P5	1042	10037	35,2	Valid	-	-	-	-	-	
8	19/06/2024	VSM	VSM	NLR	BMC	9,6	V8	38,6	46	444	P2	742	7148	16,1	Valid	-	-	-	-	-	-	-	-	-	-	
9	19/06/2024	VSM	VSM	BMC	NLR	9,1	V9	61,5	27	248	-	-	-	-	-	P5	834	7589	30,6	Valid	-	-	-	-	-	
10	19/06/2024	VHG	VHG	MMF	NLR	9,1	V10	42,3	45	307	-	-	-	-	-	-	-	-	-	-	P8	2819	24710	80,5	Valid	
											P2	SPF		16,1		P5	SPF		31,4		P8	SPF		80,9		

Trial product description: EMULSION SPF30									Dose progression: 1,15							
Trial						SIM	Trial subjects									
Nº.	Date of exposure	Applied by	Irradiated by	Read by		SIM EE (max.) W/m² eff.	Subject code	Skin ITAº	MEDwru Time (s)	MEDwru J/m² eff.	MEDwrp Time (s)	MEDwrp J/m² eff.	SPFwr	% WR	Valid/ Not valid	Comments
1	28/05/2024	VSM	VSM	NLR	BMC	10,9	V1	36,0	43	471	561	6090	12,9	55,0	Valid	
2	06/06/2024	VSM	VSM	NLR	BMC	10,0	V2	40,5	43	425	731	8370	19,7	74,6	Valid	
3	06/06/2024	VHG	VHG	MMF	NLR	10,0	V3	50,5	33	288	568	4920	17,1	48,1	Valid	
4	06/06/2024	VHG	VHG	MMF	NLR	9,6	V4	41,1	43	418	857	8250	19,7	55,9	Valid	
5	11/06/2024	BMC	BMC	NLR	VSM	9,6	V5	35,5	49	414	858	7110	17,2	64,5	Valid	
6	18/06/2024	MMF	MMF	NLR	VHG	9,6	V6	49,6	35	339	604	5820	17,2	55,8	Valid	
7	18/06/2024	MMF	MMF	NLR	VHG	9,6	V7	51,0	34	328	583	5610	17,1	48,0	Valid	
8	20/06/2024	VSM	VSM	NLR	BMC	9,6	V8	38,6	46	444	791	7620	17,2	55,7	Valid	
9	20/06/2024	VSM	VSM	BMC	NLR	9,1	V9	61,5	27	248	468	4260	17,2	55,8	Valid	
10	20/06/2024	VHG	VHG	MMF	NLR	9,1	V10	42,3	45	407	764	6960	17,1	48,1	Valid	

SPFwr	**17,2**
% WR	**56,1%**
s	**8,2**
d	**3,6**
% WR - d	**52,6%**

Trial product description: P2									Dose progression: 1,15							
Trial						SIM	Trial subjects									
Nº.	Date of exposure	Applied by	Irradiated by	Read by		SIM EE (max.) W/m² eff.	Subject code	Skin ITAº	MEDwru Time (s)	MEDwru J/m² eff.	MEDwrp Time (s)	MEDwrp J/m² eff.	SPFwr	% WR	Valid/ Not valid	Comments
1	17/05/2024	MMF	MMF	NLR	VHG	9,6	V1	49,6	36	-	-	-	-	-	Not valid	Protocol deviation
2	17/05/2024	MMF	MMF	NLR	VHG	9,6	V2	53,5	32	307	514	3735	12,2	85,9	Valid	
3	17/05/2024	MMF	MMF	NLR	VHG	9,6	V3	55,2	31	294	491	4733	16,1	100,0	Valid	
4	21/05/2024	VHG	VHG	MMF	NLR	9,6	V4	45,1	40	379	639	5313	14,0	100,0	Valid	
5	21/05/2024	MMF	MMF	NLR	VHG	9,6	V5	43,7	41	393	662	5506	14,0	74,3	Valid	
6	28/05/2024	MMF	MMF	NLR	VHG	9,6	V6	31,2	55	526	884	7342	14,0	85,8	Valid	
7	28/05/2024	MMF	MMF	NLR	VHG	9,6	V7	41,2	43	418	698	6730	16,1	100,0	Valid	
8	28/05/2024	MMF	MMF	NLR	VHG	9,6	V8	42,7	42	403	679	4266,5	10,6	63,5	Valid	
9	30/05/2024	BMC	BMC	NLR	VSM	9,6	V9	34,7	50	485	812	5909	12,2	86,0	Valid	
10	30/05/2024	VSM	VSM	NLR	VSM	10,0	V10	47,8	36	355	573	4315	12,2	73,9	Valid	
11	11/06/2024	VSM	VSM	NLR	BMC	9,0	V11	54,7	33	297	530	4170	14,0	74,7	Valid	

SPFwr	**13,3**
% WR	**83,0%**
s	**11,6**
d	**5,1**
% WR - d	**77,9%**

Annex III. UV radiation source characterization

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.

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	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 .

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	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-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 ,

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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Annex IV. Certificates of sunscreen standards.

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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LabAnalysis LIFE SCIENCE

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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