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Study report #23E1506

Related to quote #23D1506-2

DETERMINATION OF THE SUN PROTECTION FACTOR (SPF)

ACCORDING TO THE ISO 24444:2019- / Amd1:2022

MRX008-4 SPF 30 INVISIBLE

CLINICAL INVESTIGATION CENTER

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Document 1/3 including 43 pages

TABLE OF CONTENTS

KEY ELEMENTS OF THE STUDY #23E1506

DETERMINATION OF THE SUN PROTECTION FACTOR (SPF)

ACCORDING TO THE ISO 24444:2019 / Amd.1:2022

MRX008-4 SPF 30 INVISIBLE

Objective(s)	To evaluate the **Sun Protection Factor** (SPF) according to the International Norm ISO 24444:2019 (December 2019) / Amd.1:2022.
Methodology	• Randomized study • With a Reference Sunscreen Formulations depends on the expected SPF value of the tested product and that must be in the acceptance limits • Solar simulators: Solar Light Multiport 601-300W • 6 increasing doses of UV with 15% progression • Study must be carried out on at least 10 subjects, and must comply with the statistical criterion (95% CI <17% mean SPF). • Calculation formula: $\mathbf{SPFi} = \mathrm{MEDip}/\mathrm{MEDiu}$ SPFi: the individual static SPF MEDp: Minimal Erythemal Dose obtained with product MEDu: Minimal Erythemal Dose obtained without product

Kinetics

	D0	D1
Information of the subject about study conditions and collection of his informed consent	●	
Verification of inclusion and non-inclusion criteria	●	
Determination of ITA°	●	
Application of the product(s)	●	
UV exposures (at least 15 minutes after application)	●	
Visual reading of the MEDu and MEDp		●
Evaluation of the individual SPF (SPFi) of product(s)		●

Dates

Product reception	Study start	Study end	1st results by e-mail
15/05/2023	22/05/2023	30/06/2023	30/06/2023

Product

Reference	Expected SPF	Form	Application zone
MRX008-4 SPF 30 INVISIBLE	30	Light yellow dense solution	Back

Study Population

Specific inclusion criteria

- **Sex:** male or female
- **Age:** from 18 to 65 years old.
- **ITA° ≥ 2**8° and the average ITA° for the test panel shall be within the range 41° to 55°, with a minimum of three subjects within two of the three ITA° ranges: [28° to 40°] / [41° to 55°] / >56°;
- Subject with **untanned skin**: the subject has an even color tone with no variation in ITA° greater than 5° on the test area (back)
- Subject free from blemishes and hair on the test area (back)

Number of subjects analyzed	Average age
12 (10 valid)	37 ± 3 years (between 26 and 51)

<table>
<tr><td>Conclusion</td><td colspan="3">Under these study conditions:
➢ Product « MRX008-4 SPF 30 INVISIBLE » has an average SPF of 53.1.</td></tr>
<tr><td rowspan="2">Project Coordinator</td><td>Name and job title</td><td>Date</td><td>Signature</td></tr>
<tr><td>Anna LUDWIKOWSKA
Head of Solar Department</td><td>July 07, 2023</td><td>  </td></tr>
</table>

1 QUALITY CONTROL STATEMENT

The Solar project managers responsible of the final control certify that the study above was conducted as closely as possible to Good Clinical Practice (GCP-ICH), in compliance with the study protocol and EUROFINS Dermscan/Pharmascan standard operating procedures and that the study report reflects raw data.

2 STUDY PROCESS

EUROFINS Dermscan is certified ISO: 9001-2015.

EUROFINS Dermscan benefits from a governmental Research Tax Credit from the French Ministry of Research.

The study is carried out on (a) cosmetic product whose safety has been assured by the Sponsor.

The European Directive 2001/20/EC and regulations issued by the Minister of Health (The Order of the Minister of Health of May 2, 2012 regarding Good Clinical Practice, Dz.U. 2012, item 491) is not applicable. Therefore, this study is considered as non-interventional and does not require the Ethics Committee Approval and the Competent Authority Authorization.

+ See ethical requirements and regulatory standards in **Appendix 8**

This study was conducted under the following conditions:

2.1 POPULATION

2.1.1 Selection

INCLUSION CRITERIA
Specific
• **Sex**: male or female; • **Age**: between 18 and 65 years old; • **ITA°** ≥ 28° and the average ITA° for the test panel shall be within the range 41° to 55°, with a minimum of three subjects within two of the three ITA° ranges: [28° to 40°] / [41° to 55°] / >56°; • Untanned skin on the test area (back): no variation in ITA° greater than 5°between each test area.
General
• Healthy subject; • Subject having given his/her free informed, written consent; • Subject willing to adhere to the protocol and study procedures.

NON-INCLUSION CRITERIA
• Children and persons below the locally legal age of consent or >65 years; • Pregnant or lactating women; • Subjects using medication with photo-sensitizing potential; • Subjects using anti-inflammatory medication; • Subjects with systemic dermatological conditions (including dysplastic nevi); • Subjects with a history of abnormal response to the sun; • Subjects who have used tanning beds in the previous eight weeks prior to SPF testing; • Subjects having had sun exposure on the back area in the previous eight weeks prior to SPF testing; • Subjects having marks, blemishes or nevi in the test area; • Subjects presenting with existing sun damage in the test area; • Subjects having excessive hair in the area on the test on the day of testing (may be shaved up to 3 days prior to the test day); • Subjects having skeletal protrusions and extreme areas of curvature in the test area;Subject, who does not meet current Ministry of Health Covid-19 guidelines at the time of the visit.

2.1.2 Study requirements and constraints

DURING THE STUDY, THE SUBJECTS	
HAVE TO	**MUST NOT**
• Respect dates and hours of evaluation visits; • Avoid UV exposure (including artificial UV). • Wear mask during the visit at the laboratory and hand disinfection at the beginning of visit at the laboratory	• Apply any product to test areas the days of the visits* to the lab; • Apply any other similar product to test areas.

** a shower with the usual product is allowed the day of the evaluation visit(s) to the lab.*

2.1.1 Compliance assessment

The standardized applications of the products (tested product and reference) are done, at the investigation center, by the solar team. The day of the assessment, the compliance is controlled by oral questioning of the subject.

2.1.2 Protocol deviations

A protocol deviation can be defined as any non-adherence to the final protocol, including:

- wrong inclusion (inclusion criteria or non-inclusion criteria not fulfilled);
- start of a prohibited concomitant treatment;
- non-compliance of the subjects to the study schedule (missed or postponed visit);
- missing data for one or several evaluation criteria;
- low compliance of the subject with protocol (movement, …);
- premature study end or untraceable subject;

Deviations to the protocol should be classified as:

- **minor** if they don't impact the rights, safety or well-being of the subjects. They do not increase the risk for the subject and/or do not have a significant effect on the integrity of the data collected,
- **major (or protocol violations**) if they affect the rights, safety or well-being of participants. They increase the risk for the subject and/or have a significant effect on the integrity of the study data,
- **critical:** any protocol violations as mentioned above necessarily requiring the suspension or the termination of the study.

In case of minor protocol deviation, the technician or the investigator repeats the instructions and reminds the subject to follow protocol requirements / study procedures. In case of persistent or major protocol violations, the subject is declared non-compliant and withdrawn from the study because of non-compliance.

- **No protocol non-adherences was observed during the study.**

2.1.3 Concomitant treatments

All concomitant treatments are reported in the CRF and the study report.

2.1.4 Follow-up

Number of SUBJECTS							
INCLUDED	COMPLETING THE STUDY	NOT COMPLETING THE STUDY	INCLUDED IN FINAL RESULTS	NOT INCLUDED IN FINAL RESULTS			
				Data Rejection *	Non-compliance or Technical Failure **	Unused data***	Pre-test****
12	*12*	*/*	*10*	*2*	*/*	*/*	*/*

+ See observations detailed in **Appendix 7.1**

Data from a test site are considered invalidated and must be rejected in the following circumstances:

Observation	Abbreviations in MED columns result's tables	Explication
***No grade** of at least 1 for any exposed sub sites	NO MARK	All exposed subsites have grades of 0, or 0,5, and no qualifying MED (Grade 1) is observed
***All test subsites show erythema** of at least grade 1	ALL MARKED	No sites have grades of 0 or 0,5, and a MED response cannot be established
***Erythemal response(s) is (are) absent** for exposures higher than the determined MED dose (randomly absent)*	ILLOGICAL	A Grade of 0 is observed at an exposure dose higher than the determined MED, (randomly absent or illogical sequence)
****Non-compliance** of the subject	NC	Subject does not follow instructions during or after the treatment or UV exposures that could affect the outcome of the test (wipes sunscreen treated areas during application or exposures, medicates with anti-inflammatory drugs, exposes treatment areas to UV light (sunlight or other UV source), irritates treated area, etc.)
****Technical failure**: failure of equipment or procedures during the treatment phases of the procedure**	TF	**For example:** incorrect lamp intensity or fluctuations, incorrect exposure times, incorrect site application of sunscreen, and similar reasons) that would jeopardize the integrity of the treatments and conclusions
***Unused data**	Data from a test site are unused if the subject was included in this study but this tested product was not exposed.	
**** Pre-test**	When there is some doubt on the provisional SPF value of the test product, a screening should first be performed. In order to protect the subjects a lower SPF value should be used on some subjects and increased progressively on the other subjects. Data from these tests may be included in the final results provided they comply with all other requirements for a valid test result.	

For this study:

Reason for Subjects not included in final results		Counts against number of total allowable rejections (c.f §2.4.2)
Subject #	**Reason(s)**	**Yes/ no**
1	**NO MARK –** All exposed subsites have grades of 0, or 0,5, and no qualifying MED (Grade 1) is observed	**No**
6	**NO MARK –** All exposed subsites have grades of 0, or 0,5, and no qualifying MED (Grade 1) is observed	**No**

2.1.5 Demographic data

ANALYZED SUBJECTS (included in at least one analysis)	SEX	AGE (IN YEARS)			ITA°					SKIN TYPE		COMMENTS AND DETAILED DATA
		Mean ± SEM	Min.	Max.	Mean	Min.	Max.	Distribution				
12	Female	37±3	26	51	50	42	60	28°<ITA=<40°	0	Dry	0	See Appendix 7
								41°<ITA=<55°	10	Normal	12	
0	Male							>56°	2	Combination	0	

2.2 INVESTIGATIONAL PRODUCT

2.2.1 Description

Reference	Batch#	Form	Packaging	Confidentiality procedure	Storage temperature
MRX008-4 SPF 30 INVISIBLE	02123	Light yellow dense solution	2 x 30 ml	Encoded	Room temperature

2.2.2 Application

Zone	Frequency	Directions for use
Back	One standardized application by technician, 15 to 30 minutes before exposures	• Standard quantity: (2.00 ± 0.05) mg/cm² checked by a method of weighing by loss with a precision balance (quantity defined by International Standard ISO). In case of application without fingercot (naked finger) a maximum of 2,1 mg/cm² (additional 5 %) is applied to the test area • Application zone: 35cm² • To shake the product before application • With latex fingercot (chosen after a spreading test) • Spreading time: (35 ± 15) s • Checking the homogeneity with UV-A “Woods” lamp

2.2.3 Labelling

Example of labelling of each product by EUROFINS Dermscan and translation:

DERMSCAN Badanie n°	DERMSCAN Study #
Nr Ochotnika: ..... Nr Dermscan: ..... W naglej potrzebie: ..... Warunki przechowywania: ..... Przychowywać z dala od dzieci i ich zasięgu wzrokowego. Stosować pod kontrolą medyczną tylko dla potrzeb badania.	Subject#:..... Emergency telephone number:..... Dermscan ref.: ..... Conservation: ..... Keep out of reach and sight of children. To be used only under strict medical supervision for clinical trial.

2.2.4 Storage

Until the beginning of the study, products are kept at room temperature in a dedicated air-conditioned room, which is locked and access controlled.

2.2.5 Attribution to the subjects

➔ *Product(s)*

Not applicable.

➔ *Application zones*

The application zones of the studied product and P2/P8 Reference Sunscreen Formulations, as well as the untreated zone, are randomized according a table created with SAS software respected as far as possible, but can be modified in case of beauty spots, buttons, scars…on subject back.

2.2.6 Handing-out

Not applicable. The standardized applications are done by the technician at the investigation center.

2.2.7 Future

As far as possible, one sample of the study product is kept by the investigation center for a period of six months after its receipt.

- **By default, the products (used and not used) are destroyed at the end of the study according to the current internal EUROFINS Dermscan/Pharmascan procedures.**

2.3 STUDY STAGES

During the study, ambient conditions must be between 23°C ± 3.

ON D0

Subjects:

- come to the investigation center without having applied any product (excepted their usual cleaning product) to the study area since the previous evening;
- are informed about the trial objectives, the procedures and the risks of the study with information sheet;
- sign two copies of the Consent Form;
- are acclimatized for 15 minutes, in prone position, without wearing any clothes on their back.

Note: subject must be in same position during UV exposition, products application, assessments.

Technician:

- verifies inclusion and non-inclusion criteria;
- performs skin color measurements with a MINOLTA Chromameter® (CR400) in order to calculate ITA° on each site to be exposed to UV;
- defines several zones on the back:
  - one unprotected zone,
  - one protected zone with the Reference Sunscreen Formulation,
  - one protected zone for each tested product,
- applies the tested product(s) and the Reference Sunscreen Formulation according to ISO standardized method (quantity 2 mg/cm^2);
- performs UV exposition, 15 to 30 minutes after each application, with a xenon lamp Solar Light Multiport 601-300W, according to a geometric progression of 15%.

ON D1

Subjects:

- return to the investigation center, 16 to 24 hours after exposure, with no product applied on the back in the morning (except the morning wash);
- are acclimatized for 15 minutes, in same prone position as D0, and without wearing any clothes on their back.

Technician:

- evaluate the Minimal Erythemal Dose on unprotected zone (MEDiu) and on protected zone(s) with tested product(s) (MEDip) or reference, by simultaneous reading in a "blind" manner in a sufficient and uniform illumination (at least 450 lux).

The **Minimal Erythemal Dose (MED)** in human skin is defined as the lowest erythemal effective radiant exposure that produces the first perceptible unambiguous erythema with defined borders appearing over than 50% of the UV exposure subsite, 16 h to 24 h after UV exposure.

2.4 DATA ANALYSIS

The following data are analyzed:

	Parameter(s)	Statistic	Expected result
SPF	$\bar{x}$(SPFi) for tested product with Individual Sun Protection Factor (SPFi) SPFi = MEDip/MEDiu	95% CI < 17% of mean SPF	SPF equal or upper than excepted SPF
SPF P2	$\bar{\bar{x}}$(SPFi) for P2 Reference	/	Must be in the range [13.7; 18.5]
SPF P8	$\bar{\bar{x}}$(SPFi) for P8 Reference	/	Must be in the range [43.9; 82.3]

Individual data are presented in raw value tables (§3.2.2). These tables also show the statistical analysis.

2.4.1 Calculation formulas

The individual Sun Protection Factor (SPFi) is equal to the ratio of the Individual Minimal Erythemal Dose obtained with the product (MEDip) to the Individual Minimal Erythemal Dose obtained on the unprotected zone without product application (MEDiu):

$$\mathrm{SPFi} = \frac{\mathrm{MEDip}}{\mathrm{MEDiu}}$$

Individual SPF is calculated for the Reference Sunscreen Formulation and for each tested product.

The final SPF results (given to one decimal) is calculated as an arithmetical mean of all valid individual SPF (SPFi) values:

$$\mathrm{SPF} = \bar{x}(\mathrm{SPFi})$$

The minimum number of valid SPFi values must be ten and the maximum number of valid SPFi values twenty. A maximum of five results may be excluded from the calculation of the mean SPF, but each exclusion must be justified according to 2.4.2 or if protocol non-compliance has occurred. A sixth invalid result automatically invalidates the whole test for that test product and no SPF can be calculated for it.

SPF must be expressed to one decimal place by truncation.

2.4.2 Data rejection criteria

Test data are considered invalid and must be rejected according to the following circumstances:

	MEDiu	MEDip	Reference standard
No grade of at least 1 for any exposed subsites[a]	Data for subject is rejected. Does not count against total allowable rejected number of subjects.	Data for test product is rejected. Does not count against total allowable rejected number of subjects.	Data for subject is rejected. Failure counts against allowable rejected number of subjects.
All test subsites show erythema of at least grade 1[b]	Data for subject is rejected. Does not count against number of total allowable rejections.	Data for test product is rejected. Counts against number of total allowable rejections.	Data for subject is rejected. Counts against number of total allowable rejections.
erythemal response(s) is (are) absent for exposures higher than the determined MED dose (randomly absent)[c]	Data for subject is rejected. Does not count against number of total allowable rejections.	Data for subject is rejected. Counts against number of total allowable rejections.	Data for subject is rejected. Counts against number of total allowable rejections.
Non-compliance of the subject[d] OR **Technical failure**[e]	Data for subject is rejected. Does not count against number of total allowable rejections.	Data for subject is rejected. Does not count against number of total allowable rejections.	Data for subject is rejected. Does not count against number of total allowable rejections.

Observations definitions:

a **No Grade of at least 1 for any exposed sub:** All exposed subsites have grades of 0, or 0,5, and no qualifying MED (Grade 1) is observed.

b **All test sites show erythema of at least Grade 1:** No sites have grades of 0 or 0,5, and a MED response cannot be established.

c **Erythemal response(s) is (are) absent for exposures higher than the determined MED dose (randomly absent):** A Grade of 0 is observed at an exposure dose higher than the determined MED, (randomly absent or illogical sequence).

d **Non-compliance of the subject:** Subject does not follow instructions during or after the treatment or UV exposures that could affect the outcome of the test (wipes sunscreen treated areas during application or exposures, medicates with anti-inflammatory drugs, exposes treatment areas to UV light (sunlight or other UV source), irritates treated area, etc.).

e **Technical failure**: Failure of equipment or procedures during the treatment phases of the procedure (for example: incorrect lamp intensity or fluctuations, incorrect exposure times, incorrect site application of sunscreen, and similar reasons) that would jeopardize the integrity of the treatments and conclusions.

2.4.3 Statistical method

The statistical criterion for SPF measurements of the tested product is the 95 % confidence interval on the mean SPF measured which must comply with the ±17 % CI criteria of the measured mean SPF.

Consequently, the actual number of subjects tested must be defined as the number (minimum ten) required to produce a mean test product SPF with a 95 % confidence interval (CI) which falls within a range of ±17 % of the measured mean SPF for the tested.

A minimum of ten valid results is only sufficient if the statistical criterion is fulfilled. If not, the number of subjects must be increased from ten until the statistical criterion is met up to a maximum of twenty valid results.

The mean SPF of the reference sunscreen formulation used in the test must fall within the acceptance limits.

Reference sunscreen formulation	Mean SPF	Acceptance limits	
		Lower limit	Upper limit
P2	**16.1**	13.7	18.5
P8	**63.1**	43.9	82.3

2.4.4 Statistical software

The software used are EXCEL and SAS 9.4.

2.5 AUDIT AND TRIAL MONITORING VISIT

An audit and/or trial monitoring visit may be carried out at the Sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

3 PRINCIPLES AND RESULTS

3.1 SUN PROTECTION FACTOR (SPF)

3.1.1 Static SPF

The SPF test method is a laboratory method that utilizes a xenon arc lamp solar simulator of defined and known output to determine the protection provided by sunscreen products on human skin against erythema induced by solar ultraviolet rays.

The test must be restricted to the area of the back of selected human subjects.

A section of each subject's skin is exposed to ultraviolet light without any protection while another (different) section is exposed after application of the sunscreen product under test. One further section is exposed after application of an SPF reference sunscreen formulation, which is used for validation of the procedure.

To determine the SPF, 1.15 incremental series of delayed erythemal responses are induced on a number of small sub-sites on the skin. These responses are visually assessed for presence of erythema 16 h to 24 h after UV radiation, by the judgment of a trained and competent evaluator.

The individual minimal erythemal dose for unprotected skin (MEDiu) and the individual MED obtained after application of a sunscreen product (MEDip) are determined on the same subject on the same day. An individual sun protection factor (SPFi) for each subject tested is calculated as the ratio of individual MED on product protected skin divided by the individual MED on unprotected skin, as in the formula given in 2.4.

The SPF for the product is the arithmetic mean of all valid SPFi results from each subject in the test expressed to one decimal place.

The method is controlled using one of five reference sunscreen formulations to verify the test procedure. Therefore, one of the prescribed reference formulations must be measured on the same day as products are tested. Whether a low or high SPF reference formulation is to be used depends on the expected SPF of the test products:
— SPF Claim ≤ 24:any reference standard may be used for each subject;
— 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.

Visual assessment is performed in sufficient and uniform illumination. At least 450 lux in the plane parallel with the back of the test subject is required using a lamp with a colour temperature of 6 500°K.
The assessor's eyesight for normal colour vision has been checked.

Erythemal responses are assessed in a "blind" manner: assessor(s) is(are) not informed of subject test design and each of them has his own card of readings. In case of assessments by at least two assessors, readings are then compared and a discussion could be occurred in case of discrepancies. Final reading reported in the report corresponds to the assessment of the majority.

Note: technician who conducts applications can be included in the pool of assessors. However, the opinion of this technician considered only in case of discrepancies between the other assessors.

3.2 Results

According to ISO 24444, a minimum of 10 valid results is sufficient if the statistical criterion is fulfilled.
This test is done on 12 subject with 10 subjects with valid results (for both tested product and reference)

3.2.1.1 SPF Test Report (All Data)

MRX008-4 SPF 30 INVISIBLE *(application WITH finger cot)*

Static SPF

ISO 24444 (2019) Test Method					Laboratory:	Eurofins DERMSCAN		Report Date:	2023-07-07	Dose Increments:	1,15
Test Product Description:	Reference#	MRX008-4 SPF 30 INVISIBLE			STATIC SPF		Application	WITH LATEX	FINGERCOT		

	TEST				SIM	TEST SUBJECTS							
Subj.	Exposure	Applied	Exp.	Read	Sim EE (highest)	Subject	Skin	MEDiu / MEDisu		MEDip / MEDisp		SPFi	Rej.?
N°	date	by	by	by	W/m2 eff.	code	ITA°	mm:ss	J/m² eff.	mm:ss	J/m² eff.		Y? or N?
1	2023-05-22	8	8	2 5 6	10,4	ZA A	42	00:46	363	19:10	NO MARK	/	Y
2	2023-05-25	5	5	4 6 7 8	10,5	GA B	55	00:33	301	16:30	10397	34,5	N
3	2023-05-29	3	3	4 6	8,5	AD M	51	00:45	253	26:15	13460	53,2	N
4	2023-05-30	8	8	2 7	8,4	DA P	57	00:39	188	26:00	9959	52,9	N
5	2023-06-01	3	3	2 5 6 8	8,6	MI A	46	00:51	380	38:15	19641	51,6	N
6	2023-06-12	4	4	5 7	10,6	JA K	45	00:42	256	35:00	NO MARK	/	Y
7	2023-06-13	4	4	6 7	10,4	WA M	42	00:46	480	46:00	28807	60,0	N
8	2023-06-15	4	4	5 8	10,6	ŁA W	50	00:37	343	37:00	15545	45,3	N
9	2023-06-22	5	5	1 6 7	8,5	GÓ M	47	00:50	322	45:50	20365	63,2	N
10	2023-06-27	8	8	1 7	10,4	FA A	51	00:37	253	37:00	15180	60,0	N
11	2023-06-28	3	3	4 7	8,5	PR J	51	00:45	385	41:15	18393	47,7	N
12	2023-06-29	3	3	4 8	7,6	FL P	60	00:40	199	36:40	12614	63,3	N

FINAL RESULT	FULL

Test Product	MRX008-4 SPF 30 INVISIBLE											
Avg. SPF	53,1	Std. Dev.	9,1	c	6,5	CI [%]	12,2	95%CI	[46,6 ; 59,6]	17% of Mean	9	Number of valid results	10

	P8	(with fingercot)		Ref. Standard B #		P2					
Avg. SPF	74,3	Std. Dev.	16,8	c	17,6	17% of Mean	12,6		Acceptance limits	[43,9;82,3]	

	P2	with fingercot									
Avg. SPF	16,0	Std. Dev.	2,0	c	2,1	17% of Mean	2,7		Acceptance limits	[13,7;18,5]	

Legend: ***()****: value not included in data analysis*
c *= t * s / √n with: t = t value from « two-sided » Student-t test for the 95% Confidence Interval*

3.2.1.2 Test Report Valid Data (only)

***MRX008-4 SPF 30 INVISIBLE** (application WITH finger cot)*

Static SPF

ISO 24444 (2019) Test Method					Laboratory:	Eurofins DERMSCAN		Report Date:	2023-07-07		Dose Increments:	1,15	
Test Product Description:	Reference#	MRX008-4 SPF 30 INVISIBLE			STATIC SPF			Application		WITH LATEX	FINGERCOT		
	TEST				SIM	TEST SUBJECTS							
Subj.	Exposure	Applied	Exp.	Read	Sim EE (highest)	Subject	Skin	MEDiu / MEDisu		MEDip / MEDisp		SPFi	Rej.?
N°	date	by	by	by	W/m2 eff.	code	ITA°	mm:ss	J/m² eff.	mm:ss	J/m² eff.		Y? or N?
2	2023-05-25	5	5	4 6 7 8	10,5	GA B	55	00:33	301	16:30	10397	34,5	N
3	2023-05-29	3	3	4 6	8,5	AD M	51	00:45	253	26:15	13460	53,2	N
4	2023-05-30	8	8	2 7	8,4	DA P	57	00:39	188	26:00	9959	52,9	N
5	2023-06-01	3	3	2 5 6 8	8,6	MI A	46	00:51	380	38:15	19641	51,6	N
7	2023-06-13	4	4	6 7	10,4	WA M	42	00:46	480	46:00	28807	60,0	N
8	2023-06-15	4	4	5 8	10,6	ŁA W	50	00:37	343	37:00	15545	45,3	N
9	2023-06-22	5	5	1 6 7	8,5	GÓ M	47	00:50	322	45:50	20365	63,2	N
10	2023-06-27	8	8	1 7	10,4	FA A	51	00:37	253	37:00	15180	60,0	N
11	2023-06-28	3	3	4 7	8,5	PR J	51	00:45	385	41:15	18393	47,7	N
12	2023-06-29	3	3	4 8	7,6	FL P	60	00:40	199	36:40	12614	63,3	N
FINAL RESULT			FULL										
Test Product					MRX008-4 SPF 30 INVISIBLE								
Avg. SPF	53,1	Std. Dev.	9,1	c	6,5	CI [%]	12,2	95%CI	[46,6 ; 59,6]	17% of Mean	9	Number of valid results	10

Legend: ***()****: value not included in data analysis*
***c** = t * s / √n with: t = t value from « two-sided » Student-t test for the 95% Confidence Interval*

3.2.1.3 SPF Test Report Invalid Data (only)

***MRX008-4 SPF 30 INVISIBLE** (application WITH finger cot)*

Static SPF

ISO 24444 (2019) Test Method					Laboratory:	Eurofins DERMSCAN		Report Date:	2023-07-07		Dose Increments:	1,15
Test Product Description:	Reference#	MRX008-4 SPF 30 INVISIBLE			STATIC SPF			Application	WITH LATEX	FINGERCOT		
	TEST				SIM	TEST SUBJECTS						
Subj.	Exposure	Applied	Exp.	Read	Sim EE (highest)	Subject	Skin	MEDiu / MEDisu		MEDip / MEDisp		SPFi	Rej.?
N°	date	by	by	by	W/m2 eff.	code	ITA°	mm:ss	J/m² eff.	mm:ss	J/m² eff.		Y? or N?
1	2023-05-22	8	8	2 5 6	10,4	ZA A	42	00:46	363	19:10	NO MARK	/	Y
6	2023-06-12	4	4	5 7	10,6	JA K	45	00:42	256	35:00	NO MARK	/	Y

Legend: ***()***: value not included in data analysis*
***c** = t * s / √n with: t = t value from « two-sided » Student-t test for the 95% Confidence Interval*

Results of this test are reliable because:

P2/P8 Reference	$\bar{x}$ (SPF_{P2}) in the range [13.7 ; 18.5] $\bar{x}$ (SPF_{P8}) in the range [43.9 ; 82.3]	✓
MRX008-4 SPF 30 INVISIBLE	c < 17% of $\bar{x}$($SPF_{tested\ product}$)	✓

3.3 UNDESIRABLE EFFECTS / ADVERSE EVENTS

No Serious Adverse Event was reported during the study.

No Undesirable Effect was observed during the study.

4 CONCLUSION

Under these study conditions:

Product « **MRX008-4 SPF 30 INVISIBLE** »:

- has an average SPF of **53.1**.

5 CERTIFICATION

The study will be conducted according to Helsinki Declaration (1964) and its successive updates. Data are obtained using the study protocol, current internal procedures and as closely as possible to the guidance on Good Clinical Practice CPMP / ICH / 135 / 95 (R2).

This study is totally performed under the responsibility of EUROFINS Dermscan/Pharmascan.

All the observations and numerical data collected throughout the study are reported in this document and are in accordance with the obtained results.

	HEAD OF SOLAR DEPARTMENT	SOLAR PROJECT COORDINATOR ASSISTANT
Name	**Anna LUDWIKOWSKA**	**Kinga CHORĄŻY**
Date	July 7, 2023	
Signature		

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the Sponsor or independently.

The on-line publishing, on the Internet, of this study report with the names and signatures is strictly prohibited.

6 BIBLIOGRAPHY

Regulatory

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2. WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI/ Ethical Principles for Medical Research Involving Human Subjects- Helsinki Declaration (1964) and its successive updates.

3. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 30 November 2009 on cosmetic products (recast).

Sun Protection Evaluation

1- AS/NZS 2604:2021, *Sunscreen products — Evaluation and classification*

2- ISO 24444:2019: Cosmetics -- Sun protection test methods -- In vivo determination of the sun protection factor (SPF) + Amendement 1:2022

3- CHARDON, A., CRETOIS, I., HOURSEAU, C., Skin color typology and suntanning pathways, Int. J. Cosmet. Sci., 13, pp. 191–208, 1991.

4- Declaration of Helsinki, adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983 and by the 41th World Medical Assembly, Hong Kong, September 1989.

5- BURNET H, BONNOT A, BRUZZONE M, OBADIA G, BOUET A, SIRVENT A, GIRARD-ORY F./ Interest of a shutter on solar simulator for determination of the MEDu.- ISBS Congress. 2016 June 1-3rd, Lisbon (Portugal)

APPENDICES:

DETAILED RESULTS
&
ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

7 APPENDICES –DETAILED RESULTS

7.1 SUBJECTS' CHARACTERISTICS

Subject#	Last name	First name	Sex	Age	Skin type (Normal/dry)	Phototype	Comments	Inclusion date yyyy-mm-dd	End date
1	ZA	A	F	51	Normal	II	NO MARK	2023-05-22	2023-05-24
2	GA	B	F	51	Normal	I	None	2023-05-25	2023-05-26
3	AD	M	F	32	Normal	I	None	2023-05-29	2023-05-30
4	DA	P	F	31	Normal	I	None	2023-05-30	2023-05-31
5	MI	A	F	29	Normal	II	None	2023-06-01	2023-06-02
6	JA	K	F	45	Normal	II	NO MARK	2023-06-12	2023-06-13
7	WA	M	F	26	Normal	II	None	2023-06-13	2023-06-14
8	ŁA	W	F	45	Normal	I	None	2023-06-15	2023-06-16
9	GÓ	M	F	47	Normal	II	None	2023-06-22	2023-06-23
10	FA	A	F	28	Normal	I	None	2023-06-27	2023-06-28
11	PR	J	F	30	Normal	I	None	2023-06-28	2023-06-29
12	FL	P	F	28	Normal	I	None	2023-06-29	2023-06-30

	Age	Sex		Skin type	
Mean	**37**	**F**	12	**Normal**	12
Median	32	**M**	0	**Dry**	0
Minimum	26			**Combination**	0
Maximum	51			**Greasy**	0
SEM	**3**				
95% CI	6				
SD	**10**				

7.2 P2/P8 REFERENCE RESULTS

ISO 24444 (2019) Test Method					Laboratory: Eurofins DERMSCAN						Report Date: 2023-07-07			
Test Product Description: Reference#			MRX008-4 SPF 30 INVISIBLE		STATIC SPF									
	TEST				SIM	TEST SUBJECTS								
Subj.	Exposure	Applied	Exp.	Read	Sim EE (highest)	Subject	Skin	MEDiu / MEDisu		Ref. Standard A # Tested SPF		P8 55	Ref. Standard B # Tested SPF		P2 16
N°	date	by	by	by	W/m2 eff.	code	ITA°	mm:ss	J/m² eff.	mm:ss	J/m² eff.	SPFi	mm:ss	J/m2 eff.	SPFi
1	2023-05-22	8	8	2 5 6	10,4	ZA A	42	00:46	363	42:10	26428	**72,8**	00:00		
2	2023-05-25	5	5	4 6 7 8	10,5	GA B	55	00:33	301	30:15	16574	**55,0**	00:00		
3	2023-05-29	3	3	4 6	8,5	AD M	51	00:45	253	41:15	21151	**83,6**	00:00		
4	2023-05-30	8	8	2 7	8,4	DA P	57	00:39	188	35:45	18109	**96,3**	00:00		
5	2023-06-01	3	3	2 5 6 8	8,6	MI A	46	00:51	380	46:45	20874	**54,9**	00:00		
6	2023-06-12	4	4	5 7	10,6	JA K	45	00:42	256	38:30	21375	**83,4**	00:00		
7	2023-06-13	4	4	6 7	10,4	WA M	42	00:46	480	00:00			12:16	6680	**13,9**
8	2023-06-15	4	4	5 8	10,6	ŁA W	50	00:37	343	00:00			09:52	4767	**13,8**
9	2023-06-22	5	5	1 6 7	8,5	GÓ M	47	00:50	322	00:00			13:20	5152	**16,0**
10	2023-06-27	8	8	1 7	10,4	FA A	51	00:37	253	00:00			09:52	4655	**18,3**
11	2023-06-28	3	3	4 7	8,5	PR J	51	00:45	385	00:00			12:00	6153	**15,9**
12	2023-06-29	3	3	4 8	7,6	FL P	60	00:40	199	00:00			10:40	3670	**18,4**
	P8	(with fingercot)													
Avg. SPF	74,3	Std. Dev. **16,8**		c **17,6**		17% of Mean **12,6**									
	P2	with fingercot													
Avg. SPF	16,0	Std. Dev. **2,0**		c **2,1**		17% of Mean 2,7									

8 APPENDICES - ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

8.1 ADVERSE EVENT

8.1.1 Adverse Event (AE)

Any noxious symptom, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the study or the study product(s) (e.g. flu, headache, abnormal biological analysis…).

8.1.2 Undesirable Effect (UE) / Adverse Reaction (AR)

For a cosmetic product, an **undesirable effect** is defined as an adverse reaction for human health attributable to the normal or reasonably foreseeable use of the cosmetic product(s).
There are 5 levels of imputability: very likely, likely, not clearly attributable, unlikely and excluded (ANSM methodology).

The severity/intensity of undesirable effects/adverse events can be graded on a three-point scale:

- **mild**: discomfort noted, that does not disturb normal daily activities;
- **moderate**: discomfort sufficient to reduce or affect normal daily activities;
- **severe**: inability to work or have normal daily activities.

8.1.3 Serious Adverse Event (SAE) / Serious Undesirable Effect (SUE)

Any event that:

- results in death (note: death is the outcome, not the event);
- is life threatening;
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion);
- results in temporary or permanent functional incapacity or disability;
- is a congenital anomaly;
- is considered like by the investigator.

8.1.4 Documentation

All concomitant treatments are reported in the CRF (Case Report Form) and in the study report.

All Undesirable Effects are reported in the CRF and the study report.
If it requires the temporary or definitive termination of the study product, the need for a corrective treatment or the withdrawal of the subject, an Adverse Event form is completed.

All SAE/SUE are reported in the CRF and the study report.

8.1.5 Notification

The investigator declares to the Sponsor, by e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All SAE/SUE are transmitted by e-mail to the Sponsor without delay, at the latest 24 hours after knowledge of their occurrence.
A SAE/SUE declaration form signed by a physician is sent, within 48 hours, by e-mail with acknowledgement of receipt.

8.1.6 Follow-up

When an adverse event linked to the investigational product or the protocol persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution of the event or stabilization of the symptoms without releasing the Sponsor of any obligation or responsibility.

8.1.7 Occurrence of pregnancy

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the study product(s) nor the protocol and induces the immediate dropping out of the subject.
Any pregnancy that occurs during the study period is reported by e-mail to the Sponsor within 24 hours following its discovering.
A follow-up is done according to the current internal procedures until the completion/termination of the pregnancy or its interruption.

8.2 PREMATURE TERMINATION OF SUBJECT PARTICIPATION

In compliance with the Helsinki Declaration (1964) and its successive updates, subjects have the right to exit from the study at any time and for any motive.

The investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of an adverse reaction.

The Sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive however this would need to be clearly documented with a rationale as to why.

Nevertheless, premature removal of a high percentage of subjects from the study can make it difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.

Every premature exit must be classified under one of the following headings:
- presence of a non-inclusion criteria;
- Undesirable Effect / Adverse Event occurrence;
- Serious Adverse Event / Serious Adverse Effect occurrence;
- withdrawal of consent;
- lost to follow-up;
- appearance of non-inclusion criteria;
- non-adherence to the protocol;
- other reason.

No replacement is foreseen as 10% additional subjects are planned to be included in the study.

8.3 CONFIDENTIALITY AND DATA PROTECTION

In this study, EUROFINS Dermscan/Pharmascan processes personal data of subjects on behalf of the Sponsor, in accordance with the rules on the protection of personal data and, in particular, the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data. For this purpose, EUROFINS Dermscan/Pharmascan limits the collection and use of personal data to that which is needed for analysis and control purposes, by ensuring their security and integrity and by guaranteeing their confidentiality.
EUROFINS Dermscan/Pharmascan makes sure beforehand and throughout the duration of the data-processing:
- of the compliance with the obligations of the applicable data protection law,
- to inform subjects of their personal data-processing after obtaining their consent,
- to implement and maintain appropriate technical and organisational measures.

An identification code is attributed to each subject for the purpose to keep his/her identity confidential. This code consists of the first two letters/first letter of the subject's name and the first letter of his/her first name.

According to Article 14 of GDPR, the concerned subject must be informed of the identity and the contact details of the Controller and, where applicable, of the controller's representative. However, considering the objective of the study, to avoid any bias in the investigational product evaluation, the identity of the Sponsor is not revealed to the subject participating.

8.4 DATA COLLECTION AND VALIDATION

The personnel in charge of the study (technician, physician …) adds data to subject case report form and to a computerized data base.
The simple data entry is done from the case report forms by the designed technician(s) or operator(s), without any interpretation, in specific MS EXCEL databases.
Then the Project Manager or assistant checks the coherence between computed data and information in the study documents. He/She also checks formulas used in the EXCEL tables (calculation formulas, selected data…).
The coherence of data coming directly from measurement software(s) is also checked and validated by the Project Manager or assistant.
When all CRF are computed and all controls done, the database is locked.

8.5 QUALITY MANAGEMENT

In order to ensure that the clinical trials are in compliance with the Sponsor's requirement, EUROFINS Dermscan has implemented a quality management system which has been certified ISO 9001: 2015
This quality assurance system includes Good Clinical Practices (GCP) and regulation requirements.

Solar study report is written by the technician in charge of the study and controlled by the Solar Project Manager or his assistant before being sent to the sponsor. The inspection of the study report allows to confirm that the results reflect exactly the study raw data and that the study fulfils any standard and regulatory requirements.

8.6 ARCHIVES OF STUDY DOCUMENTS

<table>
<tr><td rowspan="2">STUDY DOCUMENTS AND DATA</td><td colspan="3">TIME AFTER DISPATCH OF THE FINAL REPORT:
investiga-tion center → service provider → destruction
0 1 (maximum) 10 YEARS</td></tr>
<tr><td>Paper</td><td>Stored at the investigation center</td><td>Securely archived at an approved service provider</td><td rowspan="2">Destruction of the archives unless otherwise stipulated in writing by the Sponsor</td></tr>
<tr><td>Digital</td><td colspan="2">Securely archived</td></tr>
</table>

9 INSTRUMENTATION

9.1 SOLAR SIMULATOR

UV SOURCES	
Solar Light type Multiport 601-300W and Multiport 601-300W v2.5	
Type	xenon lamp
Filters	WG320 (1.25 mm) UG11 (1mm) to eliminate IR and visible radiation
Spectrum	290 to 400 nm
Radiated surface	Six squares ≥ 0.5cm^2
Power	300 W
Minimal Erythemal Dose (MED) determination	The UV flow of each optical fiber is determined by the technician to obtain a geometric progression of 15% for all the **exposures.** As the system is used with a constant flow, all the fibers are opened at the same time.
UV LIGHT RADIOMETERS	
One specific for each Solar Light	
Radiometers	**Detectors**
Solar Light Co. PMA2100 S/N Solar Light Model DCS_2	Solar Light Co. Erythema detector PMA2103 / PMA2108

9.2 CONFORMITIES

9.2.1 Conformity of the Solarlight #22637

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L29/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W V2.5 serial number 22637
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:
Marko Weber, M.Eng.

Test performed by:
DI Wolfgang Müllner

Date: 10.03.2023
Number of pages: 20
Internal Order Number: L-2637

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory.

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SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0271	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 0272	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.2.2 Conformity of the Solarlight #24313

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
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TEST REPORT No. LE-L30/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W V2.5 serial number 24313
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:

Marko Weber, M.Eng.

Test performed by:

DI Wolfgang Müllner

Date: 10.03.2023
Number of pages: 21
Internal Order Number: L-2637

Comments:
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Bank details: Erste Bank der Österreichischen Sparkassen AG | Sort Code 20111 | Account No. 291-140-380/00 | IBAN AT112011129114038000 | BIC GIBAATWW

SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0273	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 0274	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.2.3 Conformity of the Solarlight #13560

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
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TEST REPORT No. LE-L28/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W serial number 13560
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:
Marko Weber, M.Eng.

Test performed by:
DI Wolfgang Müllner

Date: 14.03.2023
Number of pages: 21
Internal Order Number: L-2637

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
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www.seibersdorf-laboratories.at | Regional court Wiener Neustadt | Comp.No. 319187v | DVR No: 4000728 | VAT: ATU64767504 | Tax No: 192/6571 | Certified acc. to ISO 9001
Bank details: Erste Bank der Österreichischen Sparkassen AG | Sort Code 20111 | Account No. 291-140-380/00 | IBAN AT112011129114038000 | BIC GIBAATWW

SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0270	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 1150	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.2.4 Conformity of the Solarlight #27618

SEIBERSDORF LABORATORIES

ACCREDITED TESTING LABORATORY (NR. 312)
for Laser, LED and Lamp Safety
Akkreditierung Austria is a full member of the International Laboratory Accreditation Cooperation ILAC and a signatory of the MRA for "Testing, Calibration and Inspection"

TEST REPORT No. LE-L31/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W V2.5 serial number 27618
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:
Marko Weber, M.Eng.

Test performed by:
DI Wolfgang Müllner

Date: 14.03.2023
Number of pages: 21
Internal Order Number: L-2637

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory.

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Bank details: Erste Bank der Österreichischen Sparkassen AG | Sort Code 20111 | Account No. 291-140-380/00 | IBAN AT112011129114038000 | BIC GIBAATWW

SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0370	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 0371	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.2.1 Conformity of the Solarlight #28853

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TEST REPORT No. LE-L32/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W V2.5 serial number 28853
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:
Marko Weber, M.Eng.

Test performed by:
DI Wolfgang Müllner

Date: 14.03.2023
Number of pages: 20
Internal Order Number: L-2637

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory.

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www.seibersdorf-laboratories.at | Regional court Wiener Neustadt | Comp.No. 319187v | DVR No: 4000728 | VAT: ATU64787504 | Tax No: 192/6571 | Certified acc. to ISO 9001
Bank details: Erste Bank der Österreichischen Sparkassen AG | Sort Code 20111 | Account No. 291-140-380/00 | IBAN AT112011129114038000 | BIC GIBAATWW

SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0372	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 0373	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.2.1 Conformity of the Solarlight #29319

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TEST REPORT No. LE-L33/23

Scope:	Measurement of spectral irradiance of a solar simulator according to the "Guidelines for Monitoring UV Radiation Sources" (Cosmetics Europe, 2007) to evaluate the UV source compliance with various test methods and determination of correction factors for handheld UV radiometers
Customer:	Eurofins - Dermscan Poland
Ordered by:	SAM MONADERM 5, rue des violettes, 98000 Monaco, MONACO
Device under test:	Solar Light Multiport 601-300W V2.5 serial number 29319
Status of compliance:	The device under test and all investigated settings are compliant with the relevant international standards (see summary on page 2)

Authorised person:
Marko Weber, M.Eng.

Test performed by:
DI Wolfgang Müllner

Date: 10.03.2023
Number of pages: 20
Internal Order Number: L-2637

Comments:
This test report refers exclusively to the device under test and settings thereof at the date of test. Subsequent changes to the device under test are not covered by this report.
The production or transmission of extracts of the present report is subject to authorisation by the testing laboratory.

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www.seibersdorf-laboratories.at | Regional court Wiener Neustadt | Comp.No. 319187v | DVR No: 4000728 | VAT: ATU64767504 | Tax No: 192/6571 | Certified acc. to ISO 9001
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SEIBERSDORF LABORATORIES

1. Status of compliance

The compliance of the device under test with the requirements of various test methods is summarized in Table 1. Further details are given in sections 4 of this test report.

Table 1 Status of compliance for the device under test when operated with different filters and bulbs.

		Test method		
Bulb	**Setting**	**In vivo SPF (ISO 24444)**	**SPF test procedure (FDA OTC Monograph M020, 2021)**	**In vivo UVA (ISO 24442)**
ZB 0374	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant
ZB 0375	UVA	Irrelevant	Irrelevant	**Pass**
	UVA + UVB	**Pass**	**Pass**	Irrelevant

All indications of Pass/Fail in this report are opinions expressed by Seibersdorf Laboratories based on interpretations and/or observations of test results.

Remark: in-vivo UVA and SPF specifications include an irradiance limitation of 1600 W m^{-2} (1500 W m^{-2} for FDA). To meet this requirement, it might be necessary to reduce the intensity manually by closing individual ports partially. The values not to be exceeded are reported in section 5.3 of this Test Report.

9.3 APPENDICE - Reference Sunscreen Formulation

9.3.1 P2 Reference Sunscreen Formulation

RIGANO LABORATORIES S.r.l.
Industrial Consulting & Research

Date: February 18th, 2022 Prot. 18/22

ANALYSIS REPORT
P2 HIGH SPF STANDARD

(I) GENERAL DATA

Sample	P2 HIGH SPF STANDARD – Batch n° 1/22
Date of Analysis	February 2nd, 2022
Expiry Date	February 2nd, 2024 (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)	0.985 [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	26000 [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*	6.99	7.00±0.35	0.67
Benzophenone-3*	2.99	3.00±0.15	0.17

*HPLC **ISO/DIS 24444

Dr NicolaLionetti

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9.3.1 P8 Reference Sunscreen Formulation

LabAnalysis HIGH QUALITY CONTROLS ISPE Institute of Skin and Product Evaluation RIGANO Rigano Laboratories S.r.l.

Date: September 29th, 2022 Prot. 114/22

ANALYSIS REPORT

P8 SPF 63 REFERENCE STANDARD

(I) GENERAL DATA

Sample	P8 SPF 63 REFERENCE STANDARD – Batch n° 12/22
Date of Analysis	September 6th, 2022
Expiry Date	September 6th, 2023

(II) PHYSICAL-CHEMICAL DATA

Physical-chemical data	Detected data	ISO 24444:2019 acceptability limits
Appearance	Homogeneous creamy emulsion	White cream
Colour	White	
Odour	Characteristic	-
pH-value (directly)	7.2	7.1±0.3
Density	1.00 [g/cm^3]	0.97 to 1 [g/cm^3]
Viscosity (Brookfield DVIII Ultra; Spindle RV-5) 10 rpm	13000 [cps]	12000-15000 [cps]

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LabAnalysis S.r.l Unipersonale, Company under management and coordination of LabAnalysis Group S.r.l
Share Capital €103.000,00 fully paid – Registration Office of Pavia – VAT.N. 02235450182- R.E.A. CCIAA of Pavia n.257033

LabAnalysis HIGH QUALITY CONTROLS ISPE Institute of Skin and Product Evaluation RIGANO Rigano Laboratories S.r.l.

(III) ANALYTICAL DATA (Content)

Method: ISO 24444:2019 + UNI EN 16344

Analyte	Detected [% w/w]	Expected: Theoretical±5% [% w/w]	Standard coefficient of variation % [≤ 2.5%]
BIS-ETHYLHEXILOXYPHENOL METHOXYPHENYL TRIAZINE (CAS 187393-00-6)	3.10	3.00±0.15	0.28
ETHYLHEXYL METHOXYCINNAMATE (CAS 5466-77-3)	5.00	5.00±0.25	0.55
ETHYLHEXYL SALICYLATE (CAS 118-60-5)	3.08	3.00±0.15	0.25
METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL (CAS 103597-45-1)	10.34	10.00±0.50	0.39

Dr Nicola Lionetti

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