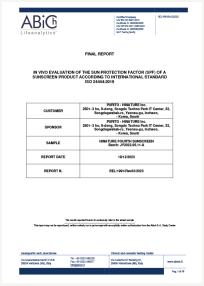
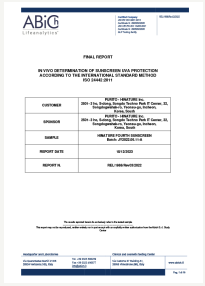
PURITO Daily Soft Touch Sunscreen
Protection Factor Final Report

“HINATURE Fourth Sunscreen” is the sample name of the Purito Seoul Daily Soft Touch Sunscreen.

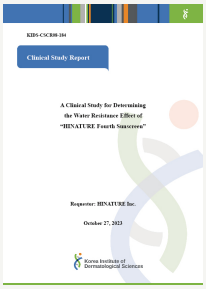
01. Sun Protector Factor (SPF) - Italy(ABICH)



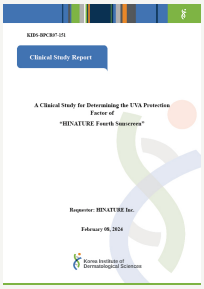
02. UVA Protection Factor (UVAPF) - Italy(ABICH)



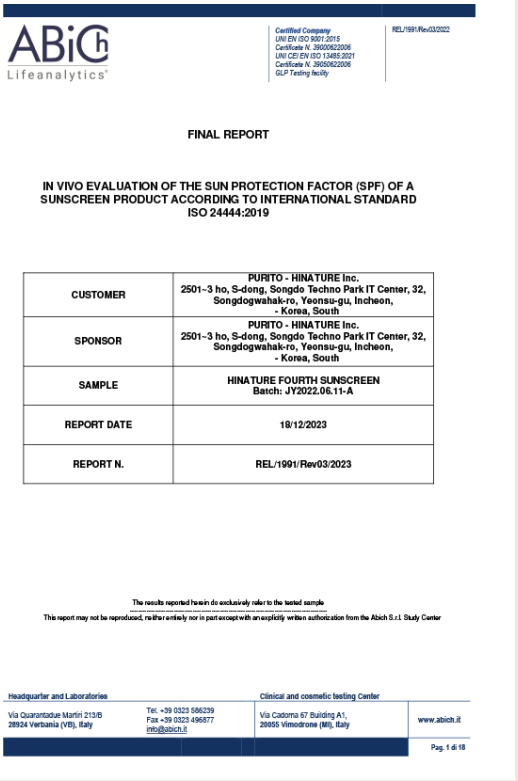
03. Sun Protector Factor (SPF) - Korea(Korea Institute of Dermatological Sciences)



04. UVA Protection Factor (UVAPF) - Korea(Korea Institute of Dermatological Sciences)



01. Sun Protector Factor (SPF) - Italy(ABICH)



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FINAL REPORT

IN VIVO EVALUATION OF THE SUN PROTECTION FACTOR (SPF) OF A SUNSCREEN PRODUCT ACCORDING TO INTERNATIONAL STANDARD ISO 24444:2019

CUSTOMER	**PURITO - HINATURE Inc. 2501-3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, - Korea, South**
SPONSOR	**PURITO - HINATURE Inc. 2501-3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, - Korea, South**
SAMPLE	**HINATURE FOURTH SUNSCREEN Batch: JY2022.06.11-A**
REPORT DATE	**19/12/2023**
REPORT N.	**REL/1991/Rev03/2023**

The results reported herein do exclusively refer to the tested sample
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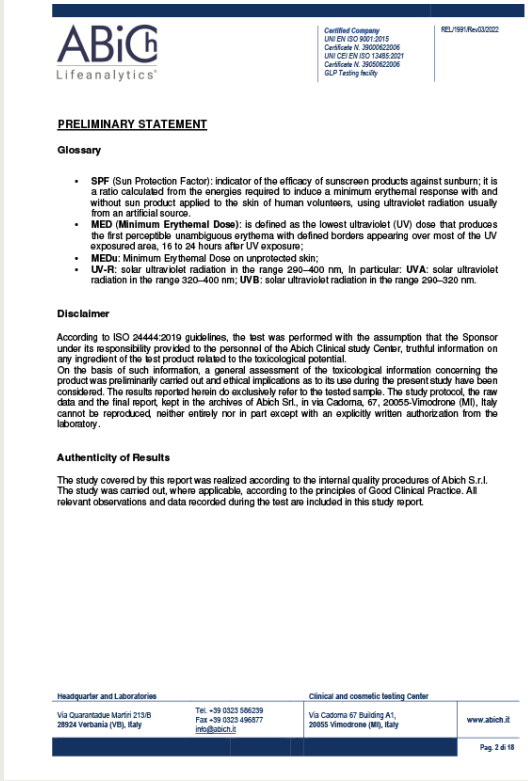

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PRELIMINARY STATEMENT

Glossary

- **SPF** (Sun Protection Factor): indicator of the efficacy of sunscreen products against sunburn; it is a ratio calculated from the energies required to induce a minimum erythemal response with and without sun product applied to the skin of human volunteers, using ultraviolet radiation usually from an artificial source.
- **MED** (**Minimum Erythemal Dose**): is defined as the lowest ultraviolet (UV) dose that produces the first perceptible unambiguous erythema with defined borders appearing over most of the UV exposured area, 16 to 24 hours after UV exposure;
- **MEDu**: Minimum Erythemal Dose on unprotected skin;
- **UV-R**: solar ultraviolet radiation in the range 290–400 nm, In particular: **UVA**: solar ultraviolet radiation in the range 320–400 nm; **UVB**: solar ultraviolet radiation in the range 290–320 nm.

Disclaimer

According to ISO 24444:2019 guidelines, the test was performed with the assumption that the Sponsor under its responsibility provided to the personnel of the Abich Clinical study Center, truthful information on any ingredient of the test product related to the toxicological potential.
On the basis of such information, a general assessment of the toxicological information concerning the product was preliminarily carried out and ethical implications as to its use during the present study have been considered. The results reported herein do exclusively refer to the tested sample. The study protocol, the raw data and the final report, kept in the archives of Abich Srl., in via Cadorna, 67, 20055-Vimodrone (MI), Italy cannot be reproduced, neither entirely nor in part except with an explicitly written authorization from the laboratory.

Authenticity of Results

The study covered by this report was realized according to the internal quality procedures of Abich S.r.l. The study was carried out, where applicable, according to the principles of Good Clinical Practice. All relevant observations and data recorded during the test are included in this study report.

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Revision history

Rev.	Date	Description
00	16/09/2022	First emission
01	26/09/2022	Typo in the table of contents
02	17/10/2022	Variation Inci
03	18/12/2023	Product name change at customer's request and inserted new study director in charge since Nov. 20 to formally sign off on review

1. PART ONE – GENERAL INFORMATION

1.1. Customer

PURITO - HINATURE Inc.
2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon - Korea, South

1.2. Sponsor

PURITO - HINATURE Inc.
2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon- Korea, South

1.3. Test Product

Name:	**HINATURE FOURTH SUNSCREEN**
Batch:	JY2022.06.11-A
Expected SPF:	50+
Aspect:	yellowish cream
Abich sample code:	3048/22-03
INCI Composition:	see annex
Pao / expiration date:	n.a.
Storage conditions:	room temperature
Received date:	15/07/22

1.4. Assay

In vivo evaluation of the sun protection factor (SPF) of a sunscreen product according to standard ISO 24444:2019

1.5. Entrusted Laboratory

Abich S.r.l.- Clinical and Cosmetological Trials Center
Via Cadorna, 67 Building A/1
20055 - Vimodrone (MI) - Italy

1.6. Study Dates

Start: 18/07/2022
End: 14/09/2022

1.7. Study Director (In charge during the execution of the study in 2022):

[redacted]

1.8. Study Director* (In charge from 20/11/23):

[redacted]

1.9. Clinical Supervisor:

[redacted]

1.10. Deviations:

No deviation from the study protocol occurred during the test.

1.11. Adverse reactions:

No adverse reactions were observed during the test.

1.12. Archiving:

The study protocol, the raw data and the final report are kept in the archives of Abich clinical Study Center, in Via Cadorna, 67, 20055-Vimodrone (MI), both in electronic format and in reduced paper format for a period of 5 years from the issue of the final report.
The control sample of the test substance and eventual specific reference material are kept for 3 months, unless a specific request is provided by the customer.

2. PART TWO – GENERAL INFORMATION OF STUDY DESIGN

2.1. Purpose of the test

The aim of the test is to determine in vivo the sun protection factor of a sunscreen product according to EU regulations.
The SPF measurement procedure is described by International Standard method ISO 24444:2019(E) (second edition 2019-12)
This study has been carried out in compliance with the most recent recommendations of the Helsinki Declaration (64th WMA General Assembly, Fortaleza, Brazil, October 2013).

2.2. Selection criteria: Panel characteristics

The study was performed on male and female volunteers, with age between 18 and 70 years, who have been identified from specified criteria of exclusion, from the database of volunteers of the Abich Test Center.
The subjects included in the SPF test panel shall have an ITA° value >28° by colorimetric methods and be untanned on the test area.
The correlation between the color of the skin and the ITA° value is represented in the following table:

Table 1

Description	ITA° Value
Very light	>55°
Light	>41 to 55°
Intermediate	>28 to 41°
Tanned (or matt)	>10 to 28°
Brown	>-30 to 10°
Black	≤-30°

Where ITA° = [arctg((L*-50)/b*)]x180/3.1416

The average of the subjects making up the test panel had an ITA° between 41° and 55°. When possible, there were subjects with ITA°s in each of the three ITA° bands, 28° to 40°, 41° to 55°, and >56°. Where this is not possible, there were at least three individuals in each of two of the three ITA° bands described in the previous sentence.

The test sites intended for UV exposure were free from blemishes and hair, and had an even color tone with no variation in ITA° greater than 5° from each other or the MED test area.

The following exclusion criteria were applied:

- Pregnant or lactating women;
- Persons below the age of consent or >70 years;
- Subjects with discolorations, any kind of skin marks, including tattoos, scars, burns, or their outcomes, excessive hairs, which can interfere with the reading of the assay;
- Subjects undergoing therapy that might interfere with the test results (i.e., photosensitising, anti-inflammatory drugs);

- Subjects having skin irritation at the application site;
- Subjects having skin diseases or anatomical skeletal protrusion which could interfere with the aim of this study;
- Subjects with skin hyperpigmentation caused from exposure to solar radiation or artificial (tanning beds);
- Subjects with a history of adverse events related to sun exposure (as abnormal response to the sun);
- Subject participating in other simultaneous studies that might interfere with the test evaluation

There shall be a sufficient interval between two successive UV exposures to the same test site for resolution of discoloration resulting from previous tests.

2.3. UV Standard

As, standards P2, P3, P5, P6, and P8 were used as described by the ISO 24444:2019 method.

Establishment of SPF for product claim: when testing is conducted for the purpose of supporting a label claim of a product intended for market the following reference standards are used for testing with the test product:
— SPF Claim ≤24: P2 or P3 reference standard (all subjects);
— 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.

Assignment of the reference standards used on specific subjects is randomized.

The table below reports the SPF values and acceptance limits for the reference standards sunscreens:

Table 2

Reference Sunscreen Formulation	Mean SPF	Acceptance Limits	
		Lower Limit	Upper Limit
P2	16.1	13.7	18.5
P3	15.7	13.7	17.7
P5	30.6	23.7	37.4
P6	43.0	31.0	54.9
P8	63.1	43.9	82.3

It is used as a methodological control to verify the test procedure.

ABICH Standard code	STD-P2; STD-P8
Name of product	STANDARD P2 SPF16; STANDARD P8 SPF63
Batch number	#7/21; #7/21
Expiration date	Standard valid during the execution of the test

2.4. Used instruments

The following instruments and materials were used in according to both reference guide- lines:

- Solar Simulator Model 601 - Dose control system Model PMA2100 - Detector UV-B PMA2103 LLG e UV-A PMA 2113 LLG di SolarLight Co: instruments used for the UV irradiation and control, equipped to simulate the solar erythemal effectiveness (last calibration May 2022 – ref. n°22205).

Table 3:
Spectral emission in %RCEE (Relative Cumulative Erythemal Effectiveness) with acceptability limits:

Spectral range (nm)	%RCEE lower limit	%RCEE upper limit
<290		<0.1%
290-300	1.0	8.0
290-310	49.0	65.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-400	99.9	100

- Minolta Chromameter CR300: Instrument for measure the volunteers skin phototype
- Analytical balance: VWR LA214I

Uniformity of the beam is measured using PMA2174 Digital Quadrant Sensor every six months or when any modifications are made to the lamp optical components, or when non – uniform erythema spots are seen in test subsites. The uniformity of the beam should be ≥90% (last calibration: April 2022).

2.5. Environmental Conditions

Product application, UV exposures and MED assessment should have to be carried out in stable conditions, with the room temperature maintained between 18 and 26 °C.

2.6. Product application

The cosmetic product must not undergo to any preliminary treatment. Liquid type products consisting of two layers must be shaken strongly before weighing in order to ensure a homogeneous dispersion.
In the case of powder products, aliquots of powder should be transferred to the skin in a grid-like manner, using a spatula or finger. Purified water or another suitable solvent that has no UV protection properties may be applied before the powder application to help the sample adhere to the application site.
Before product application, the test area may be cleaned, but only by using a dry cotton pad or equivalent.
The product is spread uniformly on the skin of the volunteers such as to obtain a quantity of test substance on the test site of 2.00 ± 0.05 mg/cm² (area of 50 cm²). The sites have to be devoid of skin damage or naevi or any other abnormalities which could prevent regular testing and has to be untanned).
A visual control as well as a gravimetrical control of the product was made before the measure.
To assure a uniform distribution, droplets of the product is applied with a dosed syringe, then spread over the whole test site with light pressure, using a finger. Spreading time was in the range of 20 to 50 seconds.

No specific sponsor requests were applied to the standard method of application, just reported

2.7. Site of Exposure

The sample is applied to the back of the volunteers in such a way to obtain a constant thickness so that the length of the UV rays' pathway through the sample can be considered homogeneous in each point.
Exposure of the test site to the sequence of UV doses starts about 15-30 minutes after the application of the product(s).

2.8. UV Exposure

The irradiation time varies according to the MED calculated for each subject and according to the estimated SPF of the test substance, using six sub-sites centered on the expected MED and exposed to incremental UV doses using a geometric progression from 1.12 to 1.25 (Tab.4). Before UV exposure of each site, the UV irradiance should be checked with the detector.

Table 4

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6
0.71X	0.80X	0.89X	1X	1.12X	1.25X

2.9. Product Removal

After UV exposures, standard and tested products are gently removed from the skin of the volunteers using a cotton pad.

2.10. Minimal Erythemal Dose (MED)

The MED is defined as the lowest UV dose that produces the first perceptible unambiguous erythema with defined borders appearing over the most of the UV exposure area, 16 to 24 h after UV exposure.

2.11. MED assessment procedure

The MED for unprotected skin (MEDu), the MED for the testing product protected skin (tpMEDp) and the MED for the standard sunscreen product (ssMEDp) are determined on the same day.
The MED are assessed 20±4 h after the UV exposure. The MED are assessed visually by a trained specialist. Visual assessment is performed with sufficient and uniform illumination (>500 lux). Calculated MED are expressed in terms of energy/surface (µj/cm²).

2.12. Sun Protection Factor

The individual Sun Protection Factor (SPFi) value for a product is defined as the ratio of the MED of product protected skin (MEDip) and the MED of unprotected skin (MEDiu) for the same subject.
The SPF of the product is the arithmetic mean of all valid SPFi obtained from all the subjects in the test, expressed to one decimal place.

$$SPF_i = MEDip / MEDiu$$

2.13. Data rejection criteria

Test data shall be rejected under the following circumstances:

- The exposure series on a subject fails to elicit an erythemal response on a test site 20±4 h after exposure
- Erythemal responses within an exposure series are randomly absent 20±4 h after exposure, not reflecting the geometric progression used;
- All sub-sites in the exposure series show an erythemal response 20±4 h after exposure.
- Subject does not follow instructions during or after the treatment or UV exposures that could affect the outcome of the test.
- Technical failure of equipment or procedures during the treatment phases of the procedure.

2.14. Evaluation and results expression

The product UV protection is measured in the UV range between 290nm and 400nm.
The actual number of subjects tested is defined as the number required to produce a mean SPF with a 95% confidence interval which falls within a range of ±17% of the measured mean SPF.
The SPF of the tested product is calculated as the arithmetical mean of all valid individual SPFi values.

$$SPF = (\Sigma\ SPF_i) / n$$

with

$$95\%CI = SPF - c \leftrightarrow SPF + c \quad \text{where} \quad c = t * s/\sqrt{n}$$

$$CI\ [\%] = 100*c/SPF \leq 17\%$$

where: n = number of subjects treated
s = standard deviation of the mean SPF
t = t value from the 'two-sided' Student-t distribution table at a probability level p = 0,05 and with degrees of freedom: v = (n-1)

2.15. Experimental Design

DAY 1:

Conducted ITA measurement

Apply the sunscreen test product and the SPF standard at 2.0 ± 0.05 mg/cm² to their respective test sites. A finger cot compatible with the sunscreen product is used to spread the product and standard homogenously over randomly chosen test sites on the back of the volunteers.

Wait at least 15 to 30 minutes after applying a sunscreen product or standard before exposing the test sites to UV radiation.

For each test subject, administer a series of UV radiation doses expressed as µJ/cm² to the test subsites within an unprotected test site using an accurately calibrated solar simulator. Select doses that are a geometric series represented by 1.12 to 1.25n.

UV exposure for final unprotected MEDiu (µJ/cm²), standard P2/P8 ssMEDp (µJ/cm²), and testing product MEDip (µJ/cm²) at the appropriate test sites.

DAY 2:

Evaluation of erythema on test subsites.

Determine the MED 16 to 24 hours after UV exposure. The person who evaluates the test should not be the same person who applied the sunscreen product to the test site or administered the UV doses. After UV doses are administered, all immediate responses should be recorded.

The final unprotected MEDiu (µJ/cm²), standard P2/P8 ssMEDp (µJ/cm²), and testing product MEDip (µJ/cm²) are determined

3. PART THREE – RESULTS AND CONCLUSIONS

3.1. Results

Table 5 – SPF test Report (All Data)
Test product: HINATURE FOURTH SUNSCREEN Batch: JY2022.06.11-A

ISO 24444 Test method					Laboratory: Abich srl						Report Date: 16/09/2022			
Test product Description: JY2022.06.11-A											Dose Increments: 1,12			
Test											Reference Standard P2		Reference Standard P8	
Subject number	Exposure Date	App/Exp by	Read by	MED (Highest) (W/m²)	Subj. Skin ITA°	MEDiu (µJ/cm2)	ssMEDp (µJ/cm2)	SPFi	Reject (Y/N)	ssMEDp (µJ/cm2)	SPF	ssMEDp (µJ/cm2)	SPF
1	19/07/2022	AC	AB	11,96	29	99600	5896800	63,0	N	1497600	16,0		
2	19/07/2022	AB	AC	7,70	60	23400	1404000	60,0	N			1404000	60,0
3	19/07/2022	AB	AC	11,96	52	46800	2901600	62,0	N			2948400	63,0
4	09/09/2022	EC	AC	11,96	28	117000	7020000	60,0	N	1918800	16,4		
5	09/09/2022	EC	AC	11,96	53	41750	2809800	67,2	N	625400	15,0		
6	09/09/2022	EC	AC	11,96	38	59280	4464000	75,3	N	918640	15,5		
7	13/09/2022	EC	AC	11,96	43	46800	3346800	67,1	N			2991600	64,0
8	13/09/2022	EC	AC	7,70	29	117000	7020000	60,0	N			7254000	62,0
9	13/09/2022	EC	AC	11,96	37	80520	5220000	62,5	N	1441600	17,5		
10	13/09/2022	EC	AC	7,70	34	74400	4464000	60,0	N			4761600	64,0
MEAN SPF								63,7			16,1		61,8
s								4,9			1,8		1,8
n								8,5			1,2		2,2
CI[%]								5,5			7,4		3,5
CI[95%] (Lower)								58,8			15,1		60,0
CI[95%] (Upper)								68,6			17,0		63,6
CI[%] < 17%								Complies			Complies		Complies
n (N° subjects)								10			6		6

Table 6 – SPF test Report (Valid Data)
Test product: HINATURE FOURTH SUNSCREEN Batch: JY2022.06.11-A

ISO 24444 Test method					Laboratory: Abich srl						Report Date: 16/09/2022			
Test product Description: JY2022.06.11-A											Dose Increments: 1,12			
Test											Reference Standard P2		Reference Standard P8	
Subject number	Exposure Date	App/Exp by	Read by	MED (Highest) (W/m²)	Subj. Skin ITA°	MEDiu (µJ/cm2)	ssMEDp (µJ/cm2)	SPFi	Reject (Y/N)	ssMEDp (µJ/cm2)	SPF	ssMEDp (µJ/cm2)	SPF
1	19/07/2022	AC	AB	11,96	29	99600	5896800	63,0	N	1497600	16,0		
2	19/07/2022	AB	AC	7,70	60	23400	1404000	60,0	N			1404000	60,0
3	19/07/2022	AB	AC	11,96	52	46800	2901600	62,0	N			2948400	63,0
4	09/09/2022	EC	AC	11,96	28	117000	7020000	60,0	N	1918800	16,4		
5	09/09/2022	EC	AC	11,96	53	41750	2809800	67,2	N	625400	15,0		
6	09/09/2022	EC	AC	11,96	38	59280	4464000	75,3	N	918640	15,5		
7	13/09/2022	EC	AC	11,96	43	46800	3346800	67,1	N			2991600	64,0
8	13/09/2022	EC	AC	7,70	29	117000	7020000	60,0	N			7254000	62,0
9	13/09/2022	EC	AC	11,96	37	80520	5220000	62,5	N	1441600	17,5		
10	13/09/2022	EC	AC	7,70	34	74400	4464000	60,0	N			4761600	64,0
MEAN SPF								63,7			16,1		61,8
s								4,9			1,8		1,8
n								8,5			1,2		2,2
CI[%]								5,5			7,4		3,5
CI[95%] (Lower)								58,8			15,1		60,0
CI[95%] (Upper)								68,6			17,0		63,6
CI[%] < 17%								Complies			Complies		Complies
n (N° subjects)								10			6		6

3.2. Conclusions

On the basis of the tests carried out, under the adopted experimental conditions, the tested sample

HINATURE FOURTH SUNSCREEN
Batch: JY2022.06.11-A

Has a mean Sun Protection Factor (SPF) of

63,7 (95% confidence interval: 5,5)

and according to the EC recommendation of September 22nd 2006 n. 2006/647/EC may be classified as:

- labelled category: **VERY HIGH PROTECTION**
- labelled sun protection factor: **50+**

The Study Director

[redacted]

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Certificate N. 39000622006
UNI CEI EN ISO 13485:2021
Certificate N. 39050622006
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4. PART FOUR
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12. Declaration WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013

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ANNEX 1

INCI Composition

Water, Propanediol, Dibutyl Adipate, Dicaprylyl Carbonate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Ethylhexyl Triazone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Amylopectin, Butylene Glycol, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Glycerin, Behenyl Alcohol, Poly C10-30 Alkyl Acrylate, Polyglyceryl-3 Methylglucose Distearate, Sodium Acrylates Crosspolymer-2, Carbomer, Tromethamine, Decyl Glucoside, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, (-)-alpha-bisabolol, Panthenol, Caprylhydroxamic Acid, Centella Asiatica Extract, Tocopherol, Ceramide NP, Dipropylene Glycol, Cholesterol, Propylene Glycol, Xanthan Gum, Glyceryl Stearate, Ceramide AS, Ceramide AP, Ceramide NS, Hydrogenated Lecithin, Ceramide EOP

ABiCh Lifeanalytics
Certified Company
UNI EN ISO 9001:2015
Certificate N. 39000622006
UNI CEI EN ISO 13485:2021
Certificate N. 39050622006
GLP Testing facility
REL/1991/Rev03/2022

ANNEX 2

HINATURE

S-dong 2501-3 Ho. Songdo Technopark IT Center Songdogwahak-ro 32, Yeonsu-gu, Incheon, Korea (21984)
Tel. 070 8833 1884 Fax. 070 8998 1884

REFNO. : HINATURE Inc._20231218(Research)_3
DATE : 18-Dec-23
TO : ABICh S.r.l.
ATTN : Agnes Malartre
CC :
PM : Sarah
SUBJECT : JY2022.06.11-A Sunscreen SPF, UVA Report Product Name Change Request.

1. ABICh S.r.l.,
Thank you very much for your kind cooperation and support.

2. The contents of [JY2022.06.11.-A] and [HINATURE FOURTH SUNSCREEN] are the same. Therefore, both products are the same product.

3. SPF, UVA report [JY2022.06.11.-A] Please rename the product to [HINATURE FORTH SUNSCREEN].

18-Dec-23

HINATURE Inc.

HINATURE Inc.
2501-3 ho, S-dong,
Songdo Techno Park IT Center,
32, Songdogwahak-ro,
Yeonsu-gu, Incheon Korea(21984)

02. UVA Protection Factor (UVAPF)
- Italy(ABICH)

FINAL REPORT

IN VIVO DETERMINATION OF SUNSCREEN UVA PROTECTION ACCORDING TO THE INTERNATIONAL STANDARD METHOD ISO 24442:2011

CUSTOMER	**PURITO - HINATURE Inc. 2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, Korea, South**
SPONSOR	**PURITO - HINATURE Inc. 2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, Korea, South**
SAMPLE	**HINATURE FOURTH SUNSCREEN Batch: JY2022.06.11-A**
REPORT DATE	**18/12/2023**
REPORT N.	**REL/1986/Rev03/2022**

The results reported herein do exclusively refer to the tested sample.

PRELIMINARY STATEMENT

Glossary

- **PPD (Persistent Pigment Darkening):** skin darkening that persists more than 2 h after the end of UVA exposure;
- **MPPDD (Minimal Persistent Pigment Darkening Dose):** lowest Ultraviolet A (UVA) dose that produces the first perceptible unambiguous persistent pigment darkening response with defined borders appearing over most of the field of UVA exposure, observed between 2 h and 24 h after the end of the UVA exposure;
- **MPPDDu:** Minimal Persistent Pigment Darkening Dose on unprotected skin;
- **MPPDDp:** Minimal Persistent Pigment Darkening Dose on protected skin;
- **UVAPF** (UVA Protection Factor): provides information on the magnitude of the protection provided explicitly in the UVA portion of the spectrum, independent of the SPF values;
- **UV-R:** solar ultraviolet radiation in the range 290–400 nm;

In particular:

- **UVA:** solar ultraviolet radiation in the range 320–400 nm (UVA I= 320 nm to 340 nm; UVA II= 340 nm to 400 nm);
- **UVB:** solar ultraviolet radiation in the range 290–320 nm.

Disclaimer

According to COLIPA guidelines, the test was performed with the assumption that the Sponsor under its responsibility provided to the personnel of the Abich Clinical study Center, truthful information on any ingredient of the test product related to the toxicological potential.
On the basis of such information, a general assessment of the toxicological information concerning the product was preliminarily carried out and ethical implications as to its use during the present study have been considered. The results reported herein do exclusively refer to the tested sample. The study protocol, the raw data and the final report, kept in the archives of Abich Srl., in via Cadorna, 67, 20055-Vimodrone (MI), Italy cannot be reproduced, neither entirely nor in part except with an explicitly written authorization from the laboratory.

Authenticity of Results

The study covered by this report was realized according to the internal quality procedures of Abich S.r.l. The study was carried out, where applicable, according to the principles of Good Clinical Practice. All relevant observations and data recorded during the test are included in this study report.

Table of contents

Revision history

Rev.	Date	Description
00	16/09/2022	First emission
01	26/09/2022	Typo in the table of contents and in the table 5-6 on pg.12-13
02	17/10/2022	Variation Inci
03	18/12/2023	Product name change at customer's request and inserted new study director in charge since Nov. 20 to formally sign off on review

1. PART ONE –GENERAL INFORMATION

1.1. Customer

PURITO - HINATURE Inc.
2501-3 ho, S-dong, Songdo Techno Park IT Center, 32,
Songdogwahak-ro, Yeonsu-gu, Incheon - Korea, South

1.2. Sponsor

PURITO - HINATURE Inc.
2501-3 ho, S-dong, Songdo Techno Park IT Center, 32,
Songdogwahak-ro, Yeonsu-gu, Incheon - Korea, South

1.3. Test Product

Name:	**HINATURE FOURTH SUNSCREEN**
Batch:	JY2022.06.11-A
Aspect:	yellowish cream
Abich sample code:	3048/22-04
INCI Composition:	see annex
Pao / expiration date:	n.a.
Storage conditions:	room temperature
Received date:	15/07/22

1.4. Assay

In vivo determination of sunscreen UVA protection according to the international standard method ISO 24442:2011

1.5. Entrusted Laboratory

Abich S.r.l.- Clinical and Cosmetological Trials Center
Via Cadorna, 67 Building A/1
20055 - Vimodrone (MI) – Italy

1.6. Study Dates

Start: 22/07/2022
End: 09/09/2022

1.7. Study Director (In charge during the execution of the study in 2022):

[redacted]

1.8. Study Director* (In charge from 20/11/23):

[redacted]

1.9. Clinical Supervisor:

[redacted]

1.10. Deviations:

No deviation from the study protocol occurred during the test.

1.11. Adverse reactions:

No adverse reactions were observed during the test.

1.12. Archiving:

The study protocol, the raw data and the final report are kept in the archives of Abich clinical Study Center, in Via Cadorna, 67, 20055-Vimodrone (MI), both in electronic format and in reduced paper format for a period of 5 years from the issue of the final report.
The control sample of the test substance and eventual specific reference material are kept for 3 months, unless a specific request is provided by the customer.

2. PART TWO – STUDY DESIGN

2.1. Purpose of the test

The aim of the test is to determine in vivo the of the UVA Protection Factor (UVAPF) using the persistent pigment darkening method according to the International Standard method ISO 24442:2011 (E) (first edition 2011-12-15).
It provides a basis for the evaluation of sunscreen products for the protection of human skin against UVA radiation from solar or other light sources.
This study has been carried out in compliance with the most recent recommendations of the Helsinki Declaration (64th WMA General Assembly, Fortaleza, Brazil, October 2013.

2.2. Panel characteristics

The study was performed on male and female volunteers, with age between 18 and 70 years, who have been identified from specified criteria of exclusion, from the database of volunteers of the Abich Test Centre.
The subjects included in the UVAPF test panel shall be phototype II, III or IV according to Fitzpatrick or shall have an ITA° value from 20° to 41° by colorimetric methods and be untanned on the test area.
The correlation between the cutaneous phototype, the color of the skin and the ITA° value is represented in the following table:

Table 1

Skin Phototype	Description	ITA° Value
I	Very light	>55°
II	Light	>41 to 55°
III	Intermediate	>28 to 41°
IV	Tanned (or matt)	>10 to 28°
V	Brown	>-30 to 10°
VI	Black	≤-30°

Where ITA° = [arctg((L*-50)/b*)]x180/3.1416

The following exclusion criteria were applied:

- Pregnant or lactating women;
- Persons below the age of consent;
- Subjects with discolorations, any kind of skin marks, including tattoos, scars, burns or their outcomes, which can interfere with the reading of the assay;
- Subjects taking medication that might interfere with the test results (i.e. photosensitising, anti-inflammatory drugs);
- Subjects having skin irritation at the application site;
- Subjects having skin diseases which could interfere with the aim of this study;
- Subjects with skin hyperpigmentation caused from exposure to solar radiation;
- Subjects with a history of adverse events related to sun exposure
- Subject participating in other simultaneous studies that might interfere with the test evaluation

There shall be a sufficient interval between two successive UV exposures to the same test site for resolution of discoloration resulting from previous tests.

2.3. Assay design

Day 1:

Spreading of a precise, homogeneous, amount of product(s) and standard over another randomly chosen test site on the back of the volunteers. Irradiation of the test sites of unprotected and protected skin.

Day 2:

Determination of the MPPDDui, MPPDDpi of product and standard.

2.4. Used instruments

The following instruments and materials were used in according to both reference guide- lines:

- Solar Simulator Model 601 - Dose control system Model PMA2100 - Detector UV-B PMA2103 LLG and UV-A PMA 2113 LLG di SolarLight Co; instruments used for the UV irradiation and control, equipped to simulate the solar erythemal effectiveness (last calibration May 2022).

Table 2:
The table below reports the specifications of the spectral output with acceptability limits:

Spectral range	Measured
<320 nm (UVB)	<0.1% of total UV
320 nm to 340 nm (UVA II)	8% to 20% of total UVA
340 nm to 400 nm (UVA I)	80% to 92% of total UVA
400 nm to 1500 nm (visible and near-IR)	<5% of total output of the source

- Minolta Chromameter CR300: Instrument for measure the volunteers skin phototype
- Analytical balance: VWR LA214i

2.5. UV Standard

The method is controlled by the use of a reference sunscreen formulation to verify the test procedure. As reference sunscreen, standard S2 was used as described by the method.

Table 3: mean UVAPF and acceptance limits for reference sunscreen formulations

Reference sunscreen formulation	Mean UVA PF	Acceptance limits	
		Lower Limit	Upper Limit
S2	12.7	10.7	14.7

2.6. Environmental Conditions

Product application, UV exposures and MED assessment should have to be carried out in stable conditions, with the room temperature maintained between 18 and 26 °C.

2.7. Product application

The cosmetic product must not undergo to any preliminary treatment. Liquid type products consisting of two layers must be shaken strongly before weighing in order to ensure a homogeneous dispersion.
In the case of powder products, aliquots of powder should be transferred to the skin in a grid-like manner, using a spatula or finger. Purified water or another suitable solvent that has no UV protection properties may be applied before the powder application to help the sample adhere to the application site.
Before product application, the test area may be cleaned, but only by using a dry cotton pad or equivalent.
The product is spread uniformly on the skin of the volunteers such as to obtain a quantity of test substance on the test site of 2.00 ± 0.05 mg/cm² (area of 50 cm²). The sites have to be devoid of skin damage or naevi or any other abnormalities which could prevent regular testing and has to be untanned). A visual control as well as a gravimetrical control of the product was made before the measure.
To assure a uniform distribution, droplets of the product is applied with a closed syringe, then spread over the whole test site with light pressure, using a finger. Spreading time was in the range of 20 to 50 seconds.

2.8. Site of Exposure

The sample is applied to the back of the volunteers in such a way to obtain a constant thickness so that the length of the UV rays' pathway through the sample can be considered homogeneous in each point.
Exposure of the test site to the sequence of UV doses starts about 15-30 minutes after the application of the product(s).

2.9. UV Exposure

The irradiation time varies according to the MPPDD calculated for each subject and according to the estimated UVApf of the test substance, using six sub-sites centered on the expected MPPDD and exposed to incremental UV doses using a geometric progression of 25% (Table 4). Before UV exposure of each site, the UV irradiance should be checked with the detector.

Table 4

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6
0.64X	0.80X	1X	1.25X	1.56X	1.95X

2.10. Product Removal

After UVA exposures, standard and tested products are gently removed from the skin of the volunteers using a cotton pad.

2.11. Minimal Persistent Pigment Darkening Dose

The MPPDD is defined as lowest Ultraviolet A (UVA) dose that produces the first perceptible unambiguous persistent pigment darkening response with defined borders appearing over most of the field of UVA exposure, observed between 2 h and 24 h after the end of the UVA exposure.

2.12. MPPDD assessment procedure

The Minimal Persistent Pigment Darkening Dose on unprotected skin (MPPDDu), the Minimal Persistent Pigment Darkening Dose on protected skin (MPPDDp) and that for the standard sunscreen product were determined on the same day.
The MPPDD was assessed between 2 h and 24 h after completion of the exposure of the last UVA exposure sites. The MPPDD were assessed visually by a trained specialist under sufficient and uniform illumination (at least 450 lux).

2.13. UVA Protection Factor

The UVAPFi is calculated for each test product for each volunteer as the ratio of the minimal UVA dose necessary to induce the defined pigmentation response on the MPPDDp and the minimal UVA dose necessary to induce the MPPDDu:

$$UVAPF_i = MPPDD_i\text{(protected skin)} / MPPDD_i\text{ (unprotected skin)}$$

The UVAPF for the product is the arithmetic mean of all valid individual UVAPFi values obtained from all subjects in the test, expressed to one decimal place.

2.14. Data rejection criteria

Test data shall be rejected under the following circumstances:

- There is no pigmenting response on any UVA exposure site;
- All subsites have a pigmenting response;
- There are random pigmenting responses that do not follow the logical sequence of the test (randomly absent responses);
- The test subject is non-compliant or becomes ill, or does not shield the test area from sunlight after exposure;
- A technical error occurs during UVA exposure

2.15. Evaluation and results expression

The product UVA protection is measured in the UV range between 320nm and 400nm. MPPDDD are expressed in terms of energy (mj/cm2).

The actual number of subjects tested is defined as the number required to produce a mean UVApf with a 95% confidence interval which falls within a range of ±17% of the measured mean UVApf.
The UVApf of the tested product is calculated as the arithmetical mean of all valid individual UVApfi values.

$$UVApf = (\Sigma\ UVApfi) / n$$

$$95\%CI = UVApf - c \leftrightarrow UVApf + c \quad \text{with} \quad \text{where} \quad c = t^* s/\sqrt{n}$$

$$CI\ [\%] = 100^*c/UVApf \leq 17\%$$

where:
n = number of subjects treated
s = standard deviation of the mean UVApf
t = t value from the 'two-sided' Student-t distribution table at a probability level p = 0,05 and with degrees of freedom: v = (n-1)

3. PART THREE –RESULTS AND CONCLUSIONS

3.1. Results

Table 5:
Tested Product Evaluation

Vol.N°	Sex	Age	Phototype	ITA°	MEPPDDu (mj/cm²)	MEPPDDp (mj/cm2)	UVAPFI
1	F	56	IV	23	37440	936000	25,0
2	F	51	IV	21	46800	936000	20,0
3	F	60	IV	10	46800	994500	21,3
4	F	62	IV	10	46800	748800	16,0
5	F	49	IV	10	46800	1053000	22,5
6	F	50	IV	10	24000	599040	25,0
7	F	54	IV	15	40950	748800	18,3
8	F	63	IV	25	37440	760500	20,3
9	F	66	III	32	32760	655200	20,0
10	F	53	IV	23	46800	936000	20,0
RESULTS			MEAN UVAPF				20,8
			s				2,8
			c				2,0
			CI[%]				9,5
			CI[%] ≤ 17%				Complies
			N° subject				10

Table 6:
S2 Standard Evaluation

Vol.N°	Phototype	MEPPDDu (mj/cm²)	MEPPDDp (mj/cm2)	UVAPFI S2
1	IV	37440	449280	12,0
2	IV	46800	585000	12,5
3	IV	46800	555750	11,9
4	IV	46800	631800	13,5
5	IV	46800	596700	12,8
6	IV	24000	315000	13,1
7	IV	40950	561600	13,7
8	IV	37440	458640	12,3
9	III	32760	430560	13,1
10	IV	46800	631800	13,5
RESULTS	MEAN UVAPF S2			12,8
	s			0,7
	c			0,5
	CI[%]			3,7
	CI[%] ≤ 17%			Complies
	N° subject			10

3.2. Conclusions

On the basis of the tests carried out, under the adopted experimental conditions, the tested sample

HINATURE FOURTH SUNSCREEN
Batch: JY2022.06.11-A

Has a mean UVA Protection Factor (UVApf) of

20,8 (95% confidence interval: 9,5)

The standard sunscreen gave as a result a mean UVApf of

12,8 (95% confidence interval: 3,7)

The Study Director

[redacted]

4. PART FOUR

BIBLIOGRAPHY

1. Fitzpatrick, t.b., The validity and practicability of sun-reactive skin types I through VI. Arch. Dermatol. 124, pp. 869-871, 1988
2. CIE Publication 15.2, CIE 1976 uniform colour spaces. Colorimetry, pp. 29-32, 198
3. Moloney FJ, Collins S, Murphy GM. Sunscreens: safety, efficacy and appropriate use. Am J Clin Dermatol. 2002;3(3):185-91.
4. Picardo M, Bocchietto E, Callegari E, Pecis L . Nuove frontiere nel campo della fotoprotezione, Congresso Sidev-ADOI Roma, Giugno 2001.
5. Bocchietto E e Pecis L . La fotoprotezione in età pediatrica e la sicurezza d'uso dei prodotti solari. Atti del IX incontro pediatrico, Ostia Lido, 21-23 marzo 2002, pp181-185.

REFERENCES

1. Cosmetics- Sun protection test methods- In vivo determination of sunscreen UVA protection. International Standard method ISO 24442:2011 (E). First edition 2011-12-15;
2. Colipa Guideline: guideline for the colorimetric determination of skin colour typing and prediction of the minimal erythemal dose (med) without uv exposure (Edition 2007)
3. Commission recommendation of 22 September 2006 n. 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto
4. Declaration WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
   Ethical Principles for Medical Research Involving Human Subjects
   Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
   29th WMA General Assembly, Tokyo, Japan, October 1975
   35th WMA General Assembly, Venice, Italy, October 1983
   41st WMA General Assembly, Hong Kong, September 1989
   48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
   52nd WMA General Assembly, Edinburgh, Scotland, October 2000
   53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
   55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
   59th WMA General Assembly, Seoul, October 2008
   64th WMA General Assembly, Fortaleza, Brazil, October 2013
5. Consensus documents Number 4. OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING "Quality assurance and GLP" 26 Oct. 1999.
6. Consensus documents Number 5. OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING "Compliance of laboratory suppliers with GLP principles" 28 Sept. 2000
7. Consensus documents Number 7. OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING "The application of to GLP principles to short term studies" 15 Sept. 1999.
8. Consensus documents Number 8. OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING "The role and responsibility of the Study Director in the GLP studies" 15 Sept. 1999.
9. E6: Good Clinical Practice: Consolidated Guideline 1996 "Guideline for Good Clinical Practice E6 (R1)"
10. Decreto Ministeriale del 15 Luglio 1997 "Recepimento delle linee guida dell'Unione europea di buona pratica clinica per la esecuzione delle sperimentazioni cliniche dei medicinali"

ANNEX 1

INCI Composition

Water, Propanediol, Dibutyl Adipate, Dicaprylyl Carbonate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Ethylhexyl Triazone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Amylopectin, Butylene Glycol, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Glycerin, Behenyl Alcohol, Poly C10-30 Alkyl Acrylate, Polyglyceryl-3 Methylglucose Distearate, Sodium Acrylates Crosspolymer-2, Carbomer, Tromethamine, Decyl Glucoside, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, (-)-alpha-bisabolol, Panthenol, Caprylhydroxamic Acid, Centella Asiatica Extract, Tocopherol, Ceramide NP, Dipropylene Glycol, Cholesterol, Propylene Glycol, Xanthan Gum, Glyceryl Stearate, Ceramide AS, Ceramide AP, Ceramide NS, Hydrogenated Lecithin, Ceramide EOP

ANNEX 2

HINATURE

S-dong 2501-3 Ho, Songdo Technopark IT Center Songdogwahak-ro 32, Yeonsu-gu, Incheon, Korea (21984)
Tel. 070 8833 1884 Fax. 070 8998 1884

REFNO.	: HINATURE Inc._20231218(Research)_3
DATE	: 18-Dec-23
TO	: ABICh S.r.l.
ATTN	: Agnes Malartre
CC	:
PM	: Sarah
SUBJECT	: JY2022.06.11-A Sunscreen SPF, UVA Report Product Name Change Request.

1. ABICh S.r.l.,
Thank you very much for your kind cooperation and support.

2. The contents of [JY2022.06.11.-A] and [HINATURE FOURTH SUNSCREEN] are the same. Therefore, both products are the same product.

3. SPF, UVA report [JY2022.06.11.-A] Please rename the product to [HINATURE FORTH SUNSCREEN].

18-Dec-23

HINATURE Inc.

HINATURE Inc.
2501-3 ho, S-dong,
Songdo Techno Park IT Center,
32, Songdogwahak-ro,
Yeonsu-gu, Incheon Korea(21984)

03. Sun Protector Factor (SPF)
- Korea(Korea Institute of Dermatological Sciences)

KIDS-CSCR08-184

Clinical Study Report

A Clinical Study for Determining the Water Resistance Effect of "HINATURE Fourth Sunscreen"

Requestor: HINATURE Inc.

October 27, 2023

Korea Institute of Dermatological Sciences

Table of contents

Korea Institute of Dermatological Sciences

Authentication

Korea Institute of Dermatological Sciences are commissioned by "HINATURE Inc." for A Clinical Study for Determining the Water Resistance Effect of "HINATURE Fourth Sunscreen", and approve it under Institutional Review Board (IRB), and perform the study in accordance with the SPF Test Method (ISO24444:2010), Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005) and the Standard Operating Procedures (SOP) of Korea Institute of Dermatological Sciences and report the result as follows.

October 27, 2023

Research Organization	Korea Institute of Dermatological Sciences	(Seal)
President	Director of Korea Institute of Dermatological Sciences Adjunct Professor of Konkuk University, Doctor of Science	In Sook An (Seal)
Principal Investigator	Director of Korea Institute of Dermatological Sciences Adjunct Professor of Konkuk University, Doctor of Science	In Sook An (Seal)
Researcher	Senior Researcher of Korea Institute of Dermatological Sciences, Master of Engineering	Woncheol Kim (Seal)

Korea Institute of Dermatological Sciences

Quality assurance confirmation

□ Test Title: A Clinical Study for Determining the Water Resistance Effect of "HINATURE Fourth Sunscreen"

□ Product code: KIDS-CSCR08-184

□ IRB certification number: KIDSIRB-2023-1002

This test is conducted in accordance with the SPF Test Method (ISO24444:2010), Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005) and the Standard Operating Procedures (SOP) of Korea Institute of Dermatological Sciences. We assured that this report is accurately reflected by the study result.

Test title	A Clinical Study for Determining the Water Resistance Effect of "HINATURE Fourth Sunscreen"				
Date	Item	Quality Assurance Checklist	Quality Assurance Check Result	Approval date	Remark
August 21, 2023	Test plan	Test planning	Approved	August 21, 2023	
August 28, 2023 ~ October 13, 2023	Test progress	Test process	Approved	October 13, 2023	
October 13, 2023	Data analysis	Data check (raw data)	Approved	October 13, 2023	
October 26, 2023	Draft report	Draft report review	Approved	October 26, 2023	
October 27, 2023	Final report	Final report review	Approved	October 27, 2023	

We certify that this research report is created based on the test result, and reflects the test data accurately.

October 27, 2023

President In Sook An (Seal)

Quality Assurance Ga Ram Kim (Seal)

Korea Institute of Dermatological Sciences

Report Summary

Test Title	A Clinical Study for Determining the Water Resistance Effect of "HINATURE Fourth Sunscreen"
Research Organization	Korea Institute of Dermatological Sciences 6F, H Business Park Building A, 25 Beobwonro 11-gil, Songpa-gu, Seoul, Republic of Korea
Requestor	HINATURE Inc. 2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, Republic of Korea
Test Product	HINATURE Fourth Sunscreen
Formulation	Cream
Test Period	August 21, 2023 ~ October 27, 2023
Methods	This test is conducted in accordance with the SPF Test Method (ISO24444:2010), Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005) and the Standard Operating Procedure (SOP) of Korea Institute of Dermatological Sciences. 1) Selection of subjects: Healthy female and male, aged from 18 to 60 years old 2) Product Application: Evenly apply 2.00 ± 0.05 mg/cm² amount to the test area. 3) Application areas: 35 cm² (7 cm x 5cm) 4) Waiting time after product application: 15-30 minutes 5) Test device: Multi-port Solar Simulator 601-300W 6) Water immersion procedure: Immerse 2 times for 20 min each 7) Drying procedure: drying 2 times in 15 minutes with no toweling 8) Assessment Methods: Evaluate the response of minimal erythemal dose (MED) within 16 -24 hours after UV irradiation 9) Acceptance criteria: The test product was considered water resistant if the value for the 90% lower unilateral confidence limit [mean %WRR - d] is greater than or equal to 50%. The 95% confidence interval (CI) should be within a range of ± 17% of the mean SPF.
Results	The mean static SPF value (SPFs) of "HINATURE Fourth Sunscreen" was 50.2 ± 5.0. The mean wet SPF value (SPFw) was 27.3 ± 2.7 and the mean of percentage water resistance retention (%WRR) was 53.9 ± 7.3%. Therefore, the 90% lower unilateral confidence limit value [mean %WRR. - d] was 50.7%, the test product is considered as a Water Resistance product. The skin adverse reaction was not observed during the study.
Principal Investigator	In Sook An, Ph.D.
Researcher	Woncheol Kim, Tae Yeop Kim, Ye Bin Jung
Dermatologist	Won Ung Shin, Kyung Goo Lee
Quality Assurance Director	Gs Ram Kim, Ph.D.
Report Date	October 27, 2023

I. Background

Exposure of the skin to ultraviolet ray may cause sun burn or skin photoaging and the increase of skin epidermis thickness, and affect Langerhans cell due to DNA destruction, causing abnormalities in the immune system or skin cancer. Due to these various hazards to the skin of ultraviolet rays, various studies and products are being developed to protect the skin from ultraviolet rays. This study intends to conduct the Clinical Study for Determining the Sun Protection Factor and the Water Resistance Effect of test product.

II. Purpose

The purpose of this test is to determining the Water Resistance effect of "**HINATURE Fourth Sunscreen**" commissioned by "**HINATURE Inc.**" in accordance with the SPF Test Method (ISO24444:2010) and Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005).

III. Test Period

August 21, 2023 ~ October 27, 2023

IV. Research Organization

Name of research organization: Korea Institute of Dermatological Sciences
Address: 6F, H Business Park Building A, 25 Beobwonro 11-gil, Songpa-gu, Seoul, Republic of Korea
Tel: +82 2-6957-8114
Fax: +82 2-6957-8004
Email: wckim@skinresearch.or.kr
Homepage: www.skinresearch.co.kr
Researcher: Woncheol Kim

V. Requestor

Name of requestor: HINATURE Inc.
Monitor: JUYEON JUNG
Address: 2501~3 ho, S-dong, Songdo Techno Park IT Center, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, Republic of Korea
Tel: +82 70-5227-0755
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Email: jungjuyeon@purito.co.kr

VI. Test methods

This test is conducted in accordance with the SPF Test Method (ISO24444:2010), Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005) and the Standard Operating Procedures (SOP) of Korea Institute of Dermatological Sciences.

1. Selection criteria of subjects

1.1 Selection criteria

- Healthy female and male of 18 ~ 60 years old without skin diseases whose Fitzpatrick skin type corresponds to Type I -Type III in the questionnaire shown in Table 1, the researcher confirmed that it falls within the range of Individual Typology Angle (ITA°) >28° according to the criteria (Table 2), and who voluntarily agreed to participate in the human testing after being fully informed of the testing process.

$$ITA° = \left\{Arc\ \ Tangent\left[\frac{L^* - 50}{b^*}\right]\right\} 180/3.1416$$

- After fully listening to explanation about the purpose and procedures of the study, schedule, compensation, and anticipated adverse reactions, the subjects filled out the "informed consent form" and "questionnaires for selection of subject" and participated in the test.
- Healthy subjects without serious diseases including skin diseases which can affect the test result.

Table 1. Table for Fitzpatrick's skin type classification

Type	Description	MED (mJ/cm²)
I	Get red always easily (very seriously), hardly get black	2 ~ 30
II	Get red easily (seriously), get black a little	25 ~ 35
III	Get red normally, get black moderately	30 ~ 50
IV	Doesn't get red so much, get black easily	45 ~ 60
V	Hardly get red, get black very much	60 ~ 80
VI	Never get red, get black very much	85 ~ 200

Table 2. Individual typology angle (ITA°)

Skin color	ITA° value Range
Very Light	ITA°>55°
Light	41° < ITA° ≤ 55°
Intermediate	28° < ITA° ≤ 41°
Tan (or matt)	10° < ITA° ≤ 28°
Brown	-30° < ITA° ≤ 10°
Black	-30° ≥ ITA°

1.2 Exclusion criteria

In case of any of followings, we excluded from the subjects.

- Female who are pregnant or breastfeeding or likely to be pregnant.
- Subjects who have the history of photo-allergy or photosensitization
- Subjects who have used skin ointment containing steroids for the treatment of skin diseases for one month or more.
- Subjects who have skin diseases such as sensitive, irritative, atopy diseases
- Subjects with skin disorders such as spots, acne, erythema, scars in the area where artificial ultraviolet ray is irradiated.
- Other Subjects who are judged to be improper by the researcher

1.3 Criteria for dropout and data rejection

Even if the selection criteria is satisfied but in case of any of followings, we dropped out such a person.

- In case of unexpected adverse events occur at the test area,
- If the subject is exposed to excessive ultraviolet rays on the test area during the course of the test, or if the result is disturbed due to excessive drinking or smoking,
- If the test is judged to be difficult to continue due to the personal circumstances of subject,
- If excessive exposure to UV rays on the test area during the course of the test makes it difficult to accurately determine the minimal erythemal dose (MED), it is excluded from the calculation of the results,
- Even if the subject is selected according to the above criteria, if erythema occurs excessively or not at all in the area irradiated with ultraviolet rays, it is excluded from the calculation of the results.

1.4 Details that are informed to the subjects

In addition to the contents of this test, unexpected risks and skin adverse reactions due to participation in the test are fully explained.

- The purpose of test is to evaluate the sunscreen effect of cosmetics.
- Our company is commissioned to evaluate the sunscreen effect from cosmetic manufacturers.
- By signing the "informed consent form", subject agrees to voluntarily participate in this test, and can refuse to participate in the test at any time, and there is no penalty for rejection.
- About the overall test process for UV protection evaluation
- There may be individual differences in the erythema reaction and pigmentation reaction of the skin caused by UV exposure.

- There is a possibility of causing an adverse reaction during the test, so there are restrictions on the subjects
- Matters regarding risks or adverse skin reactions and side effects processing from this test

2. Test product

2.1 Information of test product

- Requestor: HINATURE Inc.
- Test product: HINATURE Fourth Sunscreen
- Product code: KIDS-CSCR08-184
- Formulation: Cream
- Color: Light Yellow
- Main ingredients

Main ingredients	Contents (%)
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	3.00
Ethylhexyl Triazone	4.00
Diethylamino Hydroxybenzoyl Hexyl Benzoate	4.00
Methylene Bis-Benzotriazolyl Tetramethylbutylphenol(50%)* Decyl Glucoside* Propylene Glycol* Xanthan Gum* Water (As Methylene Bis-Benzotriazolyl Tetramethylbutylphenol)	2.00 (1.00)

* Main ingredients are described based on the data provided by requestor.

2.2 Management and storage of evaluation product

Upon the receipt of test product, the information such as the product code, receipt date, storage date shall be listed and the product shall be stored in the standard product storage room for 6 months after the completion of test, and disposed.

3. Standard reference sunscreen

The standard reference sunscreen in this test is SPF reference sunscreen formulation P2 listed in ISO24444:2010, purchased from Cosmetech Laboratories Inc., the average SPF value of reference sunscreen (P2) is 16.1 ± 2.4.

4. Minimal erythemal dose in unprotected skin (MEDu)

4.1 UV irradiation area

The test area on the back was restricted between the scapula line and the waist. Skeletal protrusions and extreme areas of curvature should be avoided.

- Distance between test site: 1 cm
- Distance between subsites: 0.8 cm
- UV radiation area of each port: 0.64 cm^2

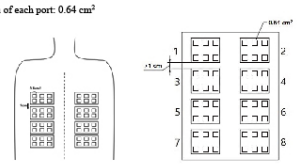

Figure 1. UV irradiation area

4.2 Light source

Multi-port Solar Simulator 601-300W (Solar Light, USA) equipped with 300W xenon arc lamps was used in this test. The filter used the Dichroic mirror and UG11 filter to selectively take light from 290 to 400nm wavelengths, blocking most of the wavelengths other than ultraviolet light, and using the WG320 filter to remove the wavelengths in UVC areas. Ultraviolet light is a square with a side length of 0.8 cm, and is radiated through six light guides, and the light intensity is individually adjusted using the aperture at the top of the light. The subjects were taken in a stable position and taken care not to move while investigating UV rays.

4.3 Light intensity meter

Model name: PMA2100, UVB detector (Solar Light, USA)

4.4 Incremental progression of UV dose

In order to determine the minimal erythemal dose of unprotected site (MEDu), UV radiation was irradiated at the unprotected area for 44 seconds:

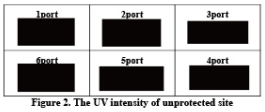

Figure 2. The UV intensity of unprotected site

4.5 Determination of unprotected minimal erythemal dose (MEDu)

The unprotected minimum erythema dose (MEDu) was determined by visual assessment of the erythema responses within the range of 20 ± 4 hours (16 to 24 hours). The observers of erythemal responses shall not be the same persons as the ones who performed product application and exposure.

Table 3. Criteria for minimal erythemal dose (MED) determination

Response	Description	Note
O	No response	
±	Erythema response less than 50% on irradiated area or is not defined borders appearing over most of the field of UV exposure	
+	Erythema response more than 50% on irradiated area with defined borders	Minimal erythemal dose (MED)
++	UV irradiated site shows 100% clear erythema response and the skin surface is swollen	
+++	UV irradiated site shows 100% clear erythema response and skin surface shows bullae and scales	

5. Determination of minimal erythemal dose in protected skin (MEDp)

5.1 Product application

- Application area: 35 cm^2 (7 x 5 cm)
- Application amount per application area: 2.00 ± 0.05 mg/cm^2
- Application method:

5.2 Incremental progression of UV dose

UV intensity calculated by multiplying the MEDu by the expected SPF of the product was set at port 4. The intensity of UV radiation is as follows (Figure 3).

(example) Calculation when MEDu1 is 30.1 uw/cm^2 and expected SPF is 50

MEDp irradiation time =

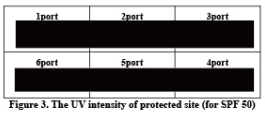

Figure 3. The UV intensity of protected site (for SPF 50)

5.3 Determination of protected minimal erythemal dose (MEDp)

The protected minimum erythema dose (MEDp) was determined by visual assessment of the erythema responses within the range of 20 ± 4 hours (16 to 24 hours). The observers of erythemal responses shall not be the same persons as the ones who performed product application and exposure.

6. Calculation and validation of SPF value

6.1 Calculation of SPF value

A SPF value for each test subject (SPFis) was calculated as follows:

$$SPFis = \frac{\text{Protected minimal erythemal dose (MEDp)}}{\text{Unprotected minimal erythemal dose (MEDu2)}}$$

To determine the SPF value of test product, data from at least 10 subjects was used and calculated the mean SPF value of them.

6.2 Statistical criterion of SPF value

The 95% confidence interval (CI) of the mean SPF should be within a range of ± 17% of the mean SPF. If the 95% confidence interval does not exist within ± 17% of the mean SPF, the number of subjects should be increased until the statistical criterion is met up to maximum of twenty valid results.

$$C = t\,value \times \frac{S}{\sqrt{n}}$$

t value: t value from the 'two-sided' Student-*t* distribution table under at a probability level p=0.05 and with (n-1) degrees of freedom

n: total numbers of subjects used

S: standard deviation

N	10	11	12	13	14	15	16	17	18	19	20
t value	2.262	2.228	2.201	2.179	2.160	2.145	2.131	2.120	2.110	2.101	2.093

7. Determination of minimal erythemal dose after water immersion (MEDw)

7.1 Water quality

- Water temperature: 27 ~ 31°C (The temperature was checked during the test.)
- Keep the room temperature constant.
- Use water that meets the water quality standards.

7.2 Immersion equipment

- Water circulation using water jet
- The test site of the subject was sufficiently submerged in water.
- The test site was prevented from contacting the bathtub and water circulation was not directly affected.

7.3 Immersion process

- Immersion time: 40 minutes immersion (Immerse 2 times for 20 min each)
- Drying time: 30 minutes (drying 2 times in 15 minutes with no toweling)
- Allow test sites to air-dry with no toweling for 15 minutes or until test site is completely dry.

8. Calculation and validation of water resistance SPF (SPFw) value

8.1 Calculation of water resistance SPF (SPFw) value

A SPFw value for each test subject (SPFiw) was calculated as follows:

$$SPFiw = \frac{\text{Protected wet minimal erythemal dose (MEDpw)}}{\text{Unprotected wet minimal erythemal dose (MEDuw)}}$$

To determine the SPFw value of test product, data from at least 10 subjects was used and calculated the mean SPFw value of them.

8.2 Calculation of percentage water resistance retention (%WRR)

A percentage water resistance retention (%WRR) value for each test subject (%WRRi) was calculated as follows:

$$\%WRRi = \frac{(SPFiw - 1)}{(SPFis - 1)} \times 100$$

To determine the %WRR of test product, data from at least 10 subjects was used and calculated the mean %WRR value of them.

8.3 Calculation of lower confidence limit on the mean percentage water resistance retention

The 90% lower unilateral confidence limit is calculated as:

$$[\text{mean \%WRR} - d]$$

with d calculated as:

$$d = t_U \times s/\sqrt{n}$$

s= standard deviation
n= total number of volunteers in test
t_U= t value from the 'one-sided' Student-t distribution table at a probability level p=0.10 and with n-1 degrees of freedom

N	10	11	12	13	14	15	16	17	18	19	20
t_u value	1.383	1.372	1.363	1.356	1.350	1.345	1.341	1.337	1.333	1.330	1.328

9. Skin adverse reaction evaluation

When the subject has a skin adverse reaction, the researcher graded it according to the severity. The adverse reaction evaluation includes the judgment of the existence of erythema, edema, scaling, itching, stinging, burning, tightness and prickling, and takes the actions in accordance with the regulation for skin abnormality treatment. The research organization is conducted with the safety of the subject as the top priority during the test period. If adverse reactions and side effects occur, the medical treatment or decision was made by dermatologist. The cost of medical treatment is paid by the requestor. The investigation will proceed until the skin adverse reaction is resolved or stable, or it is no longer possible to follow up. However, if damage is not caused by participation in the test, compensation is excluded.

VII. Test results

1. Preliminary test

Because the requestor "**HINATURE Inc.**" notified **[SPF 50+]** of expected SPF to Korea Institute of Dermatological Sciences, preliminary tests were conducted assuming that the expected SPF of the test product was [SPF 50] and the expected SPFw was [SPF 30] in accordance with the SPF Test Method (ISO24444:2010), Guidelines for Evaluating Sun Product Water Resistance (Cosmetics Europe, 2005) and the Standard Operating Procedures (SOP) of Korea Institute of Dermatological Sciences.

No	Subject ID	Sex	Age	Skin type	MEDu2 (mJ/cm²)	Reference sunscreen SPF	Test product SPFis	MEDuw (mJ/cm²)	Test product SPFiw
1	KIDS-FS0828-379	F	22	III	30.1	14.0	43.5	37.6	27.6
2	KIDS-FS0828-433	F	21	III	30.1	14.0	50.0	30.1	26.1
3	KIDS-FS0829-345	F	47	III	23.9	14.1	50.4	23.9	26.3
Total 3 subjects				**Mean**	**28.0**	**14.0**	**48.0**	**30.5**	**26.7**

As a result of the preliminary test, the SPF of the test product was 48.0 and the SPFw was 26.7, which is predicted to obtain satisfactory results of the SPF and water resistance effect in the main test. Therefore, a total of 10 subjects including the preliminary test were conducted with the expected SPF of 50 and the expected SPFw of 30.

2. Main test

2.1 Result of SPF

Based on the preliminary test results, the expected SPF was set to [SPF 50] and the expected SPFw was set to [SPF 30], and a total of 10 subjects participated in the main test.

No	Subject ID	Sex	Age	Skin type	MEDu2 (mJ/cm²)	Reference sunscreen MED (mJ/cm²)	Reference sunscreen SPF	Test product MEDp (mJ/cm²)	Test product SPFis
1	KIDS-FS0828-379	F	22	III	30.1	421.3	14.0	1309.1	43.5
2	KIDS-FS0828-433	F	21	III	30.1	421.3	14.0	1505.1	50.0
3	KIDS-FS0829-345	F	47	III	23.9	337.7	14.1	1204.7	50.4
4	KIDS-FS0912-397	F	47	II	23.9	337.7	14.1	1204.7	50.4
5	KIDS-MS0918-316	M	49	III	37.6	484.3	12.9	1730.7	46.0
6	KIDS-FS0920-496	F	23	III	15.3	270.5	17.7	839.7	54.9
7	KIDS-FS0920-480	F	28	III	30.1	421.3	14.0	1730.7	57.5
8	KIDS-FS1004-363	F	22	II	37.6	421.3	11.2	1730.7	46.0
9	KIDS-FS1010-336	F	41	III	37.6	556.9	14.8	1730.7	46.0
10	KIDS-FS1011-481	F	24	III	30.1	421.3	14.0	1730.7	57.5
Total 10 subjects		**Female 9 Male 1**	**Mean 32.4**	**I : 0 II: 2 III: 8**	**Mean 29.6**		**Mean 14.1**		**Mean 50.2**

*The Fitzpatrick skin type was determined by questionnaire evaluation and visual assessment.

2.2 Result of water resistance (SPFw)

No	Subject ID	Sex	Age	Skin type	MEDuw (mJ/cm²)	Test product MEDpw (mJ/cm²)	Test product SPFiw	%WRRi
1	KIDS-FS0828-379	F	22	III	37.6	1038.0	27.6	62.6
2	KIDS-FS0828-433	F	21	III	30.1	785.2	26.1	51.2
3	KIDS-FS0829-345	F	47	III	23.9	628.7	26.3	51.2
4	KIDS-FS0912-397	F	47	II	29.9	722.8	24.2	46.9
5	KIDS-MS0918-316	M	49	III	37.6	902.7	24.0	51.1
6	KIDS-FS0920-496	F	23	III	19.2	503.4	26.2	46.8
7	KIDS-FS0920-480	F	28	III	37.6	1038.0	27.6	47.1
8	KIDS-FS1004-363	F	22	II	37.6	1038.0	27.6	59.1
9	KIDS-FS1010-336	F	41	III	37.6	1193.3	31.7	68.3
10	KIDS-FS1011-481	F	24	III	37.6	1193.3	31.7	54.4
Total 10 subjects		**Female 9 Male 1**	**Mean 32.4**	**I : 0 II: 2 III: 8**	**Mean 32.9**		**Mean 27.3**	**Mean 53.9**

3. Acceptance criteria

The 90% lower unilateral confidence limit value [mean %WRR - d] of test product was 50.7% and the 95% confidence interval on the mean static SPF was within ± 17% of the mean static SPF. Therefore, the test product is considered as Water Resistance. The skin adverse reaction was not observed during the study.

	Mean SPF	Standard deviation	Number of subjects (n)	t value	17% of mean SPF	95% confidence interval	Validity of test
Reference sunscreen (P2)	14.1	1.6	10	2.262	2.4	1.1	Valid
Test product SPF	50.2	5.0	10	2.262	8.5	3.6	Valid
Water resistance SPF (SPFw)	27.3	2.7	10	2.262	4.6	1.9	Valid

%WRR	Standard deviation	t_a value	t_a value × S/√n	mean %WRR - d	Final result
53.9	7.3	1.383	3.2	50.7	Water Resistance

VIII. Conclusion

This test shows the result that determining the Sun Protection Factor and the Water Resistance Effect of "**HINATURE Fourth Sunscreen**" requested by "**HINATURE Inc.**"

The test was conducted on 10 subjects in total that satisfied the selection criteria.

The SPF result of the reference Sunscreen (P2) is within the range of 16.1 ± 2.4 suggested by the SPF Test Method of Cosmetics Europe (ISO 24444:2010) and the Standard Operating Procedures (SOP) of Korea Institute of Dermatological Sciences.

Since the 95% confidence interval (CI) was within a range of ± 17% of the mean SPF, this test has the suitability and reliability.

The skin adverse reaction was not observed during the entire test processes.

The mean static SPF value (SPFs) of "**HINATURE Fourth Sunscreen**" was 50.2 ± 5.0. The mean wet SPF value (SPFw) was 27.3 ± 2.7 and the mean of percentage water resistance retention (%WRR) was 53.9 ± 7.3%. Therefore, the 90% lower unilateral confidence limit value [mean %WRR - d] was 50.7%, the test product is considered as a Water Resistance product.

IX. References

No. 2019-47 regulations on functional cosmetic inspection by Ministry of food and drug safety

COLIPA Guideline International Sun Protection (SPF) test method

China Food and Drug Administration (CFDA)

[ISO24444:2010] Cosmetics-Sun Protection test methods -in vivo determination of SPF (Sun Protection Factor)

[ISO24442:2011] Cosmetics-Sun Protection test methods -in vivo determination of sunscreen UVA protection

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Appendixes

[Appendix 1] Research members of the organization

[Appendix 2] Facilities of the organization

[Appendix 3] Ingredients

[Appendix 4] Case Report Form

[Appendix 5] Compliance statement of solar simulator

[Appendix 1] Research members of the organization

■ In Sook An (director of research center, Adjunct Professor, Doctor of Science)

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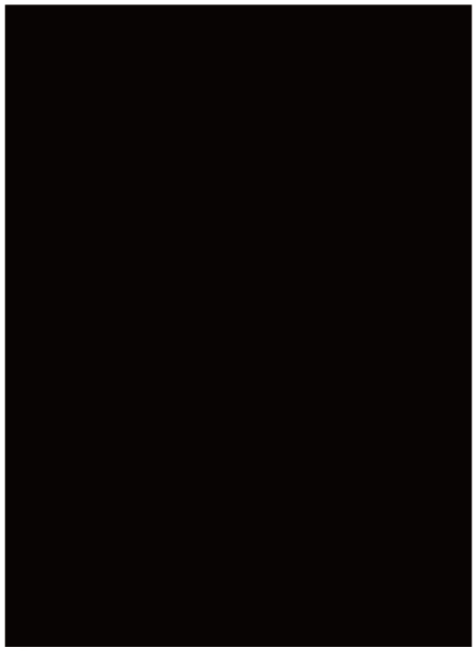
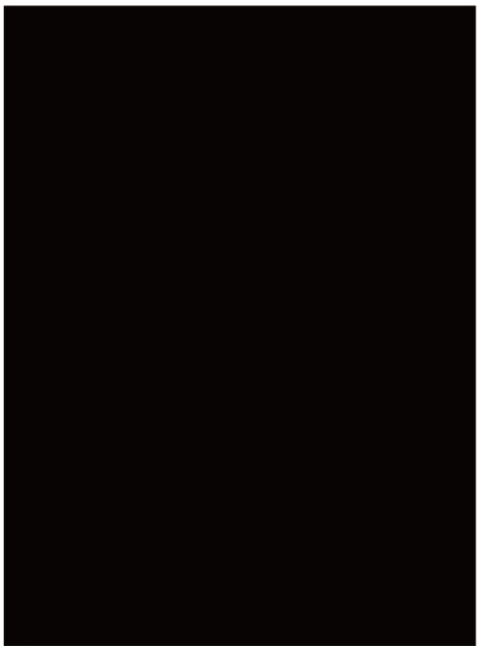
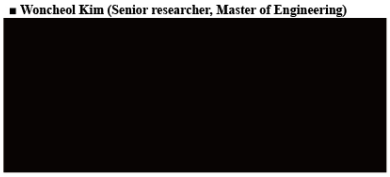
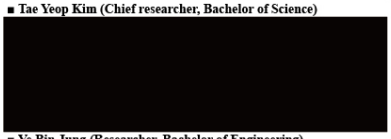




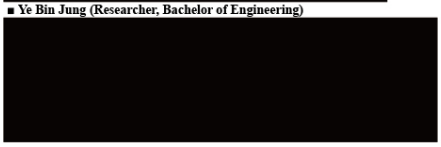
■ **Woncheol Kim (Senior researcher, Master of Engineering)**



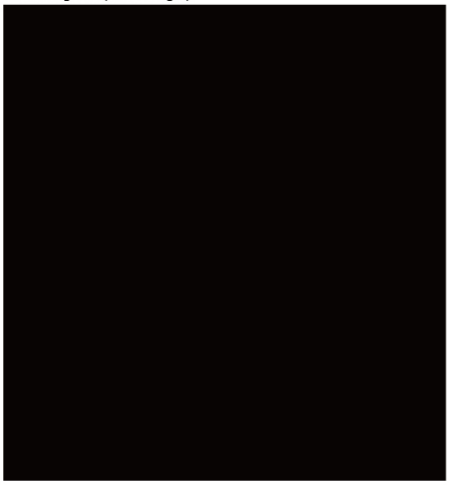
■ **Tae Yeop Kim (Chief researcher, Bachelor of Science)**



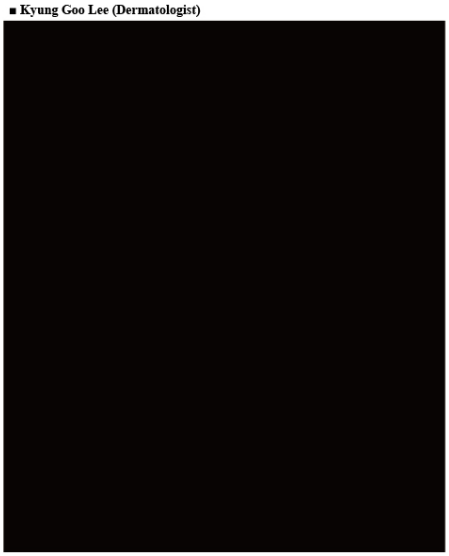
■ **Ye Bin Jung (Researcher, Bachelor of Engineering)**



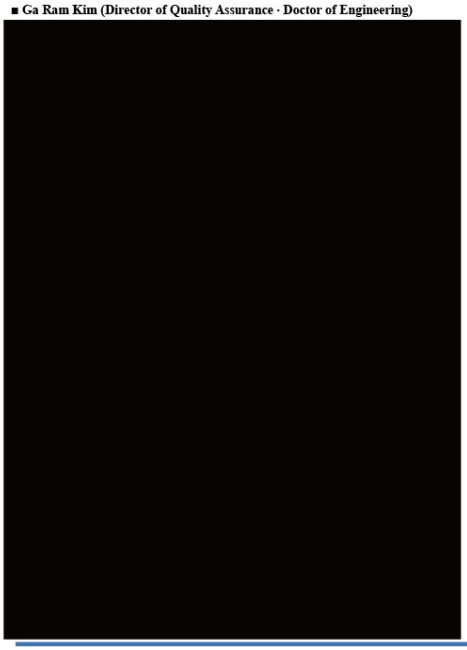
■ **Won Ung Shin (Dermatologist)**



■ Kyung Goo Lee (Dermatologist)



■ Ga Ram Kim (Director of Quality Assurance · Doctor of Engineering)



[Appendix 2] Facilities of the organization

- Korea Institute of Dermatological Sciences (KIDS) expertly performs the non-invasive clinical studies with human subjects for the safety and efficacy of functional cosmetics, common cosmetics, and other cosmetic products.
- KIDS is established by dermatologists, professors and researchers in Department of Dermatology, Cosmetic Biology, and Biological Sciences.
- All of studies in KIDS are conducted according to the laws and regulations of designation as the test institution for drugs, quasi-drugs, cosmetics, and medical devices; the guidelines of the management standards for clinical drug evaluations; the guidelines of *in vivo* clinical and *in vitro* evaluation studies; the guidelines of the experimental methods for cosmetic display and advertisements; and the guidelines of the validation of functional cosmetics of the Ministry of Food and Drug Safety, Republic of Korea; the laws of the bioethics and safety of the Ministry of Health and Welfare, Republic of Korea; and the standard operation procedure of the KIDS.
- Evaluation and Research Fields

1. Efficacy evaluation
Skin whitening
Inhibition of melanogenesis
Skin hydration
Skin sebum secretion
Skin desquamation and regeneration
Stratum corneum recovery
Stratum corneum turnover
Epidermal barrier quality
Anti-aging
Skin wrinkle
Skin lifting effects
Skin biomechanical properties and elasticity
Skin thickness and dermis density
Transepidermal water loss
Cleansing effects
Anti-microbial effects
Irritation prevention
Calming effects
Anti-inflammatory effects
Anti-acne effects
Protection and recovery against free radicals
Demodex folliculorum removal
Improvement of skin pore

Improvement of scalp condition
Anti-dandruff effects
Prevention of hair loss and hair growth
Curling effects of eyelashes
Sliming
Cellulite treatment effects
Breast lifting and firming effects
Edema reducing effects
2. Safety evaluation
Human patch test
Repeat insult patch test
Cumulative test
Stinging potential test
Modified lactic acid stinging test
Phototoxicity and photosensitization
Usage test
3. Sensory evaluation
Subjective evaluation
Questionnaire on usability assurance
4. Cell efficacy evaluation and mechanism studies
2D and 3D cell culture based experiments (keratinocytes, melanocytes, dermal fibroblasts, sebocytes, dermal papilla cells, immune cells, fat cells, primary cells, etc.)
Various biochemical experiments
Skin cell and molecular biology
Anti-aging and senescence
Melanogenesis
Anti-inflammation
Cell growth, migration, cell cycle arrest, autophagy, and apoptosis
Cell differentiation

• Major Facilities and Laboratories

Constant Temperature and Humidity Sector
Clinical Data Analysis Room
Clinical Efficacy Room
Efficacy Evaluation Room
Safety Evaluation Room
Functional Evaluation Room
UV Irradiation Room

Waterproof Evaluation Room
Cellular Efficacy Room
3D Skin Cell Culture Room
3D Image Processing Room
In Vitro Experiment Equipment Room
Studio
Dark Room and Film Analysis Room
Data Storage Room
Storage Room
Washing Room
Microscope Room
Molecular Targeted Drug and Biomedical Research Lab
Cell Culture and Analysis Room
DNA and Gene Analysis Room
Protein and Enzyme Analysis Room
Microorganism Culture and Analysis Room
Highly Functional Biomaterial Screening Room
Bioactive Material Isolation and Purification Room
Super Precisional Material Analysis Room
Freezer and Incubator Room
Volunteer Waiting Room
Volunteer Counseling Room
Volunteer Locker Room
Conference Room
Office for Director
Office for Researchers
Administrative Office

[Appendix 3] Ingredients

Water, Propanediol, Dibutyl Adipate, Dicaprylyl Carbonate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Ethylhexyl Triazone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Amylopectin, Butylene Glycol, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Glycerin, Behenyl Alcohol, Poly C10-30 Alkyl Acrylate, Polyglyceryl-3 Methylglucose Distearate, Sodium Acrylates Crosspolymer-2, Carbomer, Tromethamine, Decyl Glucoside, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, (-)-alpha-bisabolol, Panthenol, Caprylhydroxamic Acid, Centella Asiatica Extract, Tocopherol, Ceramide NP, Dipropylene Glycol, Cholesterol, Propylene Glycol, Xanthan Gum, Glyceryl Stearate, Ceramide AS, Ceramide AP, Ceramide NS, Hydrogenated Lecithin, Ceramide EOP

[Appendix 4] Case Report Form

[Appendix 5] Compliance statement of solar simulator

Radio Meter & Detector Calibration

SOLAR® LIGHT

CERTIFICATE OF CALIBRATION

INSTRUMENT DESC.	Radiometer	PROJECT NUMBER	28766
INSTRUMENT MODEL	PMA2100	DATE CALIBRATED	2/6/2023
INSTRUMENT SN	29777	CALIBRATION FREQUENCY	Annual
RANGE	0 – 5 Volts	EXPANDED UNCERTAINTY	±0.6%, k=2
REFERRING STANDARD	Mfg Spec	TEMPERATURE	24.8 °C
CALIBRATION METHOD	Transfer	HUMIDITY	17 %

The above instrument has been calibrated traceable to the National Institute of Standards and Technology (NIST). Solar Light Company's quality system is compliant with ANSI/NCSL Z540.3-2006. Unless otherwise specified, the tolerance limits are equal to the expanded uncertainty. This report may not be reproduced, except in full, without the written approval of Solar Light Company.

STANDARDS USED

- Fluke Model 189 multimeter S/N 85570068

CALIBRATION METHOD

The above instrument was calibrated by transfer from the Fluke 189 multimeter measuring a precision voltage source.

The precision voltage source is applied to each the left and right detector connector of the PMA2100 for calibration. The high range calibration factor for each connector and the common low range calibration factor are stored in the PMA2100. Any PMA21xx series detector can interface to either connector.

RESULTS

Calibration level is 0.3V for low range, 3V for high range.

NOTES

PRINT DATE February 14, 2023
CALIBRATION CERTIFIED BY

Wayne Eckman
Operations Manager

Page 1 of 1

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SOLAR® LIGHT

CERTIFICATE OF CALIBRATION

INSTRUMENT DESC.	UVA Detector	PROJECT NUMBER	28766
INSTRUMENT MODEL	PMA2118	DATE CALIBRATED	2/6/2023
INSTRUMENT SN	29517	CALIBRATION FREQUENCY	Annual
RANGE	0 – 400 mW/cm²	REFERRING STANDARD	Mfg Spec
SENSITIVITY	320 – 400 nm	CALIBRATION METHOD	Transfer
SPECTRUM TO		EXPANDED UNCERTAINTY	±5%, k=2
WHICH CALIBRATED	JCIA compliant	TEMPERATURE	25.2 °C
REFERENCE PLANE	Base of optical integrator adapter	HUMIDITY	16 %

The above instrument has been calibrated traceable to the National Institute of Standards and Technology (NIST). Solar Light Company's quality system is compliant with ANSI/NCSL Z540.3-2006. Unless otherwise specified, the tolerance limits are equal to the expanded uncertainty. This report may not be reproduced, except in full, without the written approval of Solar Light Company.

STANDARDS USED

- Solar Light Model PMA2118 UVA Detector S/N 10532

CALIBRATION METHOD

The standard UVA detector is calibrated traceable to NIST. A Solar Light Solar Simulator is used as the light source and its output spectrum complies with JCIA "Measurement Standards for UVA Protection Efficacy", Nov. 15, 1995.

The solar simulator is configured with a WG335 filter in the light path. The PMA2118 UVA detector is calibrated by transfer from the standard UVA detector at the output end of the optical integrator.

RESULTS

Calibration level is 20 [mW/cm²].

NOTES

PRINT DATE: February 14, 2023
CALIBRATION CERTIFIED BY:

Wayne Eckman
Operations Manager

Page 1 of 1

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SOLAR® LIGHT

CERTIFICATE OF CALIBRATION

INSTRUMENT DESC.	SUV Detector	PROJECT NUMBER	28766
INSTRUMENT MODEL	PMA2108	DATE CALIBRATED	2/8/2023
INSTRUMENT SN	29409	CALIBRATION FREQUENCY	Annual
RANGE	0 – 500 MED/HR	REFERRING STANDARD	Mfg Spec
SENSITIVITY	280 – 400 nm, Erythema weighted	CALIBRATION METHOD	Transfer
SPECTRUM TO		EXPANDED UNCERTAINTY	±5%, k=2
WHICH CALIBRATED	COLIPA compliant	TEMPERATURE	24.8 °C
REFERENCE PLANE	Base of optical integrator adapter	HUMIDITY	17 %

The above instrument has been calibrated traceable to the National Institute of Standards and Technology (NIST). Solar Light Company's quality system is compliant with ANSI/NCSL Z540.3-2006. Unless otherwise specified, the tolerance limits are equal to the expanded uncertainty. This report may not be reproduced, except in full, without the written approval of Solar Light Company.

STANDARDS USED

- Solar Light Model PMA2108 SUV Detector S/N 10652

CALIBRATION METHOD

The standard SUV detector is calibrated traceable to NIST. A Solar Light Solar Simulator is used as the light source and its output spectrum complies with COLIPA "International Sun Protection Factor(SPF) Test Method", May 2006. One minimal erythema dose (MED) is defined by applying the McKinlay-Diffey Erythema Action Spectrum and 21 mJ/cm² to induce minimal skin redness.

The PMA2108 SUV detector is calibrated by transfer from the standard SUV detector at the output end of the optical integrator.

RESULTS

Calibration level is 10 [MED/HR].

NOTES

PRINT DATE: February 14, 2023
CALIBRATION CERTIFIED BY:

Wayne Eckman
Operations Manager

Page 1 of 1

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Multi-port solar simulator

Solar Light Company, LLC Project No. 28766 Rev A

SPECTRORADIOMETRIC MEASUREMENTS of
MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR
Serial Number #29694
February 9, 2023

Certificate of Compliance

This certifies that the model
601-300 V2.5 UV Multiport
Serial Number 29964 with Shutter Serial Number 601786
and lamp Serial Number ZB0005
complies with the specifications set forth in the;

ISO 24444:2019 Cosmetics — Sun protection test methods — *In-vivo* determination of SPF (Sun Protection factor)
COLIPA: International Sun Protection Factor (SPF) Test Method, May 2006
Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations

ISO 24442:2022 Cosmetics — Sun protection test methods — *In-vivo* determination of sunscreen UVA protection

Japan Cosmetic Industry Association - J.C.I.A - Measurement Standards for UVA Protection (1995)

Project Number: *28766*
Date complete: *February 9, 2023*
Date Due: *February 9, 2024*

Measurements performed by:

Alexandra Raphael
Solar Light Company, LLC

Page 1

Solar Light Company, LLC — Project No. 28766 Rev A

SPECTRORADIOMETRIC MEASUREMENTS of
MODEL 601-300 V2.5 MULTIPORT, UV SOLAR SIMULATOR
Serial Number 29694 with Shutter Serial Number 691786
And lamp serial Number ZB0005
February 9, 2023

EQUIPMENT TESTED:

Model 601-300 V2.5 Multiport, UV Solar Simulator, serial number 29694 with shutter serial number 601786 configured to meet ISO 24444, COLIPA 2006, FDA 2011, JCIA standards and ISO 24442.
Lamp operation at 300 watts and occulters adjusted for a 1500W/m² maximum output.

MEASUREMENT EQUIPMENT:

- Optronic Laboratories, LLC Model OL 750-M-D, Double Grating Monochromator, Serial Number 21516220
- Optronic Laboratories, LLC Model OL 750C, Spectroradiometer Controller, Serial Number 21531478
- Optronic Laboratories, LLC Model OL 750-DH310 (S-20) Response PMT Detector Head, Serial Number 21100368
- Optronic Laboratories, LLC Model OL 750-DN320 Germanium Detector Head, Serial Number 2110066
- Optronics Model OL IS-670 (6) inch Diameter Integrating Sphere
- Standard of Spectral Irradiance model OL 752-10L S/N 21102341

MEASUREMENT METHODS:

The Optronics 750 M-D, Double Grating monochromator is configured with the Model OL 750-DH310 (S-20) Response PMT Detector Head at the exit port and a 6 inch diameter integrating sphere with a 5.8mm entrance aperture to collect the radiation. The slits used were 1.25mm entrance, 2.50mm middle, and 1.25mm aperture exit. The system wavelength drive is checked using the 313.2nm line from a low pressure mercury lamp. The system's response is measured using the standard of spectral irradiance S/N M1493e at a distance of 50cm and operated at 5.500 amperes. The system is calibrated from 250 to 1600nm in 2nm steps.

The standard lamp is replaced with the 601 Multiport UV Solar Simulator containing the shutter 6601786. The shutter is positioned in the UVA+B position. The LLG of the solar simulator is positioned at the entrance of the integrating sphere in the 8mm aperture. The spectral response of each port is measured from 250 to 1600nm in 2nm steps. The LLG of the next port is positioned at the entrance of the integrating sphere and the procedure is repeated for each of the six ports.

The shutter position was then changed to the UVA position and the spectral irradiance of all 6 ports was measured again.

CALCULATIONS:

UVA+B Shutter Position

When the shutter is located in the UVA+B position the simulator is in accordance with:

- ISO 24444: "Cosmetics — Sun protection test methods — In vivo determination of SPF (Sun Protection factor)"[2]
- COLIPA: "International Sun Protection Factor Test Method, May 2006"[3]
- Federal Register: Vol. 72, No. 117 / Friday, June 17, 2011 / Rules and Regulations[4] guidelines.

The percentage of relative cumulative erythemal effectiveness (%RCEE) for the light source is calculated. The spectral irradiance of the solar simulator is multiplied by the CIE-1987 erythema action spectrum[1] to obtain the spectral erythemal effectiveness of the source. The spectral erythemal effectiveness is then integrated from 290nm to the specified wavelengths of, 300, 310, 320, 330, 340, 350 and 400nm. This produces the cumulative erythemal effectiveness for that band. The total erythemal effectiveness is also calculated up to 400nm. Finally, the percentage **Relative Cumulative Erythemal Effectiveness** (%RCEE) is calculated for the specified wavelengths as the ratio of the cumulative erythemal effectiveness at each of these wavelength groups to the total integrated value. The acceptance limits for a source is shown below.

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Solar Light Company, LLC — Project No. 28766 Rev A

UVA Shutter Position

When the shutter is located in the UVA position the spectral output complies with:

- Japan Cosmetic Industry Association: JCIA - Measurement Standards for UVA Protection (1993)[5]
- ISO 24442: Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection (2022)[6].

The specifications are listed below.

SPECTRAL RANGE [nm]	%RCEE LOWER LIMIT	%RCEE UPPER LIMIT
<290		<0.1
290-300	2.0	8.0
290-310	49.0	55.0
290-320	85.0	90.0
290-330	91.5	95.5
290-340	94.0	97.0
290-350	55.5	98.5

COLIPA (SPF) Test Method Specifications

SPECTRAL RANGE [nm]	LIMIT [%]
UVA II Irradiance (320-340nm)	≥20%
UVA I Irradiance (340-400nm)	≥60%

Balance of UVA: UVB

Total Energy	<150 mW/cm²
UVA / Total	93% - 100%
UVB / UVA	< 0.1%
UVA2 / UVA	8.0% - 20.0%
Spectrum Continuity	Cont. (no peaks)

Persistent Pigmentation Darkening (PPD) specifications JCIA

RESULTS:

All six ports of the simulator's shutter comply with the ISO24444, COLIPA and FDA specifications for UV solar simulator acceptance limits. The %RCEE wavelength values are within the specified limits. The source spectrum is smooth and continuous as shown in the graph below. The energy below 290nm is less then 0.1% and the Visible + NIR energy is below 5%. The %RCEE values, UVB spectral response and full spectrum are shown below.

When the simulator is configured for an UVA spectrum it complies with JCIA and ISO24442 specifications.

Page 3

RESULTS of SPECTRORADIOMETRIC MEASUREMENTS

Compliance of the UV source spectrum with SPF Standard specifications

Laboratory	Harvey Trading Company	Date of control	2/9/2023
UV source (Power)	601-300 V2.5 300 Watt	Control Laboratory	Solar Light Company, LLC
Serial Number	29694	Operator	A. Raphael
Spectrum Type	UVery	Spectroradiometer	750-M-D
Filters	[illegible]	Serial Number	#21516220

Wavelength range	Accept. Limits Lower	Accept. Limits Upper	RCEE% Port 1	Port 2	Port 3	Port 4	Port 5	Port 6	Mean
< 290 nm		< 0.1%	0.011%	0.008%	0.006%	0.005%	0.003%	0.008%	0.007%
290 - 300 nm	1.0	8.0	4.2%	4.4%	4.5%	5.2%	4.0%	4.1%	4.4%
290 - 310 nm	49.0	55.0	54.9%	55.2%	55.4%	57.1%	54.2%	54.4%	55.2%
290 - 320 nm	85.0	90.0	87.2%	87.2%	87.1%	87.7%	86.7%	86.9%	**87.1%**
290 - 330 nm	91.5	95.5	93.4%	93.4%	93.2%	93.5%	93.0%	93.1%	93.2%
290 - 340 nm	94.0	97.0	95.7%	95.7%	95.6%	95.7%	95.4%	95.5%	95.6%
290 - 400 nm	100.0	100.0	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total irradiance ***	W.m⁻²	1500	1465	1481	1463	1412	1454	1460	1459
International SPF (2006)	PASSES		Passes	Passes	Passes	Passes	Passes	Passes	Passes
FDA Rules (2011)	PASSES		Passes	Passes	Passes	Passes	Passes	Passes	Passes
ISO24444 (2019)	PASSES		Passes	Passes	Passes	Passes	Passes	Passes	Passes

* One or several columns will be used according to the number of ports/channels available on the UV source
** Integrals are calculated using trapezium approximation, not rough summation.
*** Reduce UV output proportionally if 1500 W/m2 is exceeded

RESULTS of SPECTRORADIOMETRIC MEASUREMENTS of UV SOURCE

Laboratory	Harvey Trading Company	Date of control	2/9/2023
UV source (Power)	601-300 V2.5 300 Watt	Control Laboratory	Solar Light Company, LLC
Serial Number	29694	Operator	A. Raphael
Spectrum Type	UVery	Spectroradiometer	750-M-D
Filters	[illegible]	Serial Number	#21516220

Energetic Irradiance	Unit	Port 1	Port 2	Port 3	Port 4	Port 5	Port 6	Mean
250-290 nm	W.m⁻²	0.0010	0.0007	0.0005	0.0004	0.0003	0.0007	0.0006
<290 nm	W.m⁻²	0.0011	0.0008	0.0006	0.0005	0.0003	0.0009	0.0007
UVB (290-320 nm)	W.m⁻²	153.7	160.7	154.5	148.5	151.0	155.7	155.0
UVA (320-400 nm)	W.m⁻²	1293	1300	1293	1243	1280	1293	1288
UVA-2 (320-340 nm)	W.m⁻²	403.4	405.3	394.0	383.3	391.1	397.0	393.9
UVA-1 (340-400 nm)	W.m⁻²	889	900	899	830	895	895	894
Total UV (290-400 nm)	W.m⁻²	1446	1466	1447	1393	1437	1449	1443
Visible (400-780 nm)	W.m⁻²	15.0	13.8	14.2	18.8	16.2	14.4	14.7
NIR (780-1600 nm)	W.m⁻²	1.604	1.221	1.316	2.135	1.621	1.209	1.518
UV+VIS (290-700 nm)	W.m⁻²	1465	1480	1461	1410	1452	1459	1456
Total (UV+VIS+NIR)	W.m⁻²	1465	1481	1463	1412	1454	1460	1459
Ratio UVA / UVB	Ratio	8.13	8.12	8.37	[illegible]	8.52	8.31	8.31
Ratio UVA1 / UVA2	Ratio	2.22	2.22	2.28	2.61	2.29	2.24	2.27
Ratio VIS+IR / Total	Ratio	1.13%	1.02%	1.06%	1.34%	1.15%	1.00%	1.11%
Eryth. Eff. Irradiance		**Port 1**	**Port 2**	**Port 3**	**Port 4**	**Port 5**	**Port 6**	**Mean**
UVery	W.m⁻²ery	10.5	10.7	10.3	10.3	9.9	10.2	10.3
UVe irradiance	MED.min-1	2.99	3.05	2.95	2.95	2.83	2.91	2.94
UVe irradiance	MED.hr-1	179.4	182.7	177.1	177.0	169.6	174.5	176.7
Time per stdMED*	hh:mm:ss	0:00:20	0:00:20	0:00:20	0:00:20	0:00:21	0:00:21	0:00:20
UV dose per stdMED*	J/m²	30,054	28,850	29,425	28,257	30,504	29,034	29,380
UVB dose per stdMED*	J/m²	3,164	3,165	3,161	3,046	3,206	3,205	3,158
UVA dose per stdMED*	J/m²	25,850	25,723	26,284	25,281	27,298	26,629	26,240
UVB dose per SED	J/m²	12,324	12,249	12,516	12,029	12,999	12,080	12,436
UVA dose per SED	J/m²	13,840	13,757	14,072	13,485	14,525	14,201	13,960
RCEE (min. - max.)	**and**	**Compliance with SPF Standard specifications**						
< 290 nm (< 0.1)	%	0.01%	0.01%	0.01%	0.00%	0.00%	0.01%	0.01%
290-300 nm (1.0 - 8.0)	%	4.2%	4.4%	4.5%	5.2%	4.0%	4.1%	4.4%
290-310 nm (49.0 - 55.0)	%	54.9%	55.2%	55.4%	57.1%	54.2%	54.4%	55.2%
290-320 nm (85.0 - 90.0)	%	87.2%	87.2%	87.1%	87.7%	86.7%	86.9%	87.1%
290-330 nm (91.5 - 95.5)	%	93.4%	93.4%	93.2%	93.5%	93.0%	93.1%	93.2%
290-340 nm (94.0 - 97.0)	%	95.7%	95.7%	95.6%	95.7%	95.4%	95.5%	95.6%
290-350 nm (95.5 - 98.5)	%	97.4%	97.4%	97.3%	97.4%	97.2%	97.3%	97.3%
Total irrad. (UV+Vis<1600)	W.m⁻²	1465	1480	1461	1410	1452	1459	1456
UVA2 portion (≥ 20%)	%	27.7%	27.7%	27.2%	28.4%	27.3%	27.5%	27.3%
UVA1 portion (≥ 50%)	%	68.3%	68.9%	68.5%	71.5%	68.5%	69.2%	69.4%
International SPF (2006)	PASSES	Passes	Passes	Passes	Passes	Passes	Passes	Passes
FDA Rules (2011)	PASSES	Passes	Passes	Passes	Passes	Passes	Passes	Passes
ISO24444 (2019)	PASSES	Passes	Passes	Passes	Passes	Passes	Passes	Passes