Sun Protection Factor Final Report

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Report Date: 8/09/2021	**FSTI Study/Sample #: 21-640**
Sponsor Formula #: [redacted]	**Sponsor Lot #:** [redacted]
Sponsor: [redacted]	**Sample Description: Watermelon Glow Shield SPF 50**

Summary:
The sponsor test product sample, Formula # [redacted] was tested under the guidelines of Florida Suncare Testing, Inc. SOP# 2020-01 in accordance with ISO 24444:2019(E).

The ten (10) subject test panel study yielded a mean Static (without water immersion) SPF value of **51.8 (CI% 9.43)**. See Table 1, on page ten (10) of this report, for a summary of all the data yielded in this study.

The ISO P8 reference sunscreen formulation, most recently tested on ten (10) subjects, yielded a mean Static SPF value of 62.7 (CI% 8.82), within the allowable acceptance limits specified in ISO 24444:2019, Annex C, Section C.1. See Table 2, Page eleven (11) for a summary of the data for the P8 standard sunscreen.

Approvals:

Sherriel Wallace **Sherriel Wallace** **FSTI Clinical Research Director**	8/9/2021 **Date**
MD **Jeffrey Parks, MD** **Board Certified Dermatologist**	8/9/21 **Date**

FSTI SAMPLE NUMBER: 21-640

SPONSOR: [redacted]

SPONSOR FORMULA NUMBER: [redacted]

STUDY STARTING DATE: July 9, 2021 **STUDY COMPLETION DATE:** August 3, 2021

I. OBJECTIVE

To measure the Sun Protection Factor (SPF) value, in-vivo, for the sponsor sunscreen formula in accordance with ISO 24444:2019(E), and Florida Suncare Testing, Inc. SOP# 2020-01. The SPF is a ratio calculated from the energies required to induce a minimum erythemal response with and without sunscreen product applied.

II. STUDY TYPE

Ten (10) subject, Static SPF study, with a final report furnished to the sponsor, which includes subject demographics, individual and mean SPF values of the sponsor's test sunscreen product, along with all statistics and calculations as described in ISO 24444:2019, Annex D.

III. SAMPLE DESCRIPTION

Watermelon Glow Shield SPF 50, Formula # [redacted] FSTI Sample # 21-640.

IV. TEST METHOD

The International Standard ISO 24444:2019(E) test method provided the basis for the evaluation of the sponsor sunscreen product's level of protection on human skin against erythema or sunburn in this study. This study was conducted using multiport solar simulators that utilize a xenon arc lamp of defined and known output to determine the level of protection provided by sunscreen products on human skin and is applicable to products that contain any component able to absorb, reflect or scatter ultraviolet (UV) rays and which are intended to come in contact with human skin.

The test was restricted to the area of the back of selected human subjects. A section of each subject's skin was exposed to ultraviolet light without any protection, while another (different) section was exposed after application of the sunscreen test product in this study. One additional section was exposed after application of the SPF reference sunscreen formulation used in this study, for purposes of validation of the test procedure.

To determine the sun protection factor (SPF) of the sponsor test sample evaluated in this study, an incremental series of delayed erythemal responses were induced on five (5) small (0.8 cm) subsites on each test subject's skin. These responses were visually assessed (blinded) for presence of erythema 16 to 24 hours following UV exposures, by a trained and competent evaluator.

V. TEST MATERIAL HANDLING

[redacted] test sample, labeled formula #[redacted], was assigned Florida Suncare Testing, Inc. sample number 21-640 and entered into the SPF test submission log.

VI. ARCHIVING

All original protocols, raw data sheets, and copies of final reports are maintained on the premises of Florida Suncare Testing, Inc., in limited access storage files in accordance with FSTI SOP# 2008-10. A duplicate copy of all final reports is kept on a secured, password-protected, Florida Suncare Testing, Inc. computer hard drive.

VII. PANEL DESIGN

Number of Subjects enrolled 10

Number of Subjects completing study 10

Age Range .....19 – 61

Male .....4 Female 6

Number of subjects in each of the three ITA Bands: 28-40 (1) 41-55 (3) 56 or > (6)

VIII. PANEL COMPOSITION

A. Selection Criteria of Test Subjects

A trained technician examined each subject to ensure that there is no condition which might put the subject at risk and that the results of the test cannot be compromised by adverse skin conditions such as sun damage, pigmentation marks and previous history of abnormal responses to the sun. In addition, subjects below the age of consent or above the age of 70, ISO 24444:2019(E), 5.1.3, or those who have participated in a previous UV exposure test within the past eight weeks, ISO 24444:2019(E), 5.1.4, were not enrolled. Informed, written and signed consent was obtained and retained from all test subjects enrolled, ISO 24444:2019(E), 5.1.5.

B. Skin Phototype of the Test Subjects

Only fair-skinned subjects, male and female, with measured ITA values greater than or equal to 28 by colorimetric methods were selected, ISO 24444:2019(E), 5.1.2. The average of the subjects making up the panel had an ITA value between 41 and 55. When possible there will be subjects with ITA values in each of the three ITA bands, 28-40, 41-55 and >56. Where this is not possible, there will be three (3) subjects in each of two (2) of the three (3) groups. See Section VII., Panel Design, for the number of panelists in each ITA band for this study. Test sites were free of blemishes and hair with even skin color with no variation greater than a ITA value of 5 from each other in the test area.

Colorimetric ITA values and skin color categories are defined by the colorimetric descriptors of Chardon et al. using the CIE (1976) $L^*A^*B^*$ color space, as described in ISO 24444:2019(E), Annex A, A.2.1.

Skin Color Categories	ITA Values Ranges
Very Light	> 55
Light	> 41 to 55
Intermediate	> 28 to 41
Tan or Matte	> 10 to 28
Brown	> - 30 to 10
Black	= or < - 30

C. Non-Inclusion Criteria

The following non-inclusion criteria as specified in ISO 24444:2019(E), Sec. A.2.3 and A.2.4 shall automatically not allow inclusion of a subject into the test group:

1. Children and persons below the age of consent or older than 70 years of age
2. Pregnant or lactating women
3. Subjects using a medication with photo-sensitizing potential
4. Subjects using anti-inflammatory medications
5. Subjects with dermatological conditions
6. Subjects with a history of abnormal response to the sun
7. Subject using tanning beds in the previous 8 weeks prior to testing
8. Subjects having sun exposure on the back within 8 weeks prior to SPF testing
9. Subjects with marks, blemishes or nevi with existing sun damage in test area
10. Subjects who have participated in UV testing within the previous 8 weeks
11. Subjects with hair, protrusions or extreme areas of curvature in the test area
12. Subjects with tan marks from previous testing which are still visible

D. Number of Test Subjects

Ten (10) subjects were enrolled in this study, all yielding valid results. The minimum number of valid SPF results shall be ten (10) and the maximum number of valid SPF results shall be twenty (20) to complete a study, as noted in ISO 24444:2019(E), 5.2. In order to achieve between 10 and 20 valid results, a maximum of five individual invalid results may be excluded from the calculation of the mean SPF. For the test to be considered valid for the first ten (10) subjects, the resulting range of of the 95% CI (confidence interval) of the mean shall be + or – 17%. If it is not within + or - 17% of the mean SPF, the number of subjects shall be increased stepwise from the minimum number of ten (10) until the 95% statistical criteria is met. Consequently, the actual number of test subjects used will fall between a minimum of ten (10) and a maximum of twenty-five (25) subjects. (i.e. a maximum of 20 valid results plus 5 rejected invalid results). Note: Results may only be declared invalid and excluded from the calculation of the mean SPF according to ISO 24444:2019(E), 9.5.3 (See Data Rejection Criteria, Section XIV.)

IX. INFORMED CONSENT

An informed consent was signed by each volunteer prior to initiating the study describing the purpose of the study, the test procedure, potential risks and benefits of participating, as well as the limits of liability. Each subject completed an extensive medical history form and was assigned a subject identification number. These forms are available for inspection on the premises of Florida Suncare Testing, Inc. only.

X. LIGHT SOURCE

1. A Xenon Arc Solar Simulator lamp, which provides a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,600 watts per square meter (W/m^2) of total irradiance for all wavelengths between 250 and 1,400 nm was utilized. The spectral output of the solar simulators has UVB filtering that complies with the spectral output requirements for ISO 24444:2019, Sec. 6.2, 6.3, 6.4 and Annex B.

2. The output of UV irradiance was measured prior to any UV exposures, utilizing a Solar Light Co. PMA 2100 radiometer equipped with a 2105 Erythema DCS Detector.

3. As specified in ISO 24444:2019(E), Sec. 7.1, a complete spectroradiometric check was performed by an independent expert. **See Attachments:** Attachment One (1) and Attachment Two (2) for a complete report of the spectroradiometric measurements of the UV source for the two (2) multiport solar simulators used in this study.

XI. REFERENCE SUNSCREEN FORMULATION

1. The use of a reference sunscreen formulation P5 as described in ISO 24444:2019(E), Sec. 8.1., was used to verify the test procedure in this study. Therefore, the static SPF value of the prescribed reference sunscreen formulation was measured on the same day as the test product. The reference sunscreen formula to be used depends on the expected SPF of the test product in this study. When testing is conducted for the purpose of supporting a label claim of a product intended for the market, as in this study, the following reference standards shall be used for testing along with the sponsor test product, ISO 24444:2019(E), Sec. 8.2.2:
    2. For expected SPF values less than or equal to 24, P8 or P3 reference standards (all subjects).
    3. For expected SPF values equal to or greater than 25, but less than 50, P5 or P6 reference standards (on at least five subjects) and P5 or P3 on the remaining subjects.
    4. For expected SPF values equal to or greater than 50, P8 reference standards (on at least five subjects) and P8 or P3 on the remaining subjects.
    5. Additional subjects may be added as necessary to achieve means within the acceptance range. If P5, P6 or P8 standards are used on a particular subject, there is no necessity to include a lower SPF reference standard on that subject, even though lower SPF test products may be included in the same test.
    6. Mean SPF and acceptance ranges for reference sunscreen formulations, as shown in ISO 24444:2019(E), Annex C, Sec. C.1 are as follows: **P8**, 16.1 (13.7 to 18.5), **P3**, 15.7 (13.7 to 17.7), **P5**, 30.6 (23.7 to 37.4), **P6**, 43.0 (31.0 to 54.9), **P8**, 63.1 (43.9 to 82.3)

XII. GENERALTESTING PROCEDURE

Day 1 or Test Day

Subject Enrollment

The test subjects reported to the testing laboratory and received a complete explanation of the study procedures. Those who participated signed a written, witnessed consent form, and a permission to release personal health information form and provided a brief medical history. The technician did a final examination of the subject's back, between the belt-line and shoulder blades and determined their suitability to participate in this study.

Test Conditions/Position of the Test Subjects

Product application, UV exposures and MED assessment were carried out in stable conditions, with room temperatures between 20 and 26 degrees Celsius. All procedures, to include product application, UV exposures and grading were carried out with the subject prone, lying face down.

Procedure for UV Exposure

Five (5) exposure sub-sites, as specified in ISO 24444:2019(E), Sec. 9.4.11, were used for both the unprotected (MEDu) and protected (MEDp) exposure sub-sites. The exposure sub-sites were a minimum of 0.5 cm^2 with a distance between sub-sites of at least 0.8 cm. Exposure sub-sites were at least 1 cm from the border of the test site.

1. MEDu UV Dose Administration

A. For the unprotected test site (MEDiu), the center of the range of UV doses applied, expressed in terms of dose (J/m2 or mj/cm2), were established using the subject's provisional MEDiu, or estimated provisional MEDiu, prior to the man test. ISO 24444:2019(E), Sec. 9.4.12. This is performed up to one week prior to the main test. The ITA was used to define the range of unprotected MEDiu doses for the provisional or the test day unprotected MEDiu determination, if no provisional MEDu determination was made. ISO 24444:2019(E), Sec. 9.4.13. For the unprotected site, a minimum of 5 sub-sites centered on the provisional/estimated MEDiu were exposed to incremental UV doses using a geometric dose progression of 1.15x. Other geometric progressions may be used (e.g. 1.25, 1.20. 1.12, etc). but must be consistent throughout the test for both unprotected and protected dose sites. ISO 24444:2019(E), Sec. 9.4.14.1.

B. The MEDiu for this study was administered in the following 5 dose series, with X representing the amount of UV energy projected to produce the test subject's MEDiu.

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.78X	0.87X	1.00X	1.15X	1.32X

2. Product Application/Amount of Product Applied/Mode of Delivery

Product application was performed as specified in ISO 24444:2019(E), Sec. 9.4.1 to Sec. 9.4.9., to 50 square centimeter, randomly located test sites, drawn in the designated locations on the subject's back, (between the scapula line and waist) using a template and an indelible marker. Test sites were free of blemishes and hair with even skin color, with no variation greater than a ITA value of 5 from each other in the test area. A product density of 2 mg/cm^2 (+ or – 0.05 mg/cm^2) was delivered to the test area, weighed using a balance with a sensitivity of at least 0.01mg. The test products were permitted to dry 15 to 30 minutes prior to UV exposure or water resistance testing.

3. Product Application Technique

The application technique utilized in this study was dependent on the product type, as described in ISO 24444:2019(E), Sec. 9.4.8.1. For Lotions, creams, oils, pump sprays, gels, and liquid test products Method A was utilized. To aid uniform coverage, droplets of the test products were deposited within the test site, then spread over the whole test site, first with circular movements to gather the droplets, then with horizontal and vertical directions using light pressure. The test samples were spread in the range of 15 to 35 seconds depending on the ease of spreading. Following application, and prior to any UV exposures, the product applied test sites were checked with a "black light" in order to visualize the uniformity of the application. The test products were permitted to dry 15 to 30 minutes prior to UV exposure or water resistance testing, as specified in ISO 24444:2019(E), Sec. 9.4.10.

4. MEDp UV Dose Administration

For the product-protected test sites (MEDip), the range of UV doses applied, expressed in terms of dose (J/m2 or mj/cm2), were the multiple of the expected SPF value of the sponsor test product or reference sunscreen formula and the provisional or estimated MEDiu for the subject. ISO 24444:2019(E), Sec. 9.4.14.2. A minimum of 5 sub-sites centered on the provisional/ estimated MEDu were exposed to incremental UV doses using a geometric dose progression of 1.15x. Other geometric progressions may be used (e.g. 1.25, 1.20. 1.12, etc). but must be consistent throughout the test for both unprotected and protected dose sites. The dose progressions for this study were as follows:

P8 63.1 SPF Standard Sunscreen Formulas - Static

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.76X	0.87X	1.00X	1.15X	1.32X

Projected SPF 50.0 Sponsor Test Sunscreen Formula - Static)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.76X	0.87X	1.00X	1.15X	1.32X

Day 2 or Day 3

Evaluation of Responses to UV Doses for MEDp and Repeat MEDu

1. Test subjects returned to the testing laboratory within 16 to 24 hours following completion of the MEDip doses for evaluation of the responses, having limited any additional UV exposure, to determine each individual subject's product protected MED (MEDip). ISO 24444:2019(E), Sec 9.5.2.

2. The MEDip was assessed visually by a trained evaluator, performed in an area with matt-colored walls, with at least 450 lux of light. ISO 24444:2019(E), Sec 9.5.2.

3. The study was conducted in two (2) phases in a double-blinded manner. The subjects, as well as the designated staff member who graded the MED responses of the test product, were blinded as to the identity of the test materials, application sites and UV exposures. In order that the person who evaluated the test subsites was not biased, he/she was not the same person who applied the sunscreen drug protect to the test site or administered the UV doses. ISO 24444:2019(E), Sec 9.5.2.4.

4. The subject's Minimal Erythemal Dose (MED) is the lowest erythemal effective radiant exposure that produces the first perceptible unambiguous erythema with defined borders appearing over more than 50% of the UV exposure subsite, 16 to 24 hours after UV exposure.

XIII. CALCULATION OF SUN PROTECTION AND STATISTICS

1. SPF values were calculated for all test products by calculating the ratio of the MEDp value produced in the sunscreen protected sites to the MEDu produced in the unprotected test area, for each individual using the following calculation as specified in ISO 24444:2019(E) Sec. 10.1:

MEDip / MEDiu= SPFi value

2. The SPF value for the test product and the reference sunscreen formula was calculated as the arithmetical mean of all valid individual SPF values, expressed to one decimal point.
3. The minimum number of valid SPFi values shall be 10 and the maximum number of SPFi values shall be 20 in order to complete the study.
4. A maximum of 5 results may be excluded from the calculation of the mean SPF, but each exclusion had to be justified. A sixth invalid result would invalidate the test.
5. The 95% confidence interval (CI) must fall within a range of + or – 17% of the measured mean SPF of the test product and the reference sunscreen formula.
6. The minimum of 10 valid results is only sufficient if the statistical criteria are met, otherwise the number of subjects is increased up from 10 until the statistical criterion is met, up to a maximum of 20. ISO 24444:2019(E) Sec. 10.2.3.
7. The mean SPF value of the P5 reference sunscreen formula used in this study (17.5) fell within the acceptance range of 13.7 – 18.5, thus validating the results in this study. ISO 24444:2019(E) Sec. 10.4.

Day 2 or Day 3

Evaluation of Responses to UV Doses for MEDp and Repeat MEDu

1. Test subjects returned to the testing laboratory within 16 to 24 hours following completion of the MEDip doses for evaluation of the responses, having limited any additional UV exposure, to determine each individual subject's product protected MED (MEDip). ISO 24444:2019(E), Sec 9.5.2.

2. The MEDip was assessed visually by a trained evaluator, performed in an area with matt-colored walls, with at least 450 lux of light. ISO 24444:2019(E), Sec 9.5.2.

3. The study was conducted in two (2) phases in a double-blinded manner. The subjects, as well as the designated staff member who graded the MED responses of the test product, were blinded as to the identity of the test materials, application sites and UV exposures. In order that the person who evaluated the test subsites was not biased, he/she was not the same person who applied the sunscreen drug protect to the test site or administered the UV doses. ISO 24444:2019(E), Sec 9.5.2.4.

4. The subject's Minimal Erythemal Dose (MED) is the lowest erythemal effective radiant exposure that produces the first perceptible unambiguous erythema with defined borders appearing over more than 50% of the UV exposure subsite, 16 to 24 hours after UV exposure.

XIII. CALCULATION OF SUN PROTECTION AND STATISTICS

1. SPF values were calculated for all test products by calculating the ratio of the MEDp value produced in the sunscreen protected sites to the MEDu produced in the unprotected test area, for each individual using the following calculation as specified in ISO 24444:2019(E) Sec. 10.1:

MEDip / MEDiu= SPFi value

2. The SPF value for the test product and the reference sunscreen formula was calculated as the arithmetical mean of all valid individual SPF values, expressed to one decimal point.
3. The minimum number of valid SPFi values shall be 10 and the maximum number of SPFi values shall be 20 in order to complete the study.
4. A maximum of 5 results may be excluded from the calculation of the mean SPF, but each exclusion had to be justified. A sixth invalid result would invalidate the test.
5. The 95% confidence interval (CI) must fall within a range of + or – 17% of the measured mean SPF of the test product and the reference sunscreen formula.
6. The minimum of 10 valid results is only sufficient if the statistical criteria are met, otherwise the number of subjects is increased up from 10 until the statistical criterion is met, up to a maximum of 20. ISO 24444:2019(E) Sec. 10.2.3.
7. The mean SPF value of the P5 reference sunscreen formula used in this study (17.5) fell within the acceptance range of 13.7 – 18.5, thus validating the results in this study. ISO 24444:2019(E) Sec. 10.4.

XIV. DATA REJECTION CRITERIA

1. There are four (4) primary reasons for rejection of study data as noted in ISO 24444:2019(E), Sec. 9.5.3.
   a. No grade of at least 1 for any exposed product-protected on unprotected test subsites.
   b. All test subsites show erythema of at least grade 1.
   c. Erythemal responses were inconsistent or randomly absent for exposures higher than the determined MED dose.
   d. Non-compliance of the test subject or a technical failure of the equipment or test procedure.
2. When one of the above criteria applies to the exposure series on unprotected skin or the reference sunscreen product exposure sites, then all data for all test products for that subject is invalid and shall be rejected.
3. When one of the above criteria applies to the test product exposure series, then all data for that test product is invalid and shall be rejected.
4. If invalid data (MEDiu or MEDip) has to be rejected for any product on more than 5 subjects, then the whole test for that product is invalid and shall be rejected. ISO 24444:2019(E), Sec. 9.5.4.

XV. RESULTS

A total of ten (10) healthy subjects who fulfilled the test panel participation criteria were inducted into this investigation. The demographic data is shown in Section VII., Panel Design. The individual and mean SPF values of the [redacted] test product, Watermelon Glow Shield SPF 50, Formula # [redacted] FSTI Sample # 21-640, are shown in Table 1, page 10.

XVI. ADVERSE EXPERIENCES

No adverse experiences were reported during this study.

XVII. CONCLUSIONS

The Sun Protection Factor (SPF) of the above sample described herein; tested under Static "Without Water Immersion" conditions, yielded the following SPF values:

Sponsor Formula Number	FSTI Sample Number	Mean Static SPF	CI %
[redacted]	21-640	51.8	9.43

The ISO P8 reference sunscreen formulation, tested most recently on ten (10) subjects, yielded a mean Static SPF value of 62.7 (acceptance limits 43.9 – 82.3), within the allowable acceptance limits specified in ISO 24444:2019, Annex C, Section C.1.

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References:

ISO 24444:2019(E)

FLORIDA SUNCARE TESTING, INC.
ISO 24444:2019(E)

TABLE 1

Study Number: 21-640

Sponsor: Glow Recipe

Formula Number: [redacted] Lot Number: [redacted]

Sample Description: Watermelon Glow Shield SPF 50

Report Date: August 9, 2021 Dose Increments: 15%

	TEST				SIM	TEST SUBJECTS							
Subj.	Exposure	App	Exp	Read	Sim EE (highest)	Subject	Skin	MEDu		MEDp 21-640		SPFi 21-640	Rej.?
N°	Date	by	by	by	W/m²eff.	Code	ITA°	Sec.	J/m² eff.	Sec.	J/m² eff.	SPFi	Y/N
1	7/9/2021	DC	DC	SW	12.2	2998	56	19	179	740	8979	50.2	No
2	7/9/2021	DC	DC	SW	12.2	2863	56	19	179	740	8979	50.2	No
3	7/15/2021	DC	DC	SW	12.2	2824	46	22	205	1115	8918	43.5	No
4	7/21/2021	DC	DC	KF	12.2	1057	66	15	136	740	6800	50.0	No
5	7/21/2021	DC	DC	SW	12.2	2436	62	17	157	854	7850	50.0	No
6	7/26/2021	TD	TD	SW	12.2	2067	56	19	179	973	11814	66.0	No
7	7/28/2021	DC	DC	SW	12.2	2244	42	29	263	1430	15123	57.5	No
8	7/29/2021	TD	TD	SW	12.2	3106	47	25	202	1261	11600	57.5	No
9	7/29/2021	DC	DC	SW	12.2	2437	36	29	302	1430	15123	50.0	No
10	8/2/2021	DC	DC	SW	12.2	2374	57	19	179	973	7787	43.5	No
11													
12													
13													

MEAN SPF:	51.8
STD DEVIATION:	6.82
STD ERROR OF MEAN:	2.16
STD % ERROR OF MEAN:	4.16
Statistical Criteria:	
C = (t value) . SEM	4.88
CI %	9.43%
95% CI = SPF - C to SPF + C	46.9 - 56.7