A STEPWISE IN VIVO STUDY TO DETERMINE THE SUN PROTECTION FACTOR OF ONE PRODUCT FOLLOWING THE FDA STATIC METHOD.

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[redacted]

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by [redacted] were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

[redacted]

QUALITY ASSURANCE STATEMENT

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

[redacted]

[redacted]

[redacted]

[redacted]

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SUMMARY

1. This was a stepwise single blind study in healthy volunteers to determine the Sun Protection Factor (SPF) of one test product when compared to unprotected skin after the sites were exposed to an artificial "sun" light source based on the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 for the determination of the SPF value.

2. This study protocol followed the procedure outlined in the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] (formerly Docket No. 1978N-0038), RIN 0910-AF43, Labelling and Effectiveness Testing; Sunscreen Drug Products for Over-the Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011]. Each subject was treated with a series of five light exposures in order to determine the MED for unprotected skin. Subsites were graded 20 ± 4 (16 to 24) hours after the MED exposure. The MED was assessed as being the lowest dose that elicited minimally perceptible erythema at a subsite.

3. Following MED determination, three test areas were outlined on the back, above the MED test area. The control standard preparation (mean SPF 16.3) was applied to one area, one area remained untreated to re-determine the MED and the test preparation was applied to the remaining area. UV exposures commenced 15 – 30 minutes after application of the test products. Length of exposure was determined by reference to the individual subject's MED. For products with an expected SPF greater than 15, the exposures were 0.76x, 0.87x, 1.00x, 1.15x and 1.32x (where x equals the expected SPF of the product).

4. The erythema level of the test and control subsites was assessed 20 ± 4 (16 to 24) hours after exposure and the MED for "protected" skin was determined. Individual and mean SPF values were then calculated.

5. The static SPF value for the standard preparation was 16.33 (Label SPF = 15), the study can therefore be considered valid.

6. Mean Static SPF results (N=10) for the test article:

Test article 1 – Daily Dose Hydra-Ceramide Boost + SPF 40[redacted]) achieved a mean SPF value of 44.20. The calculated Label SPF = 42.

KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
[redacted]	The PI will be responsible for ensuring sufficient resources are available to conduct the study according to Good Clinical Practice (GCP), for reporting any serious adverse events to the Sponsor, the study design, compiling the results and writing the clinical report.
[redacted]	The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report.
[redacted]	The PS will be responsible for the conduct of the study on a daily basis.
[redacted]	The PC will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor of this study.

INTRODUCTION AND OBJECTIVE

A stepwise study in healthy volunteers to determine the static Sun Protection Factor (SPF) against the full solar ultraviolet (UV) spectrum (290 – 400 nm) of one Sun Protection product. Static SPF was determined without water immersion. Sunscreen protection against the full solar ultraviolet (UV) spectrum (290 - 400 nm) was measured and expressed as the Sun Protection Factor (SPF).

This study protocol followed the procedure outlined in the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] (formerly Docket No. 1978N-0038), RIN 0910-AF43, Labelling and Effectiveness Testing; Sunscreen Drug Products for Over-the Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011].

MATERIALS AND METHODS

1. STUDY DESIGN

The study was conducted single blind, in a single centre.

A total of 10 subjects (5+5) were dosed with the test article.

2. SELECTION OF SUBJECTS

2.1. SCREENING

A total of 10 subjects (5+5) were recruited into the study that satisfied the following inclusion and exclusion criteria, and who were prepared to accept the prohibitions and restrictions and who gave written informed consent (Appendices 1 and 2).

The suitability of each potential subject was confirmed before their acceptance by review of a study specific pre-treatment questionnaire (Appendix 3).

2.2. INCLUSION CRITERIA

a. Healthy male and female volunteers aged 18 years and older.
b. Self-assessed skin type I (always burn easily; never tans), II (always burns easily; tans minimally) or III (burns moderately; tans gradually), according to the Fitzpatrick scale based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.
c. Completed written informed consent.

2.3. Exclusion Criteria

a. Pregnancy or lactation.
b. Inadequate precautions/procedures to prevent pregnancy (women of childbearing potential only).
c. A current skin disease of any type apart from mild acne
d. Heavy alcohol consumption (i.e. more than 21 units per week or 8 units a day for men, more than 14 units per week or 4 units a day for women).
e. Significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological disease.
f. A history of multiple drug hypersensitivity.
g. Concomitant medication associated with photosensitivity reactions or which is likely to affect the response of the test articles or confuse the results of the study.
h. Presence of uneven skin tones, pigmentation, scarring, or having excessive hair on the back (or are unwilling to have the hair clipped) that would interfere with the interpretation of the results.
i. Greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.
j. A high number of naevi (arbitrarily assigned as >100) on the body.
k. Participation in a Sun Protection Factor test (SPF test) or follow-up work within the last 2 months.
l. Subject has exhibited sensitization or questionable sensitization in an SPF test.
m. Previous history of skin tumours/malignancy.
n. Regular UVA sunbed users.
o. A history of abnormal response to the sun.

2.4. Prohibitions and Restrictions

a. Discontinuation of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.
b. Discontinuation of sun bed or sun lamp use, and avoidance of exposure of the test sites to natural sunlight for the duration of the study.

3. MATERIALS

3.1. Test Articles

The Sponsor provided the ingredient listing (Appendix 4) and certified that the product supplied to [redacted] for the clinical trial had been manufactured/formulated with ingredients that are safe and suitable for the product's stated purpose.

The 7% Padimate O / 3% Oxybenzone Standard was used as a control.

The Sponsor confirmed the test article does not contain antibiotics, antiseptics, steroids, hormones, or any other substances at levels of concentration requiring label declaration by the relevant regulatory authorities.

The following sunscreen preparation was tested:

1. Daily Dose Hydra-Ceramide Boost + SPF 40[redacted]

It was the responsibility of the Sponsor to determine, for each batch of test article, the identity, strength, purity, composition, and other characteristics which appropriately defined the test article before its use in the study. The determination of its stability and documentation of methods of synthesis and derivation were also the Sponsor's responsibility.

It was the responsibility of the Sponsor that the test article met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty are fully met by the Sponsor prior to receipt of the test article at[redacted]. No liability with regard to safe receipt or costs involved in carriage of goods to any[redacted] site would have been accepted.

On study completion, any remaining unused test article was disposed of, unless otherwise requested by the Sponsor, after issuance of the final report or 28 days after study completion, whichever came first. Sponsors requesting the return of products were liable for any costs incurred.

4. METHOD

4.1. ARTIFICIAL LIGHT SOURCE

UV radiation was obtained from a 300W multiport solar simulator Model 601 V2.5 (Solar Light Company, Glenside PA). The unit was allowed to warm up for 20 minutes before use.

The % RCEE (relative cumulative erythemal effectiveness) limits were as follows:

WAVELENGTH (nm)	% RCEE ACCEPTANCE 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	99.9-100.0

4.2. AMBIENT CONDITIONS

All procedures were performed in stable conditions at a temperature within the range of 18°C and 26°C.

4.3. INFORMED CONSENT, SCREENING AND TEST SITE IDENTIFICATION

On day 1 of the study, potential study participants reported to the testing facility for screening. Informed Consent was obtained, demographics collected, and study eligibility was confirmed. Test sites were checked for any conditions that could have affected evaluations or subject safety.

4.4. TREATMENT

4.4.1 MED (MINIMAL ERYTHEMAL DOSE) DETERMINATION

Each subject was treated with a series of five light exposures in order to determine the MED for unprotected skin. Each exposure time was 1.25 times greater than the previous one.

The MED study area was outlined on the lower back between waist and scapula and lateral to the midline. Subjects were exposed sat upright in a backless chair and the test sites outlined while the subject was in this position.

A template of the study area containing four subsites, each 3 cm x 2.5 cm, were marked on the back. The template was located ensuring that no moles or skin lesions were present in any of these subsites. Only the subsites were exposed. A record of individual exposure times and subsites was kept. After test exposure, any immediate skin responses were noted, and subjects were instructed to keep the test area covered from sunlight or other sources of UV light for the next 24 hours before they returned to the study centre.

4.4.2 MED ASSESSMENT

Subsites were graded 20±4 (16 to 24) hours after the MED exposure. The MED was assessed as being the lowest dose that elicited minimally perceptible erythema at a subsite (see Section 4.4.1).

4.4.3 TEST ARTICLE SPF (STATIC) DETERMINATION

Three test areas (each area consisting of test site square ≥ 30 cm^2 divided into test subsite areas ≥ 0.5cm^2 with approximately 0.8 cm distance between subsites) were outlined on the back between shoulder blade and shoulder and parallel to the midline, above the MED test area.

The areas were located ensuring that no moles or skin lesions were present in any of these subsites. To one area was applied the SPF standard preparation (7% Padimate O / 3% Oxybenzone Standard), one area remained untreated to re-determine the MED and the test article was applied to the remaining test site area. The test articles were applied by pipette by one technician at a dose of 2 mg or 2 µl per cm^2 (±2.5%) and spread over the four subsites with a gloved finger, which had been pre-saturated with the test article being applied.

Test article application was timed so that the UV exposures commenced 15 minutes to 30 minutes after application. Subjects were exposed sitting upright in a backless chair. Only the subsites were exposed. A record of individual exposure times and subsites was kept.

The UV exposures for test products and PADIMATE O/OXYBENZONE SPF STANDARD were calculated from previously determined MED (US) and the intended SPF. For products with an expected SPF less than 8, the exposures were MEDu times 0.64x, 0.80x, 1.00x, 1.25x and 1.56x. For products with an expected SPF between 8 and 15, the exposures were 0.69x, 0.83x, 1.00x, 1.20x and 1.44x. For products with an expected SPF greater than 15, the exposures were MEDu times 0.76x, 0.87x, 1.00x, 1.15x and 1.32x where x equals the expected SPF of the product.

Subjects were instructed to keep the test areas covered from sunlight or other sources of UV light for the next 24 hours and to return to the study centre after this time for assessment.

4.4.4 SPF DETERMINATION

The SPF values of the test article was determined (see Section 4.4.5).

4.4.5 SPF ASSESSMENT AND CALCULATION

Determination of the Test Product's SPF Value:

Sixteen to twenty-four hours post-exposure, the subjects returned to the testing facility for visual evaluation of erythema responses. The trained technician who evaluated the MED did not know the identity of the test products application sites and UV exposures. Also, he/she was not the same person to have applied the sunscreen products to the test site or administered the doses of UV radiation.

Calculation of SPF:

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

$$SPF_i = \frac{MED_p}{MED_u}$$

Where MED_p is the "protected" result divided by the MED_u is the "unprotected" result.

Calculate the mean SPF and the standard deviation (s) from the SPF_i values.

Calculate the standard error (SE) which equals $s/\sqrt{n}$ where n = the number of subjects who provided valid test results.

$$SE = \frac{s}{\sqrt{n}}$$

The upper 5% point (A) will be obtained from the Student's t distribution table with n-1 degrees of freedom (t). A will be calculated as follows:

$A = t \cdot SE$

The label SPF for panels using a minimum of 10 evaluable subjects is the largest whole number less than the mean SPF minus A. In order for the SPF determination of a test products to be considered valid, the SPF value of the SPF standard should fall within the standard deviation range of the expected SPF (i.e., 16.3 ± 3.43).

$Label\ SPF = \overline{SPF} - A$

The SPF of the products after 80-minute water immersion was calculated in the same manner as above.

4.4.6 SKIN ASSESSMENT

Andrew King assessed all skin on all days, whilst the subject was standing, in a room with natural wall colour. Illumination of the study areas was by means of a 60-Watt pearl bulb at a distance from the study area of approximately 30 cm.

The following grading scale was used:

0.0 = no perceptible erythema

0.5 = ambiguous erythema or not having clear borders

1.0 = minimally perceptible erythema having clear border (MED)

2.0 = moderate erythema

3.0 = severe erythema with edema

The series of UV-exposures should produce at least a first subsite without erythema (grade of 0.0) and one or more sites with responses ranging from minimal erythema to well-defined erythema. The lowest UV dose producing the endpoint of minimal erythema determines the individual's MED (grade 1.0).

Any instance of painful erythema or severe erythema with a grade of 3 or greater was considered an adverse experience.

5. STUDY ETHICS

5.1 DECLARATION OF HELSINKI

The study will conform to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013).

5.2 INDEMNITY PROVISION

The Sponsor shall be responsible, without regard to legal liability, and shall indemnify [redacted], or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of [redacted] employees or any persons undertaking or involved in the study by arrangement with [redacted].

6. QUALITY ASSURANCE

The study will be carried out within the spirit of the ICH Guidelines on Good Clinical Practice, 1996 (1) and other recognised guidelines. An audit of the final report will be completed, for accuracy and completeness of presentation. Additionally, the study may be subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and [redacted] procedures.

[redacted] management of any findings that may affect the integrity of the study.

7. RETENTION OF DATA

All raw data generated by [redacted] during the course of the study, and including protocol and final report, will be retained in the [redacted] for a minimum period of five years from study completion. In the event of original data being transferred to the Sponsor at their request, exact copies will be so retained. At no time will archived data be destroyed without prior written approval of the Sponsor. All study data will be available at any time, by appointment, for inspection by the Sponsor or their authorised representative.

8. REFERENCES

1. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Note for Guidance on Good Clinical Practice, Consolidated Guideline. Step 4, Consolidated Guideline, 1/5/96. CPMP/ICH/135/95.

2. FDA 21 CFR Parts 201 and 310 Sunscreen Drug Products for Over-the-Counter Human Use; Labelling and Effectiveness Testing [Docket no. FDA-1978-N-0018] (Formerly Docket No. 1978N-0038) RIN 0910-AF43.

3. The validity and practicability of sun-reactive skin types I through IV. Archives Dermatol. 124 p. 869-871 (1988).

4. World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA 310 (20): 2191–2194. doi:10.1001/jama.2013.281053

[redacted]

RESULTS

1 LOCATION AND DATES OF THE STUDY

The study was performed at [redacted], between w/c 26th April 2021 and w/e 20th May 2021.

2 SUBJECTS

10 subjects of both sexes were recruited into and completed the study.

Figure 1: [redacted] Demographics

Subject	Tech Initials	Age	Gender	Ethnicity	Fitzpatrick	MED
1	AK	18	M	CAUCASIAN	I	15
2	AK	45	F	CAUCASIAN	III	33
3	AK	25	F	CAUCASIAN	III	25
4	AK	39	M	CAUCASIAN	III	36
5	AK	50	F	CAUCASIAN	I	19
6	AK	51	F	CAUCASIAN	III	25
7	AK	44	F	CAUCASIAN	III	28
8	AK	47	M	CAUCASIAN	II	21
9	AK	22	M	CAUCASIAN	III	34
10	AK	56	F	CAUCASIAN	II	20

3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY

No adverse events or reactions were reported, no subjects withdrew. The study was completed by all 10 subjects.

4 QUALITY OF UV IRRADIATION

The percentage RCEE (relative cumulative erythemal effectiveness) for the solar simulator used in this study was within the acceptable lower and upper limits directed by the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 SPF test methods - In vivo determination of Sun Protection Factor (SPF).

5 ASSESSMENTS

Individual and mean SPF values, their standard deviations and confidence intervals for all 10 subjects are presented in Tables 1 and 2.

[redacted]

The static SPF value for the standard preparation was 16.33 (Label SPF = 15), the study can therefore be considered valid.

Mean Static SPF results (N=10) for the test article:

Test article 1 – Daily Dose Hydra-Ceramide Boost + SPF 40 [redacted] achieved a mean SPF value of 44.20. The calculated Label SPF = 42.

[redacted]

TABLE 1 – INDIVIDUAL AND MEAN SPF VALUES FOR TEST ARTICLE 1 – Daily Dose Hydra-Ceramide Boost + SPF 40[redacted])

1 - Daily Dose Hydra-Ceramide Boost + SPF 40[redacted]	SITE	1		2		3		4		5		Re-determined MED	Individual SPF
SUB NO	MED	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE		
1	**15**	453.69	0.0	521.74	0.0	600.00	0.0	690.00	1.0	793.50	1.0	**15**	46.00
2	**33**	998.11	0.0	1147.83	0.0	1320.00	1.0	1518.00	1.0	1745.70	2.0	**33**	40.00
3	**25**	756.14	0.0	869.57	0.0	1000.00	0.0	1150.00	1.0	1322.50	1.0	**25**	46.00
4	**36**	1088.85	0.0	1252.17	0.0	1440.00	0.0	1656.00	1.0	1904.40	1.0	**36**	46.00
5	**19**	574.67	0.0	660.87	0.0	760.00	1.0	874.00	1.0	1005.10	2.0	**19**	40.00
6	**25**	756.14	0.0	869.57	0.0	1000.00	0.0	1150.00	1.0	1322.50	1.0	**25**	46.00
7	**28**	846.88	0.0	973.91	0.0	1120.00	0.0	1288.00	1.0	1481.20	1.0	**28**	46.00
8	**21**	635.16	0.0	730.43	0.0	840.00	0.0	966.00	1.0	1110.90	1.0	**21**	46.00
9	**34**	1028.36	0.0	1182.61	0.0	1360.00	1.0	1564.00	2.0	1798.60	2.0	**34**	40.00
10	**20**	604.91	0.0	695.65	0.0	800.00	0.5	920.00	1.0	1058.00	2.0	**20**	46.00
Mean													44.20
Std Dev													2.90
SE													0.92
95% CI													2.07
Label SPF calculated													42.13

TABLE 2 – INDIVIDUAL AND MEAN SPF VALUES FOR FDA SPF STANDARD PREPARATION (7% PADIMATE, 3% OXYBENZONE)

2 - Standard Reference SPF (7% padimate, 3% oxybenzone) SPF 16.3	SITE	1		2		3		4		5		Re-determined MED	Individual SPF
SUB NO	MED	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE	TIME (SECS)	GRADE		
1	**15**	184.88	0.0	212.61	0.0	244.50	1.0	281.18	2.0	323.35	2.0	**15**	16.30
2	**33**	406.73	0.0	467.74	0.0	537.90	1.0	618.59	1.0	711.37	2.0	**33**	16.30
3	**25**	308.13	0.0	354.35	0.0	407.50	1.0	468.63	1.0	538.92	2.0	**25**	16.30
4	**36**	443.71	0.0	510.26	0.0	586.80	1.0	674.82	1.0	776.04	2.0	**36**	16.30
5	**19**	234.18	0.0	269.30	0.0	309.70	0.5	356.16	1.0	409.58	2.0	**19**	18.75
6	**25**	308.13	0.0	354.35	0.0	407.50	1.0	468.63	1.0	538.92	2.0	**25**	16.30
7	**28**	345.10	0.0	396.87	0.0	456.40	1.0	524.86	1.0	603.59	2.0	**28**	16.30
8	**21**	258.83	0.0	297.65	1.0	342.30	1.0	393.65	2.0	452.69	2.0	**21**	14.17
9	**34**	419.05	0.0	481.91	0.0	554.20	1.0	637.33	2.0	732.93	2.0	**34**	16.30
10	**20**	246.50	0.0	283.48	0.0	326.00	1.0	374.90	1.0	431.14	2.0	**20**	16.30
Mean													16.33
Std Dev													1.08
SE													0.34
95% CI													0.77
Label SPF calculated													15.56

[redacted]

APPENDIX 1: CONSENT FORM

[redacted] Subject #: _____

INTRODUCTION

You are being asked to participate in a research study. Prior to giving your consent to be a subject, it is important that you take the time to read and understand what your participation would involve. This consent form may contain technical language which you may not understand. If you do not understand any of this consent form, please ask the clinical staff any questions you may have.

You will be provided with a signed copy of this consent form and any other necessary written information prior to the start of the study.

OBJECTIVE

The objective of this research study is to determine the sun protection factor (SPF) of one test article after exposure to simulated sunlight (UV light).

TEST ARTICLES

The test articles applied by study staff to designated test sites located on the back.

STUDY PROCEDURES

You will be one of approximately 10 subjects (5+5) enrolled onto this study. Your participation in this study will last approximately four days and will include four visits to the testing facility.

Visit 1 (Study day 1): Prior to acceptance on the study, you will be consented and screened for eligibility to participate in the study. You will be supplied with a gown to wear, as we need to see your back. We will mark out five squares, 2.5 cm x 3 cm on your back and whilst you sit upright on a backless chair, we will expose these squares to UV light from a special sunlamp. Each square will be exposed to simulated sunlight for a different length of time so that we can find out the time needed to produce a faint pinkness (slight skin redness).

Visit 2 (Study day 2): You will be supplied with a gown to wear. We will assess the degree of pinkness to the sites previously exposed to the artificial sunlight. We may need to expose a new area of your back to the same type of simulated sunlight (UV light) to determine the more exact time to produce this faint pinkness.

Visit 3 (Study day 3): We will assess your back on this day. We will then mark out several areas on your back. On these different areas, we will apply the test products and one area will remain untreated. We will then expose three squares 2.5 cm x 3 cm per test area to UV light for different times depending on your skin sensitivity. These times are equivalent to up to a day's natural sun exposure depending on the expected SPF of the product.

Visit 4 (Study day 4): We will assess your back on this day.

RISKS

To the best of our knowledge, these products are not expected to induce an allergic reaction. While the potential for irritation or other reactions during this study are minimal, it is possible for a reaction to occur. Expected reactions for these test articles categories are mild in nature and may include the following: redness, itching, peeling or blistering. You will have slight redness to your skin (like a mild sunburn) only in the areas exposed to the artificial (simulated) sunlight. In addition to the risks described, there may be other risks that are currently unforeseeable.

No significant adverse reactions are expected to occur. However, if you develop an adverse reaction or complication as a result of your participation in this study, medical treatment will be provided by clinical staff nurses at [redacted] or you will be referred for appropriate treatment at no cost to you, as long as you have followed the study instructions. Provisions of such medical care is not an admission of legal responsibility. You will be followed by [redacted] until the adverse reaction has resolved. No additional compensation will be available to you. Neither the sponsoring company nor the investigating company will be held responsible for any future medical expenses.

[redacted]

FEMALES OF CHILDBEARING POTENTIAL

Pregnant and/or nursing women may not take part in this study. Signing and dating this consent form means that you are stating that you are not pregnant, planning a pregnancy, or nursing at the start of the study.

The test products may involve unknown risks to you, your nursing infant, or your unborn child if you become pregnant while on the study. By signing this form, you agree to practice an acceptable method of birth control for the duration of the study.

BENEFITS

While it is likely that you will not receive any direct benefit from your participation in the study, the study results may have the potential to increase scientific knowledge about skincare products and may allow for new and improved products to be marketed.

CONFIDENTIALITY

Information concerning you that is obtained in connection with this study will be kept confidential by [redacted], except that the sponsoring company whose products are being tested will receive a copy of the study records. The data will be uniquely coded to protect your identity. In addition, the study investigator, third party regulatory authorities, including the U.S. Food and Drug Administration (FDA), or the sponsor (including monitors and auditors), may inspect the records of the study. Therefore, total privacy cannot be guaranteed.

Your signature on the Informed Consent provides your permission for these agencies to view your personal information and the study data.

COMPENSATION FOR INJURY

No significant adverse reactions are expected to occur. However, if you develop an adverse reaction or complication as a result of your participation in this study, medical treatment will be provided by clinical study staff at [redacted] or you will be referred for appropriate treatment at no cost to you. Provisions of such medical care are not an admission of legal responsibility. You will be followed by [redacted] until the adverse reaction has resolved. No additional compensation will be available to you. Neither the sponsoring company nor the investigating company will be held responsible for any future medical expenses.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. We will get this information from you in the event this becomes necessary. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare. The sponsor will not use this information for any other purpose.

IN CASE OF STUDY RELATED INJURY

If you are injured while participating in this study, [redacted] will provide you with treatment. If your illness or injury is the result of the study products or any procedure required by the study that you would not have undergone were it not for your participation in the study, the sponsor will pay usual and customary medical fees for reasonable and necessary treatment, provided you have not already otherwise been properly reimbursed by your insurance, a government program, or other third party coverage for such medical expenses. The sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, procedures which would have been performed even if you were not participating in the study, your negligence or wilful misconduct, or the negligence or wilful misconduct of institution, principal investigators, or third parties. No funds have been set aside by the sponsor to compensate you for lost wages, disability, or discomfort due to your participation in this study. You do not give up any legal rights as a research participant by signing this consent form.

[redacted]

NEW FINDINGS

Any new information that is discovered during the study and which may influence your willingness to continue in the study will be made available to you.

MEDICAL TREATMENT

In the event of an emergency, dial 999. If you receive any medical care during the course of the study, inform medical personnel that you are participating in a research study. Please [redacted] as soon as possible to inform them of your condition.

CONTACT

If you have any questions about this study or in the case of an emergency, contact [redacted] on [redacted] during normal business hours.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled. However, you must contact the test facility and inform a clinical staff member of your decision to withdraw from the study.

If you agree to participate in the study, you are also agreeing to provide [redacted] with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, you may be asked to discontinue participation.

Your participation in the study may be discontinued at any time without your consent by [redacted] regulatory agencies, or the sponsoring company for reasons of but not limited to a severe side effect and accompanying illness, or if you do not follow study instructions.

NON-DISCLOSURE

As a condition to your participation in the study you are asked not to discuss any information regarding the products that you are testing, your experiences with the products, or your opinion of the products with anyone outside of the testing facility. By your signature on the Consent you are agreeing to abide by this condition of participation.

PHOTOGRAPHY AUTHORIZATION

As an additional part of this study, study staff may take photographs or videotape during the study. These photos or videos may be used for the following purposes: training of [redacted], documentation of study procedures/results or upon request of the sponsor. By signing this consent form, you are giving your authorization for [redacted] to take, use, reproduce, and distribute these photographs/videotapes taken during your participation in this study.

COMPENSATION

If you agree to participate in this study, you will be paid £XX upon completion of the study.

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If, at the discretion of the Investigator, it is best to discontinue my participation for reasons other than a failure to obey the directions of the study, I will be paid in full or for the portion of the study I have completed once the study is over.

CONSENT

I have read all of the pages of this consent form and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am at least eighteen years old and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject. I will receive a copy of this signed consent document.

[redacted]

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate, having read the information provided above.

_____

Subject's Name Printed: First **Middle Initial** **Last**

_____

Subject's Signature **Date**

_____

Signature of Person Conducting Consent Discussion **Date**

_____

Subject Number

APPENDIX 2: SUBJECT INFORMATION SHEET

[redacted] Subject No.: _____

You have agreed to participate in a research study. By agreeing to participate, you are also agreeing to the following prohibitions and restrictions:

- Discontinuation of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.
- Discontinuation of sun bed or sun lamp use, and avoidance of exposure of the test sites to natural sunlight for the duration of the study.
- Prevention of test areas from getting wet for the duration of the study.

Study schedule:

Monday	**Tuesday**	**Wednesday**	**Thursday**
26th April for subjects 1-5 and 17th May for subjects 6-10	27th April for subjects 1-5 and 18th May for subjects 6-10	28th April for subjects 1-5 and 19th May for subjects 6-10	29th April for subjects 1-5 and 20th May for subjects 6-10
Visit 1	***Visit 2***	***Visit 3***	***Visit 4***
Baseline measure.	***Assessment of the degree of pinkness to the skin.***	***Assessment of the degree of pinkness to the skin where necessary.***	***Assessment of the degree of pinkness to the skin.***
Area of the back to be exposed to UV light for different lengths of time to produce a faint pinkness to the skin.	***(A new area of skin on the back may then be exposed to UV light for a more exact time to produce a faint pinkness to the skin.)***	***Three test areas will be marked out on your back, the test articles applied and then exposed to UV light for different times depending on your skin sensitivity.***	***Compensation***

*You must come in for all visits; no misses will be allowed. If you are unable to come in for a visit, your participation will be discontinued.

Upon completion of this study on 29th April 2021 or 20th May 2021, you will receive £XX for your participation.

If you have any questions about this study or in the case of a suspected allergic reaction, call [redacted] during normal business hours.

[redacted]

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

[redacted] Subject No. _____

FOR OFFICE USE ONLY		
Subject's Initials		
Subject's DOB: _____ Subject's Age: ____		
MALE/FEMALE		

STRICTLY CONFIDENTIAL

Inclusion Criteria (NO – Exclude)		Yes	No
1.	Subject is a healthy male or female, aged 18 years or older.	☐	☐
2.	Subject has self-assessed skin type I (always burns easily; never tans), II (always burns easily; tans minimally) or III (burns moderately; tans gradually), according to the Fitzpatrick scale based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.	☐	☐
3.	Subject has signed a written informed consent.	☐	☐
Exclusion Criteria (YES – Exclude)		**Yes**	**No**
1.	Subject is pregnant, nursing, or planning to become pregnant. Male N/A ☐	☐	☐
2.	Subject is using an inadequate method of birth control.	☐	☐
3.	Subject reports a current skin disease of any type apart from mild facial acne.	☐	☐
4.	Subject has heavy alcohol consumption (i.e. more than 21 units/week or 8 units/day for men, more than 14 units/week or 4 units/day for women).	☐	☐
5.	Subject has a significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological or neurological disease.	☐	☐
6.	Subject has a history of multiple drug hypersensitivity.	☐	☐
7.	Subject is taking concomitant medication associated with photosensitivity reactions which is likely to affect the response of the test articles or confuse the results of the study.	☐	☐
8.	Presence of uneven skin tones, pigmentation, scarring, or having excessive hair on the back (or are unwilling to have the hair clipped) that would interfere with the interpretation of the results.	☐	☐
9.	Subject has greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.	☐	☐
10.	Subject has a high number of naevi (arbitrary assigned a >100) on the body.	☐	☐
11.	Subject has participated in a Sun Protection Factor test (SPF test) or follow-up work within the last 2 months.	☐	☐
12.	Subject has exhibited sensitization or questionable sensitization in an SPF test.	☐	☐
13.	Subject has a history of skin tumours.	☐	☐

[redacted]

14.	Subject is a regular sunbed user.	☐	☐
15.	Subject has a history of abnormal response to the sun.	☐	☐
Prohibitions and Restrictions (NO – Exclude)		Yes	No
1.	Subject agrees to discontinue use of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.	☐	☐
2.	Subject agrees to discontinue use of sun beds or sun lamps, and to avoid exposure of the test sites to natural sunlight for the duration of the study.	☐	☐

Have you ever had any skin problems related to the use of any of the following types of material?

Material	Yes	No	When? – Which products? – What happens?
SPF Products			
Other Personal Care Products – please specify			

Questionnaire checked and confirmed by:

_____ _____

Signature Date

APPENDIX 4: TEST ARTICLE INGREDIENT LISTINGS

TEST ARTICLE 1 – Daily Dose Hydra-Ceramide Boost + SPF 40 [redacted]

INCI NAME	*% INCI*
ACTIVE INGREDIENTS	
OCTOCRYLENE	10.000000
HOMOSALATE	9.000000
ETHYLHEXYL SALICYLATE (OCTISALATE)	5.000000
BUTYL METHOXYDIBENZOYLMETHANE (AVOBENZONE)	2.000000
INACTIVE INGREDIENTS	
CAPRYLIC/CAPRIC TRIGLYCERIDE	
C12-15 ALKYL BENZOATE	
DICAPRYLYL ETHER	
BUTYLOCTYL SALICYLATE	
POLYBUTENE	
ETHYL OLIVATE	
ROSA CANINA SEED OIL	
JOJOBA OIL/MACADAMIA SEED OIL ESTERS	
HYDROGENATED POLYCYCLOPENTADIENE	
SQUALANE	
GLYCINE SOJA (SOYBEAN) OIL	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL	
SQUALENE	
POLYGLYCERYL-3 DIISOSTEARATE	
TOCOPHEROL	
ORYZA SATIVA (RICE) EXTRACT	
ORYZA SATIVA (RICE) GERM EXTRACT	
AVENA SATIVA (OAT) KERNEL OIL	
PHYTOSTERYL MACADAMIATE	
Ceramide NP (CERAMIDE III B)	
OLEA EUROPAEA (OLIVE) LEAF EXTRACT	
BACILLUS FERMENT	
PHYTOSTEROLS	
RICINUS COMMUNIS (CASTOR) SEED OIL	
SODIUM HYALURONATE	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	

[redacted]

EXECUTIVE SUMMARY REPORT

[redacted]	[redacted]
Title:	An in-vitro test to determine the UVA protection Factor (UVA-PF) relative to the ultraviolet B (UVB) protection of one test article based on the FDA 21CFR201.327. (j) Broad Spectrum method.
Sponsor:	Supergoop 149 5th Ave 8th Floor New York NY, 10010 USA
[redacted]	[redacted]
Date:	1st March 2022
Conclusions:	It can be concluded that the test article meets UVA labelling requirements, and the test article can be classified as broad-spectrum protection.
References:	FDA 21CFR201.327.(J) BROAD SPECTRUM METHOD

[redacted]

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study.

[redacted]

TEST ARTICLE 1 – Daily Dose Bioretinol SPF 40[redacted]

FDA 2019 Method
Results Report

Sample: DAILY DOSE BIORETINOL SPF 40 NON NANO
[redacted]

Operator: ELLA SMITH
[redacted]

Comment:

Date: 20/01/2022 11:07:16

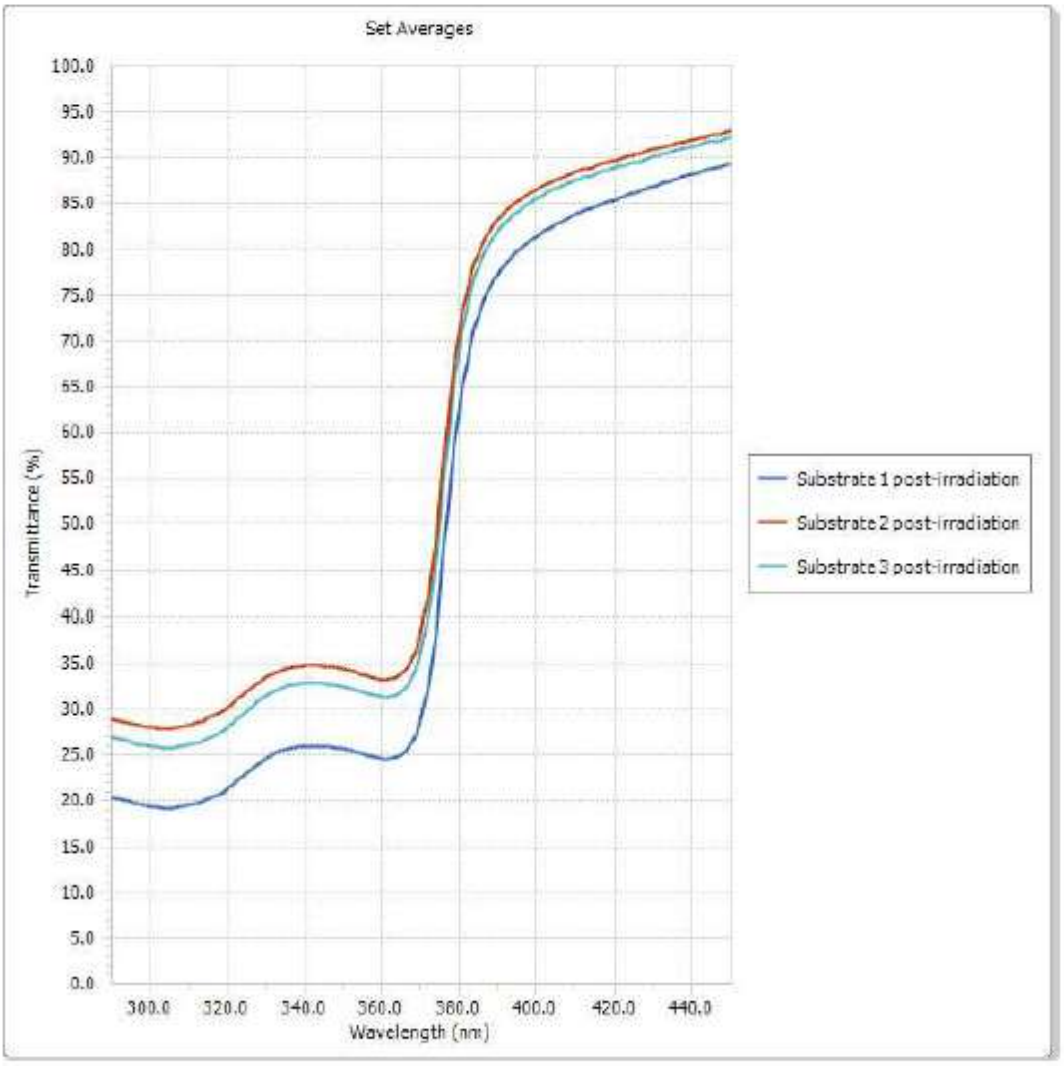
Unit serial number: 0922216910

Product Results

UVA I / UV Ratio Mean	0.764
Critical Wavelength Mean	370.33
Broad Spectrum Protection	Pass

Substrate Data

	UVA I area per unit lambda	UV area per unit lambda	UVA I / UV ratio	Critical Wavelength	Broad Spectrum Protection
Substrate 1 post-irradiation	0.399	0.521	0.766	371.00	Pass
Substrate 2 post-irradiation	0.308	0.404	0.763	370.00	Pass
Substrate 3 post-irradiation	0.327	0.428	0.763	370.00	Pass


Set Averages
Transmittance (%)
100.0
95.0
90.0
85.0
80.0
75.0
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
300.0
320.0
340.0
360.0
380.0
400.0
420.0
440.0
Wavelength (nm)
Substrate 1 post-irradiation
Substrate 2 post-irradiation
Substrate 3 post-irradiation

TEST ARTICLE INGREDIENT LISTING

TEST ARTICLE 1 – DAILY DOSE BIORETINOL SPF 40[redacted]

ACTIVE INGREDIENTS	**PURPOSE**
Zinc Oxide 16.5%	Sunscreen

Inactive Ingredients:

Aqua/Water/Eau, Dicaprylyl Ether, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Silica, Olive Oil Polyglyceryl-6 Esters, Isohexadecane, Glycerin, Sorbitan Oleate, VP/Hexadecene Copolymer, Polyhydroxystearic Acid, Polyglyceryl-6 Pentaoleate, Propanediol, Bakuchiol, Ethylhexylglycerin, Isododecane, Sodium Chloride, Tocopherol, Disteardimonium Hectorite, Camellia Sinensis Leaf Extract, Propylene Carbonate, Quercus Robur Bark Extract, Quercus Robur Wood Extract, Vitis Vinifera (Grape) Seed Extract, Carnosine, Trisodium Ethylenediamine Disuccinate