KRAVEBEAUTY

Hey KB fam,

You made it to the report! We appreciate you digging in with us.

The safety and efficacy of our Beet The Sun SPF have, and always will be, our top priority. We've long acknowledged the known variability and inconsistencies that come with SPF testing. This is why we choose to go beyond standard regulatory requirements by implementing a dual-testing process for all our SPF products. We want that extra layer of confidence for you.

This means that every formulation is validated by two different, independent laboratories, exceeding the requirements of the FDA.

You will find the results of our two complete SPF tests for this product on the following pages.
As always, don't forget to apply your sunscreen!

Thank you for being on this journey with us.

Liah Yoo
Founder
KraveBeauty

Cantor Research Laboratories, Inc.

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EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA 2011) - STATIC

CR Ref. No.: KRB.U0823-C.SF10

Date: November 9, 2022

Sponsor: Krave Beauty, LLC
228 Park Ave. S # 74705
New York, NY 10003-1502

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the static Sun Protection Factor (SPF) on human skin. This study is defined by the U.S. Food and Drug Administration in "Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph", 21 CFR Parts 201 and 310, Subpart D (Federal Register / Vol.76, No. 117 / Friday, June 17, 2011; Docket number FDA-1978-N-0018.) A xenon arc solar simulator was used as the UV source.

2.0 Sample Description:

On August 23, 2022, one test sample labeled Beet the Sun SPF 40 [redacted] was received from Krave Beauty, LLC and assigned CR Lab No. U0823-C.

3.0 Test Material Handling:

Upon arrival at Cantor Research Laboratories, Inc., the test material was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and test(s) requested.

Samples are retained for a minimum period of three months beyond submission of final report unless otherwise specified by the sponsor. If the sample is known to be in support of governmental applications, samples are kept a minimum of two years beyond final report submission. Sample disposal is conducted in compliance with appropriate federal, state and local ordinances.

4.0 Panel Composition:

Healthy volunteers over eighteen years of age were recruited for this study. A trained technician performed a physical examination of the panelist's back to determine if study eligibility criteria were satisfied. The panel consisted of fair-skin individuals with skin types I, II or III, based on the first 30 to 45 minutes of sun exposure after a winter season of no sun exposure, defined as follows: (Federal Register / Vol.76, No. 117 / Friday, June 17, 2011).

Type I - Always burns easily; never tans (sensitive)
Type II - Always burns easily; tans minimally (sensitive)
Type III - Burns moderately; tans gradually (light brown) (normal)

4.1 Standards for Inclusion in the Study:

a. Individuals eighteen years of age or older.
b. Individuals free of any dermatological or systemic disorder which would have interfered with the results, at the discretion of the investigator.
c. Individuals free of any acute or chronic disease that might have interfered with or increased the risk of study participation.
d. Individuals with skin type I, II, and III only, as described above.
e. Individuals with no uneven skin tones, pigmentation, scars, or other irregularities in test site areas that would have interfered with SPF determination.
f. Individuals who have completed a preliminary medical history form mandated by Cantor Research Laboratories, Inc. and were in general good health.
g. Individuals, who have read, understood and signed an informed consent document relating to the specific type of study to which they were subscribing.
h. Individuals who were able to cooperate with the investigator and research staff, willing to have test materials applied according to the protocol, and complete the full course of the study.
i. Individuals who were willing to refrain from using sunscreen products, sunbathing or tanning bed use on the test sites, twenty four hours prior to study initiation and the entire duration of the study.
j. Individuals with excessive hair on their back who were willing to clip.

4.2 Standards of Exclusion from the Study:

a. Individuals who were currently under a doctor's care.
b. Individuals who were taking any medication (topical or systemic) that may have masked or interfered with the test results.
c. Individuals with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes or any disease that would have increased the risk associated with study participation.
d. Individuals diagnosed with chronic skin allergies.
e. Individuals with a history of adverse effects upon sun exposure.
f. Female volunteers who indicated that they were pregnant or nursing.
g. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions or uneven pigmentation in the test sites.
h. Individuals with known hypersensitivity to any sunscreen products.

4.3 Informed Consent and Medical History Forms:

Each panelist completed an extensive medical history form and was assigned a permanent identification number. An informed consent was obtained from each volunteer describing the reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents. These forms are only available for inspection on the premises of Cantor Research Laboratories, Inc. Reference 21 CFR Ch. 1 Part 50, Subpart B.

4.4 Panel Demographics:

Number of panelists enrolled		10
Number of panelists completed study		10
Age Range		36 – 68
Sex	Male	7
	Female	3
Race	Caucasian	2
	Hispanic	3
	Asian	1
	African American	4

5.0 Institutional Review Board (IRB):

The annual IRB of Cantor Research Laboratories, Inc. consists of five or more individuals from diverse backgrounds. They are chosen from the local community to review and approve clinical study documents like protocols, SOPs, ICFs, AE/SAE procedures, reports, etc. that are presented to them. A few members from within the company are also present for technical expertise only to answer questions, if any and do not participate in the voting process. The outcome of the IRB, list of members etc. is kept on file at Cantor Research Laboratories, Inc. and is available for inspection during the hours of operation. Reference: CFR Title 21 Part 56, Subparts A, B, C, and D.

6.0 Artificial Light Source:

The light source employed is a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S, 15S or Model 16S) having a continuous emission spectrum in the UVA and UVB wavelength range from 290 to 400nm. Xenon arc is selected on the basis of its black body radiation temperature of 6000K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight.

This device is equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1mm thick Schott WG-320 filter (which absorbs all radiation below 290nm) to produce simulation of the solar UVA-UVB spectrum. A 1mm thick UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remaining visible radiation. UVB radiation was monitored continuously during exposure using a Model DCS-1 Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter). Measurements were taken at a position within 8mm from the surface of the skin. The solar simulator was allowed a warm up time of at least fifteen minutes before use and power supply output was recorded.

Realignment and certification of the Light Sources and calibration of the sunburn meters are conducted annually by independent certification facilities and more often as necessary at the discretion of the operating technician or investigator. The spectral analysis of the solar simulators used in this study is in compliance with the above mentioned monograph.

7.0 Procedure:

Static SPF Determination (Including Padimate O/Oxybenzone SPF Standard):

The procedure for this study is outlined in the Federal Register / Vol.76, No. 117 / Friday, June 17, 2011. The infrascapular area of the back to the right and left of the midline was used. Within this area, 30cm^2 rectangular test sites were delineated with a gentian violet surgical skin marker. Each test subsite was a minimum of 0.5cm^2 and separated from each other by at least 0.8cm as per the above mentioned monograph. Sites were observed to ensure uniform pigmentation, skin tone and texture, and absence of warts, moles, nevi, scars, blemishes and active dermal lesions. Any areas that might be expected to produce erratic results were not used for UV exposures.

One test site area served to determine each panelist's Minimal Erythema Dose (MED). Five UV exposures were administered within this site. The individual panelist's MED is the shortest time of exposure that produces minimally perceptible erythema at sixteen to twenty four hours post irradiation.

The Padimate O/Oxybenzone SPF Standard was stirred, weighed in a syringe and applied to the test site using a finger cot. The test material was stirred, weighed in a syringe and applied to the test site using a finger cot. Both standard and test material were dispensed at a final concentration of 2.0mg/cm^2. Evenness of each application was confirmed under a Wood's Lamp.

The UV exposures for the protected sites were calculated from the previously determined MED and the expected SPF as follows (where x equals the expected SPF of the product):

Padimate O/Oxybenzone Standard (SPF 15):	MED times 0.69x, 0.83x, 1.00x, 1.20x, and 1.44x
U0823-C (SPF 40):	MED times 0.76x, 0.87x, 1.00x, 1.15x, and 1.32x

At least fifteen minutes after application, the protected sites received a series of five UV exposures. On the actual day of testing another series of exposures similar to the one given on the previous day was administered to an adjacent untreated site of unprotected skin to re-determine the MED. All immediate responses were recorded after UV radiation exposure from the solar simulator.

8.0 Evaluation of Responses:

The panelists were instructed to return to the testing facility sixteen to twenty four hours post exposure for evaluation of delayed erythemic responses. The technician who evaluated the MED did not know the identity of the test product application sites and UV exposures.

Visual grading scale:

0 = No Erythema
? = Questionable Erythema
1 = Minimal Erythema
2 = Slight Erythema
3 = Well-Defined Erythema
4 = Erythema and Edema
5 = Erythema and Edema in vesicles

Evaluation of the erythema responses was done in a room which is equipped with warm white fluorescent lighting which provides at least 450 lux of illumination.

9.0 Statistical Determination of the SPF:

9.1 Calculation of SPF :

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

$$SPF_i = \frac{\text{Protected MED (MEDp)}}{\text{Unprotected MED (MEDu)}}$$

9.2 Calculation of the mean SPF:

The mean SPF value ($\overline{SPF}$) as well as the standard deviation (s) was calculated from the SPF_i values.

9.3 Calculation of the Standard Error:

The standard error (SE) was also calculated, where n equals the number of subjects who provided valid results.

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

9.4 Calculation of t Value:

The t value was calculated from the t distribution which corresponds to the upper 5% point with n-1 degrees of freedom.

9.5 Determination of the labeled SPF Value:

The labeled SPF value, is equal to the largest whole number less than the $\overline{SPF} - (t * SE)$.

To be considered a valid test panel:

- The test panel must include a minimum of ten valid test results. A maximum of 3 subjects may be rejected; therefore a test panel may include up to thirteen total test subjects.
- The SPF value of the Padimate O/Oxybenzone SPF standard should fall within the SE range of the expected SPF (i.e. 16.3 +/- 3.43).

10.0 Rejection Criteria:

Panelist's results are rejected and the panelist replaced if:

a. An exposure series failed to elicit an MED response on either the unprotected or protected test sites. The test was considered a technical failure even if the MED response is observed in the protected site.

b. The responses on the protected area were randomly absent or inconsistent with the UV doses administered, indicating uneven product spreading, non-constant light irradiance or an unstable product.

c. All exposures in a series elicit erythemal responses - thus prohibiting any MED calculation.

d. The test subject is noncompliant.

11.0 Adverse Reactions:

Panelists were instructed to promptly report adverse effects to the investigator. The investigator would then determine the need for an interim examination and, if warranted, termination from the study. Any adverse effect(s), spontaneously expressed by the panelist or observed by the investigator or research staff, during or after the study were recorded on an Adverse Effect(s)/Intercurrent Event(s) Report.

12.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the panelists.

13.0 Results:

Please see attached Table.

14.0 Archiving and Confidentiality:

Hard copies of records such as raw data sheets, correspondence between the sponsor and Cantor Research Laboratories, Inc., executed ICFs, IRB approvals, AEs/SAEs associated with the study, etc. are maintained on the premises of Cantor Research Laboratories, Inc. in limited access storage files marked "Archive" for at least five years or more when specified by appropriate regulatory requirements. Electronic backups of reports are done on a secured server and a copy kept in an offsite secure location. Other study related information and documents such as forms, subject database, etc. are stored in a secure place at the lab.

The Principle Investigator (PI) & employees of Cantor Research Laboratories, Inc. will keep the test product, test related information, and the sponsor's identity confidential.

15.0 Conclusion:

The Sun Protection Factor (SPF) of the test material [CR Lab No.: U0823-C; Client No.: Beet the Sun SPF 40 [redacted] when tested on ten panelists as described herein under static conditions yielded the mean SPF value of 43.00, which can claim an SPF label of 40, according to the reference.

The mean SPF of the Padimate O/Oxybenzone SPF Standard (SPF 15) standard on the same panel was 16.20.

Shyla Cantor, Ph.D.
Principle Investigator

Bindu Sibi, B.S.
Technician

Eric Bow, H.S.
Technician

Usha Chacko, B.S.
Laboratory Manager

Rachel Babu, B.A.
Quality Assurance Supervisor

11/9/22
Date

EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA 2011) - STATIC

Table

Sponsor: Krave Beauty, LLC
CR Lab No.: U0823-C
Client No.: Beet the Sun SPF 40 [redacted]
Expected SPF: 40

Exp Date	Subject #	Subject ID #	Age	Sex	Race	Type	Lamp Output MED/Hr	Lamp Output I (Amps)	Minimal Erythemal Dose MEDu (J/m²)	MEDp (J/m²) STD (ssMEDp)	MEDp (J/m²) Product (tpMEDp)	SPF Value STD (ssMEDp)	SPF Value Product (tpMEDp)
9/1	1	03 9447	36	M	A	III	131.9	5.0	56.69	1020.40	2607.74	18.00	46.00
9/7	2	03 9374	57	F	C	II	129.9	7.5	46.20	693.00	1848.00	15.00	40.00
9/8	3	03 9324	56	M	AA	III	129.5	6.5	56.69	850.35	2607.74	15.00	46.00
9/28	4	03 9865	61	M	H	II	131.9	6.5	46.20	693.00	1848.00	15.00	40.00
9/28	5	03 9441	55	M	H	III	130.6	7.5	56.69	850.35	2267.60	15.00	40.00
10/5	6	03 9878	37	M	AA	III	129.9	6.5	56.69	1020.42	2267.60	18.00	40.00
10/20	7	03 8416	43	F	H	III	131.8	5.5	56.69	1020.42	2607.74	18.00	46.00
11/1	8	03 9062	59	M	AA	III	131.1	7.0	56.69	850.35	2607.74	15.00	46.00
11/2	9	03 9738	40	M	AA	III	129.6	7.5	56.69	1020.42	2607.74	18.00	46.00
11/3	10	03 8958	68	F	C	I	130.2	5.5	46.20	693.00	1848.00	15.00	40.00
Mean SPF (x)												**16.20**	**43.00**
Standard Deviation (s)												**1.55**	**3.16**
Standard Error (SE)												**0.49**	**1.00**
Number of Subjects (n)												**10**	**10**
Upper 5% t DIST. (t)												**2.262**	**2.262**
Label SPF												**15**	**40**

< Erythema in all subsites
* Data not included in calculations

I: Intensity of Light Source
MED/HR: Minimal Erythemal Dose per Hour
MEDu: Minimal Erythemal Dose of Unprotected Skin
MEDp: Minimal Erythemal Dose of Protected Skin
ssMEDp: Minimal Erythemal Dose of Skin Protected by Sunscreen Standard
tpMEDp: Minimal Erythemal Dose of Skin Protected by Test Product

STD: 2011 FDA Standard Padimate O/Oxybenzone

Study Period: This study was conducted from August 30, 2022 through November 4, 2022.

GLOBAL PRODUCT TESTING

An in vivo study to determine the sun protection factor of one product following FDA Static Test Method.

Prepared for:

Krave Beauty LLC
135 E. 57th Street, Floor 14,
New York
New York, 10022
USA

Prepared by:

PCR Corp
8 Richmond Road
Dukes Park
Chelmsford
Essex
CM2 6UA
United Kingdom

Draft Report v1: 22nd July 2022
Final Report: 3rd August 2022

Princeton Consumer Research Corp

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GLOBAL PRODUCT TESTING

An in vivo study to determine the sun protection factor of one product following FDA Static Test Method.

PCR CORP REPORT NO: KRASPF2C

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 PCR Corp were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt
(Principal Investigator)

B Drewitt
.....
Date 03 / 08 / 2022

Bryan Baker
(Project Manager)

C Gould
.....
Charlie Gould (PP)
Date 03 / 08 / 2022

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.

Laura Walsh
(Quality Assurance)

Laura Walsh
.....
Date 03 / 08 / 2022

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CONTENTS

MATERIALS AND METHODS **7**
1. STUDY DESIGN **7**
2. SELECTION OF SUBJECTS **7**
2.1. SCREENING 7
2.2. INCLUSION CRITERIA 8
2.3. Exclusion Criteria 8
2.4. Prohibitions and Restrictions 9
3. Materials **9**
3.1. Test Articles 9
4. Method **10**
4.1. ARTIFICIAL LIGHT SOURCE 10
4.2. AMBIENT CONDITIONS 11
4.3. INFORMED CONSENT, SCREENING AND TEST SITE IDENTIFICATION 11
4.4. TREATMENT 11
4.4.1 MED (MINIMAL ERYTHEMAL DOSE) DETERMINATION 11
4.4.2 MED ASSESSMENT 11
4.4.3 TEST ARTICLE SPF (STATIC) DETERMINATION 12
4.4.4 SPF DETERMINATION 12
4.4.5 SPF ASSESSMENT AND CALCULATION 13
4.4.8 SKIN ASSESSMENT 14
5. study ethics **15**
5.1 DECLARATION OF HELSINKI 15
5.2 INDEMNITY PROVISION 15
6. quality assurance **15**
7. retention of data **16**
8. references **16**
1 LOCATION AND DATES OF THE STUDY **17**
2 SUBJECTS **17**
3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY **17**
4 QUALITY OF UV IRRADIATION **17**
5 ASSESSMENTS **18**

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Key Study Personnel and Responsibilities

Key personnel	General responsibilities
Principal Investigator (PI) Barrie Drewitt PCR Corp Baypoint Commerce Center 9600 Koger Blvd N St. Petersburg Florida, 33702 USA Tel: (727) 576-7300	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.
Project Manager (PM) Bryan Baker PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: 01245 934050	The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report.
Project Supervisor (PS) Terrie Bennett PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: 01245 934050	The PS will be responsible for the conduct of the study on a daily basis.
Project Co-ordinator (PC) Dianna Lee Krave Beauty LLC 135 E. 57th Street, Floor 14, New York New York, 10022 USA Email: dianna@kravebeauty.com	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

1. This was a single blind study in healthy volunteers to determine the sun protection factor (SPF) of one sun protection 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 one 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 will be MEDu times 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 mean static SPF value for the standard preparation was 16.33 (Label SPF = 15), the study can therefore be considered valid.

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

Test article 1 – Beet The Sun SPF 40 achieved a mean SPF value of 44.80. The calculated Label SPF = 42.

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Introduction and Objective

A 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 were dosed with the test article.

2. SELECTION OF SUBJECTS

2.1. SCREENING

A total of 10 subjects 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).

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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.

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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 PCR Corp 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(s) do 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. Beet The Sun SPF 40

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.

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It was the responsibility of the Sponsor that the test articles 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 PCR Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any PCR Corp site would have been accepted.

On study completion, any remaining unused test articles were 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

GLOBAL PRODUCT TESTING

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).

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4.4.3 TEST ARTICLE SPF (STATIC) DETERMINATION

Three test areas (each area consisting of test site square ≥ 30 cm2 divided into test subsite areas ≥ 0.5cm2 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 cm2 (±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 articles were determined (see Section 4.4.5).

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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:

$A = t \cdot SE$

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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*

4.4.8 SKIN ASSESSMENT

Terrie Bennett 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 PCR Corp, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury arising out of the administration or use of the test article, or of any procedure required under this protocol as a result of a subject participating in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

6. QUALITY ASSURANCE

The study will be carried out within the spirit of the ICH Guidelines on Good Clinical Practice (ICH E6_R2) 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 PCR Corp procedures.

PCR Corp Quality Assurance will inform PCR Corp management of any findings that may affect the integrity of the study.

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7. RETENTION OF DATA

All raw data generated by PCR Corp during the course of the study, and including protocol and final report, will be retained in the PCR Corp Archive 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. ICH E6_R2, INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE, Current Step 4 version dated 9 November 2016.
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

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RESULTS

1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, between w/c 4th July 2022 and w/e 8th July 2022.

2 SUBJECTS

10 subjects of both sexes were recruited into the study and completed the study. The age and sex composition of these subjects is presented in Figure 1.

Figure 1: KRASPF2C Demographics

Subject	Tech Initials	Age	Gender	Ethnicity	Fitzpatrick	MED
1	AK	18	Male	CAUCASIAN	III	30
2	AK	53	Female	CAUCASIAN	II	21
3	AK	20	Male	CAUCASIAN	I	16
4	AK	42	Male	CAUCASIAN	III	31
5	AK	35	Female	CAUCASIAN	III	25
6	AK	44	Female	CAUCASIAN	II	24
7	AK	48	Female	CAUCASIAN	III	29
8	AK	48	Male	CAUCASIAN	III	26
9	AK	38	Female	CAUCASIAN	I	17
10	AK	57	Male	CAUCASIAN	III	33

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).

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5 ASSESSMENTS

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

The mean 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 – Beet The Sun SPF 40 achieved a mean SPF value of 44.80. The calculated Label SPF = 42.

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Table 1 – INDIVIDUAL AND MEAN SPF VALUES FOR TEST ARTICLE 1 – Beet The Sun SPF 40

1 - Beet The Sun SPF 40	SITE	1			2			3			4			5			Re-determined MED	Individual SPF
SUB NO	MED	TIME (SECS)	J/m2 eff	GRADE	TIME (SECS)	J/m2 eff	GRADE	TIME (SECS)	J/m2 eff	GRADE	TIME (SECS)	J/m2 eff	GRADE	TIME (SECS)	J/m2 eff	GRADE		
1	**30**	907	7259	0.0	1043	8348	0.0	1200	9600	0.0	1380	11040	1.0	1587	12696	1.0	**30**	46.00
2	**21**	635	5081	0.0	730	5843	0.0	840	6720	0.5	966	7728	1.0	1111	8887	2.0	**21**	46.00
3	**16**	484	3871	0.0	557	4452	0.0	640	5120	1.0	736	5888	1.0	846	6771	2.0	**16**	40.00
4	**31**	938	7501	0.0	1078	8626	0.0	1240	9920	0.0	1426	11408	1.0	1640	13119	1.0	**31**	46.00
5	**25**	756	6049	0.0	870	6957	0.0	1000	8000	0.0	1150	9200	1.0	1323	10580	1.0	**25**	46.00
6	**24**	726	5807	0.0	835	6678	0.0	960	7680	0.0	1104	8832	1.0	1270	10157	1.0	**24**	46.00
7	**29**	877	7017	0.0	1009	8070	0.0	1160	9280	0.0	1334	10672	1.0	1534	12273	1.0	**29**	46.00
8	**26**	786	6291	0.0	904	7235	0.0	1040	8320	1.0	1196	9568	2.0	1375	11003	2.0	**26**	40.00
9	**17**	514	4113	0.0	591	4730	0.0	680	5440	0.0	782	6256	1.0	899	7194	1.0	**17**	46.00
10	**33**	998	7985	0.0	1148	9183	0.0	1320	10560	0.5	1518	12144	1.0	1746	13966	2.0	**33**	46.00
Mean																		44.80
Std Dev																		2.53
SE																		0.80
95% CI																		1.81
Label SPF calculated																		42.99

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)	J/cm2 eff	GRADE	TIME (SECS)	J/cm2 eff	GRADE	TIME (SECS)	J/cm2 eff	GRADE	TIME (SECS)	J/cm2 eff	GRADE	TIME (SECS)	J/cm2 eff	GRADE		
1	**30**	370	2958	0.0	425	3402	1.0	489	3912	1.0	562	4499	2.0	647	5174	2.0	**30**	14.17
2	**21**	259	2071	0.0	298	2381	0.0	342	2738	1.0	394	3149	1.0	453	3622	2.0	**21**	16.30
3	**16**	197	1578	0.0	227	1814	0.0	261	2086	1.0	300	2399	1.0	345	2759	2.0	**16**	16.30
4	**31**	382	3057	0.0	439	3515	0.0	505	4042	1.0	581	4649	1.0	668	5346	2.0	**31**	16.30
5	**25**	308	2465	0.0	354	2835	0.0	408	3260	1.0	469	3749	1.0	539	4311	2.0	**25**	16.30
6	**24**	296	2366	0.0	340	2721	0.0	391	3130	0.5	450	3599	1.0	517	4139	2.0	**24**	18.75
7	**29**	357	2859	0.0	411	3288	0.0	473	3782	1.0	544	4349	1.0	625	5001	2.0	**29**	16.30
8	**26**	320	2564	0.0	369	2948	0.0	424	3390	1.0	487	3899	2.0	560	4484	2.0	**26**	16.30
9	**17**	210	1676	0.0	241	1928	0.0	277	2217	1.0	319	2549	2.0	366	2932	2.0	**17**	16.30
10	**33**	407	3254	0.0	468	3742	0.0	538	4303	1.0	619	4949	1.0	711	5691	2.0	**33**	16.30
Mean																		16.33
Std Dev																		1.08
SE																		0.34
95% CI																		0.77
Label SPF calculated																		15.56

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APPENDIX 1: CONSENT FORM

Study Code: KRASPF2C 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 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 on the study. You will be supplied with a gown to wear, as we need to see your back. We will mark out six 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.

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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 PCR Corp 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 PCR Corp 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.

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 PCR Corp, 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), IRB/IEC or the sponsor (including monitors and auditors), may inspect the records of the study. Therefore, total privacy cannot be guaranteed.

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

IN CASE OF STUDY RELATED INJURY

If you are injured while participating in this study, PCR Corp 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.

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 PCR Corp, 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 PCR Corp 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.

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.

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.

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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 contact PCR Corp staff 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 **Terrie Bennett** on **01245 934050** 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 PCR Corp 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 PCR Corp, 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 PCR materials, PCR advertising, documentation of study procedures/results or upon request of the sponsor. By signing this consent form, you are giving your authorization for PCR 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.

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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.

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

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APPENDIX 2: SUBJECT INFORMATION SHEET

Study Code: KRASPF2C 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
4th July ***Visit 1*** ***Baseline measure.*** ***Area of the back to be exposed to UV light for different lengths of time to produce a faint pinkness to the skin.***	5th July ***Visit 2*** ***Assessment of the degree of 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.)***	6th July ***Visit 3*** ***Assessment of the degree of pinkness to the skin where necessary.*** ***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.***	7th July ***Visit 4*** ***Assessment of the degree of pinkness to the skin.*** ***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 7th July 2022, 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 **Terrie Bennett** on **01245 934050** during normal business hours.

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APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

Study Code: KRASPF2C 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	☐	☐

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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.	☐	☐
14.	Subject is a regular sunbed user.	☐	☐
15.	Subject has a history of abnormal response to the sun.	☐	☐

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?
Sunscreen/SPF Products			
Other Personal Care Products – please specify			

Questionnaire checked and confirmed by:

Signature Date

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APPENDIX 4: TEST ARTICLE INGREDIENT LISTING

TEST ARTICLE 1 – BEET THE SUN SPF 40

ACTIVES:
HOMOSALATE 10%
OCTISALATE 5%
AVOBENZONE 3%
Octocrylene 3%

INACTIVES:
WATER (AQUA/EAU), PROPANEDIOL, PENTYLENE GLYCOL, 1,2-HEXANEDIOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, BETA VULGARIS ROOT EXTRACT, BISABOLOL, CAPRYLYL GLYCOL, CITRIC ACID, ETHYLHEXYL METHOXYCRYLENE, EUGENIA CARYOPHYLLUS BUD EXTRACT, HYALURONIC ACID, HYDROXYACETOPHENONE, ISOHEXADECANE, POLYSORBATE 80, SALIX ALBA BARK EXTRACT, SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, SODIUM HYDROXIDE, SOLIDAGO VIRGAUREA EXTRACT, SORBITAN OLEATE, TOCOPHERYL ACETATE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, XANTHAN GUM

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AN IN VIVO STUDY TO DETERMINE THE SUN PROTECTION FACTOR OF ONE PRODUCT FOLLOWING ISO:24444 COSMETICS – SUN PROTECTION TEST METHODS.

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AN IN VIVO STUDY TO DETERMINE THE SUN PROTECTION FACTOR OF ONE PRODUCT FOLLOWING ISO:24444 COSMETICS – SUN PROTECTION TEST METHODS.

PCR CORP REPORT NO: KRASPF3C

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 PCR Corp were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt
(Principal Investigator) ..... B Drewitt

Date 03 / 10 / 2022

Saffron Drewitt-Barlow
(Project Manager) .....

Date 05 / 10 / 2022

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.

Bryan Baker
(Quality Assurance) ..... Bryan Baker

Date 04 / 10 / 2022

CONTENTS

INTRODUCTION AND OBJECTIVE **6**
MATERIALS AND METHODS **6**
1. Study design **6**
2. Selection of subjects **6**
2.1. Screening 6
2.2. Inclusion Criteria 6
2.3. Exclusion Criteria 7
2.4. Prohibitions and Restrictions 7
3. Materials **7**
3.1. Test Articles 7
4. Method **9**
4.1. ARTIFICIAL LIGHT SOURCE 9
4.3.1 MED (MINIMAL ERYTHEMAL DOSE) DETERMINATIONS 10
4.3.2 MED ASSESSMENT 10
4.3.3 DAY 1 - TEST ARTICLE SPF DETERMINATION 10
4.3.4 DAY 2 –SPF DETERMINATION 12
4.3.5 SPF ASSESSMENT AND CALCULATION 12
5. Study ethics **15**
5.1 DECLARATION OF HELSINKI 15
6. Quality assurance **15**
7. Retention of data **15**
8. References **16**
RESULTS **17**
1 LOCATION AND DATES OF THE STUDY **17**
2 SUBJECTS **17**
3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY **17**
4 QUALITY OF UV IRRADIATION **17**
5 ASSESSMENTS **17**

SUMMARY

1. This was a single blind study in healthy volunteers to determine the sun protection factor (SPF) of one sun protection product when compared to unprotected skin after the sites were exposed to an artificial "sun" light source based on the ISO 24444:2019 "Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF)".

2. 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 P6 standard preparation (SPF range of 31.0 – 54.9) (Subjects 1 – 5) and P2 standard preparation (SPF range of 13.7 - 18.5) (Subjects 6 – 10) were 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 product application. Length of exposure was determined by reference to the individual subject's MED. The exposure time for the control article and for the test article was 1.12 times greater than the previous one.

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 were determined. Individual and mean SPF values were then calculated.

5. The mean SPF value for the P6 standard preparation was 44.0. Since the expected SPF for this preparation was between 31.0 and 54.9 the study can be considered valid.

   The mean SPF value for the P2 standard preparation was 16.1. Since the expected static SPF for this preparation was between 13.7 and 18.5 the study can be considered valid.

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

   Test article 1 – Beet the sun SPF40 (Expected SPF 40) achieved a mean SPF value of 43.3.

KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
Principal Investigator (PI) Barrie Drewitt PCR Corp Baypoint Commerce Center 9600 Koger Blvd N St. Petersburg Florida, 33702 USA Tel: (727) 576-7300	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.
Project Manager (PM) Saffron Drewitt-Barlow PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: 01245 934050	The Project Manager (PM) will be involved with the study design, compiling the results, and writing the clinical report.
Project Supervisor (PS) Terrie Bennett PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: 01245 934050	The PS will be responsible for the conduct of the study on a daily basis.
Project Co-ordinator (PC) Dianna Lee Krave Beauty LLC 135 E. 57th Street, Floor 14, New York New York, 10022 USA Email: dianna@kravebeauty.com	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 study in healthy volunteers to determine the sun protection factor (SPF) of one Sun Protection product when compared to unprotected skin after the sites were exposed to an artificial "sun" light source (based on the ISO 24444:2019 SPF test methods - In vivo determination of Sun Protection Factor (SPF).

MATERIALS AND METHODS

1. STUDY DESIGN

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

A total of 10 subjects were dosed with the test article.

2. SELECTION OF SUBJECTS

2.1. SCREENING

A total of ten subjects 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 to 70 years.
b. Subject shall be selected using the colourimetric ITA° value. The skin of the subject shall have a colourimetric ITA° value of ≥28° (Intermediate >28° to 41°; Light >41° to 55°; Very light >55°).
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. Greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.
i. A high number of naevi (arbitrarily assigned as >100) on the body.
j. Participation in a Sun Protection Factor test (SPF test), photoallergy test, or phototoxicity test, or follow-up work within the last 2 months.
k. Subject has exhibited sensitisation or questionable sensitisation in an SPF test.
l. Previous history of skin tumours.
m. Use of tanning equipment in the past 2 months.
n. 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.
c. Prevention of test areas from getting wet 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 PCR Corp for the clinical trial had been manufactured/formulated with ingredients that are safe and suitable for the product's stated purpose.

The Sponsor confirms that:

The test articles do 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. Beet the sun SPF40 (Expected SPF 40)

2. Standard Reference Products

The P6 standard preparation (supplied by PCR Corp) with an expected mean SPF value of 43.0 (SPF range of 31.0 – 54.9) will be included in the study for subjects 1 to 5.

The P2 standard preparation (supplied by PCR Corp) with an expected mean SPF value of 16.1 (SPF range of 13.7 – 18.5) will be included in the study for subjects 6 - 10.

Amount of Product Applied/Area:

The amount of test product and reference standard was 2.00 ± 0.05 mg/cm^2. The minimum total area for a test site for product application was 30 cm^2 and the maximum was 60 cm^2.

Mode of Delivery/Application:

Products were applied by use of a finger cot unless it interfered with even application. A new finger cot was used for each new application of product and was not pre-saturated with the test product. If a naked finger was used for spreading, it would have been cleaned between test products.

Liquid products (e.g. lotions, liquids, milks, creams, sprays and sticks): were pipetted onto the surface of the skin in small droplets and then spread over the site test site using light pressure. Spreading time was in the range of 35 ± 15 seconds.

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 articles 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 PCR Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any PCR Corp site would have been accepted.

On study completion any remaining unused test articles were 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. Treatment

4.3.1 MED (MINIMAL ERYTHEMAL DOSE) DETERMINATIONS

Provisional Unprotected MEDu determination: Each subject was treated with a series of five or six light exposures in order to determine the provisional MED for unprotected skin. Provisional MEDu was determined up to one week before the test product exposure procedures. Each exposure time was 1.25 times greater than the previous one.

Provisional MEDu determinations: The MED study area was outlined on the lower back between waist and scapula and lateral to the midline. Subjects were exposed upright in a backless chair (or prone on a treatment table) and the test sites outlined while the subject was in this position.

A template of the study area containing five or six subsites, each 3 cm x 2.5 cm, was 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.

The range of UV doses applied were established using the estimated or anticipated MED based on the subject's ITA°. A minimum of five sub-sites centred on the estimated MED were exposed with incremental UV doses using a recommended geometric progression on 1.25 x. Other geometric progressions of less than 1.25 x may have been used (e.g. 1.2; 1.15; 1.12) but should have been consistent throughout the test. A record of individual exposure dose for each subsite 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.

4.3.2 MED ASSESSMENT

Subsites were graded in the same position as exposure was conducted 20±4 (16 to 24) hours after the MED exposure. The MED was assessed as being the lowest dose that elicited a qualifying unambiguous erythema at a subsite (see Section 4.4). If the series of UV exposures on a subject failed to elicit any erythemal response on any subsite, or if all the sub-sites in the exposure series show an erythemal response or are randomly absent, then the MED determination would have needed to be repeated at higher or lower exposure doses.

4.3.3 DAY 1 - TEST ARTICLE SPF DETERMINATION

The test sites intended for UV exposure were free from blemishes and had an even colour tone.

The minimum total area for a test site for product application was 30 cm^2 and the maximum was 60 cm^2.

There was a minimum distance of 1 cm between the borders of adjacent test sites.

Before product application, the test area may have been cleaned by using a dry cotton pad or equivalent.

The test sites were delineated by a method which did not interfere with the test or harm the subject e.g. skin marker and/or a template made from non-absorbent material.

Three test areas 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. One area had the reference standard applied, one area remained untreated to re-determine the unprotected MED and the test article was applied to the remaining area. The positions of the test products and reference sunscreen test sites were distributed randomly on the backs of subjects over the whole test group. The unprotected test site used to determine MEDu was randomised as one of the test sites across the test area and across subjects.

The test articles were applied by appropriate means by one technician at a dose of 2 mg or 2 µl per cm^2 (±2.5%) and spread over the five subsites with a gloved finger, which had not been pre-saturated with the test article. Spreading time was in the range of 35±15 seconds.

Test article application was timed so that the UV exposures commenced 15 minutes to 30 minutes after application.

Subjects were exposed sitting in an upright position in a backless chair (or prone on a treatment table). Only the subsites of each test area were exposed. A record of individual exposure doses and subsites were kept.

Length of exposure was determined by reference to the individual subject's provisional MED and the expected SPF of the test product. The "middle" of the range received a UV dose equal to the subject's MED multiplied by the expected SPF of the test article under study. Each exposure time was 1.12 times greater than the previous one for each test article and the control article.

Care was taken to ensure that no moles or skin lesions were exposed to UV light. Any immediate responses to UV exposure were noted.

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.

4.3.4 DAY 2 –SPF DETERMINATION

The SPF of the test article was assessed using the scoring scale in section 4.4. Assessments were performed by a trained evaluator 20±4 hours post UV exposure.

4.3.5 SPF ASSESSMENT AND CALCULATION

Calculation of the individual static SPF (SPFi)
The SPF_i of both the reference sunscreen and the products under test for each subject was calculated as below:

$$SPF_i = \frac{\text{MED (protected skin)}}{\text{MED (unprotected skin)}} = \frac{MED_P}{MED_U}$$

SPF_i was expressed to one decimal place.

Calculation of the product SPF
The SPF result for the test products and for the reference sunscreen formulation was calculated as the mean of all valid SPF_i values.

$$SPF = \frac{(\Sigma SPFi)}{n}$$

The Standard deviation, s, is given by:

$$s = \sqrt{\left\{\frac{\left[\Sigma\left(SPFi^2\right)\right] - \left[\frac{(\Sigma SPFi)^2}{n}\right]}{(n-1)}\right\}}$$

95% Confidence Interval:

The 95% CI for the mean SPF is expressed by:

95%CI = SPF – c to SPF + c

Where c is calculated as:

c = (t value) x SEM = [(t value) x s]/√n

Where SEM = standard error of the mean and n is the total number of subjects used.

Student t Distribution Table:

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

The minimum number of valid SPF_i values shall be ten and the maximum number of valid SPF_i values twenty. A maximum of five results may be excluded from the calculation of the mean SPF, but each exclusion shall be justified. A sixth invalid result automatically invalidates the whole test for that test product and no SPF can be calculated for it.

SPF was expressed to one decimal point.

Statistical Criterion

The statistical criterion for all SPF measurements is that the 95% Confidence Interval of the mean SPF measured shall fall within a range of ±17% of the measured mean SPF. This applies to test products and reference sunscreen products.

If the SPF measurement is not within ±17 % of the mean SPF, the number of subjects shall be increased stepwise from the minimum number of 10 until the 95 % CI statistical criterion is met (up to a maximum of 20 valid results from a maximum of 25 subjects tested). If the statistical criterion has not been met after 20 valid results from a maximum of 25 subjects, then the test shall be rejected.

Acceptance SPF ranges for the reference sunscreens are shown in the table below. If the mean SPF obtained in any test does not fall within the acceptance limits of the reference values, then the entire test (i.e. all test products) shall be rejected. If the 95% confidence interval on the mean SPF for the reference sunscreen falls outside a range defined by the mean reference sunscreen SPF ±17 %, then the entire test (i.e. all test products) shall be rejected.

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

Data Rejection Criteria:

Test data are deemed invalid and shall be rejected under the following circumstances:

- the series of UV exposures on a subject fails to elicit an erythemal response on any sub-site, 20 h ± 4 h after exposure.
- erythemal responses within an exposure series are randomly absent 20 h ± 4 h after exposure.
- all sub-sites in the exposure series show an erythemal response 20 h ± 4 h after exposure.

When one of the above criteria applies to the exposure series on unprotected skin or to the reference sunscreen formulation exposure sites, then all data for all products on that subject are invalid and shall be rejected. When one of the above rejection criteria applies to a test product treated exposure series, then all data for that test product on that subject are invalid and shall be rejected.

If invalid data (whether MEDu or MEDp) have to be rejected for any one product on more than five subjects, then the whole test for that product is invalid and shall be rejected. If invalid data have to be rejected for the reference sunscreen on more than five subjects, then the whole test is invalid and shall be rejected. Any additional exposure to the test area will invalidate the whole test.

4.4. Skin assessment

Terrie Bennett 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 erythema present
0.5 = ambiguous erythema, and/or no clear border, and/or not filling more than 50% of the exposure subsite
1.0 = perceptible unambiguous erythema with defined borders filling more than 50% of the exposure subsite (MED if it is the lowest exposure dose with grade 1)
2.0 = moderate to intense erythema

The series of UV-exposures should have produced at least a one subsite grade of ≤ 0.5 and one or more sites with responses ranging from 1 to 2. The lowest UV dose producing the endpoint of grade 1 or higher is the individual's MEDp.

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 PCR Corp, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury arising out of the administration or use of the test article, or of any procedure required under this protocol as a result of a subject participating in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

6. QUALITY ASSURANCE

The study will be carried out within the spirit of the ICH Guidelines on Good Clinical Practice (ICH E6_R2) 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 PCR Corp procedures.

PCR Corp Quality Assurance will inform PCR Corp management of any findings that may affect the integrity of the study.

7. RETENTION OF DATA

All raw data generated by PCR Corp during the course of the study, and including protocol and Final Report, will be retained in the PCR Corp Archive 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. ICH E6_R2, INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE, Current Step 4 version dated 9 November 2016.

2. ISO 24444:2019 (E)

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

RESULTS

1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, between w/c 5th September 2022 and w/e 9th September 2022.

2 SUBJECTS

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

Figure 1: KRASPF3C

Subject	Age	Gender	ITA
1	35	M	52.4
2	34	F	39.5
3	48	F	54.3
4	57	M	43.7
5	56	M	60.7
6	24	F	58.3
7	18	M	51.5
8	60	F	61.4
9	22	F	39.7
10	59	M	42.0
MEAN ITA			**50.4**

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 ISO 24444:2019 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 to 3.

The mean SPF value for the P6 standard preparation was 44.0. Since the expected SPF for this preparation was between 31.0 and 54.9 the study can be considered valid.

The mean SPF value for the P2 standard preparation was 16.1 Since the expected static SPF for this preparation was between 13.7 and 18.5 the study can be considered valid.

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

Test article 1 – Beet the sun SPF40 (Expected SPF 40) achieved a mean SPF value of 43.3.

Since all Confidence Intervals (CI's) were within 17% of each mean SPF value for the test article, the minimum number of 10 subjects was acceptable for this study.

TABLE 1 – INDIVIDUAL AND MEAN SPF VALUES FOR TEST ARTICLE 1 – Beet the sun SPF40 (Expected SPF 40)

1 - Beet the sun SPF40 (Expected SPF 40)																				
Expected SPF	Skin ITA	MEDu		MEDp															Re-determined MEDu (J/m2 eff)	SPFi
40.0				1			2			3			4			5				
SUB NO		Seconds	J/m2 eff	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade		
1	52.4	26	208	828	6624	0.0	927	7419	0.0	1039	8309	0.0	1163	9306	1.0	1303	10423	1.0	208	44.8
2	39.5	36	286	1138	9105	0.0	1275	10198	0.0	1428	11421	0.5	1599	12792	1.0	1791	14327	2.0	286	44.8
3	54.3	25	198	788	6304	0.0	883	7061	0.0	989	7908	1.0	1107	8857	1.0	1240	9920	2.0	198	40.0
4	43.7	32	258	1030	8238	0.0	1153	9226	0.0	1292	10334	0.5	1447	11574	1.0	1620	12962	2.0	258	44.8
5	60.7	21	167	664	5314	0.0	744	5952	0.0	833	6666	0.0	933	7466	1.0	1045	8362	1.0	167	44.8
6	58.3	22	178	709	5670	0.0	794	6350	0.0	889	7112	1.0	996	7966	2.0	1115	8921	2.0	178	40.0
7	51.5	27	213	847	6780	0.0	949	7593	0.0	1063	8504	1.0	1191	9525	1.0	1333	10668	2.0	213	40.0
8	61.4	20	164	652	5214	0.0	730	5839	0.0	818	6540	0.5	916	7325	1.0	1025	8204	2.0	164	44.8
9	39.7	36	284	1133	9062	0.0	1269	10150	0.0	1421	11368	0.0	1591	12732	1.0	1782	14260	1.0	284	44.8
10	42.0	34	269	1073	8582	0.0	1201	9612	0.0	1346	10765	0.0	1507	12057	1.0	1688	13504	1.0	269	44.8
Mean	50.4																			43.3
Std Dev	8.6																			2.3
95% CI																				1.60

TABLE 2 – INDIVIDUAL AND MEAN SPF VALUES FOR P6 standard

REFERENCE SAMPLE P6																				
Expected SPF	Skin ITA	MEDu		MEDp															Re-determined MEDu (J/m2 eff)	SPFi
43.0				1			2			3			4			5				
SUB NO		Seconds	J/m2 eff	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade		
1	52.4	26	208	890	7121	0.0	997	7975	0.0	1117	8932	0.5	1251	10004	1.0	1401	11205	2.0	208	48.1
2	39.5	36	286	1223	9788	0.0	1370	10962	0.0	1535	12278	1.0	1719	13751	1.0	1925	15401	2.0	286	43.0
3	54.3	25	198	847	6777	0.0	949	7590	0.0	1063	8501	1.0	1190	9522	2.0	1333	10664	2.0	198	43.0
4	43.7	32	258	1107	8856	0.0	1240	9918	0.0	1389	11109	1.0	1555	12442	1.0	1742	13935	2.0	258	43.0
5	60.7	21	167	714	5713	0.0	800	6398	0.0	896	7166	1.0	1003	8026	1.0	1124	8989	2.0	167	43.0
Mean	50.1																			44.0
Std Dev	8.5																			2.2
95% CI																				2.70

TABLE 3 – INDIVIDUAL AND MEAN SPF VALUES FOR P2 standard

REFERENCE SAMPLE P2																				
Expected SPF	Skin ITA	MEDu		MEDp															Re-determined MEDu (J/m2 eff)	SPFi
16.1				1			2			3			4			5				
SUB NO		Seconds	J/m2 eff	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade	Seconds	J/m2 eff	Grade		
6	58.3	22	178	285	2282	0.0	319	2556	0.0	358	2863	1.0	401	3206	1.0	449	3591	2.0	178	16.1
7	51.5	27	213	341	2729	0.0	382	3056	0.0	428	3423	1.0	479	3834	2.0	537	4294	2.0	213	16.1
8	61.4	20	164	262	2099	0.0	294	2350	0.0	329	2632	1.0	369	2948	1.0	413	3302	2.0	164	16.1
9	39.7	36	284	456	3648	0.0	511	4085	0.0	572	4576	1.0	641	5125	1.0	717	5740	2.0	284	16.1
10	42.0	34	269	432	3454	0.0	484	3869	0.0	542	4333	1.0	607	4853	1.0	679	5435	2.0	269	16.1
Mean	50.6																			16.1
Std Dev	9.6																			0.0
95% CI																				#NUM!

APPENDIX 1: CONSENT FORM

Study Code: KRASPF3C 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. A control will also be tested to validate the study.

TEST ARTICLES
The test articles will be applied on the back by study staff and may include cosmetics, personal care products, toiletries, sunscreens, etc.

STUDY PROCEDURES
You will be one of approximately 10 subjects enrolled onto this study. Your participation in this study will last approximately five days and will include three 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 on the study. We will mark out an area, 5 cm x 6 cm on your back while you are sitting upright on a backless chair. We will expose this site to UV light from a sunlamp. The site will be exposed with five different intensities of UV light so that we can find out the dose needed to produce an area of faint pinkness.

Visit 2 (Study Day 2): We will assess the degree of pinkness at the sites. If we do not see the expected pinkness needed, we may perform an additional exposure of a new area of your back to UV light to determine the more exact dose to produce this faint pinkness.

If not needed: We will then mark out three - 5 cm x 6 cm areas on your back. On these different areas we will apply the test product, a control and one area will remain untreated. We will then expose each test area to UV light at 5 different strengths based on the sensitivity of your skin and the SPF of the test products.

Visit 3 (Study Day 3): We will assess your back on this day. Once all procedures are complete, your participation will be considered complete, and compensation will be provided.

RISKS

Exposure to UV rays (simulated sunlight) will result in redness (slight sunburn) to the areas exposed to the UV light. This redness is expected to fade over the next 3-7 days. The UV exposed sites may also tan, and the tan sites may persist for up to six (6) months or longer.

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. 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 at PCR Corp 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 PCR Corp 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.

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 PCR Corp, 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), IRB/IEC 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.

IN CASE OF STUDY RELATED INJURY

If you are injured while participating in this study, PCR Corp 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.

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 PCR Corp, 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 PCR Corp 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.

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.

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 contact PCR Corp staff as soon as possible to inform them of your condition.

WHO TO CONTACT
If you have any questions about this study or in the case of an emergency, contact **Terrie Bennett** on **01245 934 050** 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 PCR Corp 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 PCR Corp, 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 AUTHORISATION
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 PCR staff, PCR advertising, documentation of study procedures/results or upon request of the sponsor. By signing this consent form, you are giving your authorisation for PCR 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.

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

Study Code: KRASPF3C

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.

You will be assigned to the following study schedule:

Monday	Tuesday	Wednesday
5th September ***Visit 1*** ***Baseline measure. Area of the back to be exposed to UV light for different lengths of time to produce a faint pinkness to the skin.***	6th September ***Visit 2*** ***Assessment of the degree of pinkness to the skin where necessary.*** ***Three new 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.***	7th September ***Visit 3*** ***Assessment of the degree of pinkness to the skin.*** ***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 7th September 2022, 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 **Terrie Bennett** on **01245 934 050** during normal business hours.

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

Study Code: KRASPF3C Subject No:

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

STRICTLY CONFIDENTIAL

Inclusion Criteria		Yes	No
1.	Subject is a healthy male or female, aged 18 years to 70 years.	☐	☐
2.	The skin of the subject shall have a colourimetric ITA° value of ≥28° (Intermediate >28° to 41°; Light >41° to 55°; Very light >55°).	☐	☐
3.	Subject has completed written informed consent.	☐	☐
Exclusion Criteria		**Yes**	**No**
1.	Subject is pregnant, nursing, or planning to become pregnant. Male N/A ☐	☐	☐
2.	Subject reports inadequate precaution/procedures to prevent pregnancy (women of childbearing potential only).	☐	☐
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.	Subject has greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.	☐	☐
9.	Subject has a high number of naevi (arbitrary assigned a >100) on the body.	☐	☐
10.	Subject has participated in a Sun Protection Factor test (SPF test) or follow-up work within the last 21 days.	☐	☐
11.	Subject has exhibited sensitization or questionable sensitization in an SPF test.	☐	☐
12.	Subject has a history of skin cancer.	☐	☐
13.	Subject is a regular sunbed user.	☐	☐
14.	Subject has a history of abnormal response to the sun.	☐	☐
Prohibitions and Restrictions		**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.	☐	☐
3.	Subject agrees to prevent test areas from getting wet 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?
Sun Protection oils/lotions/creams			
Other Personal Care Products – please specify			

Questionnaire checked and confirmed by:

_____ _____

Signature Date

APPENDIX 4: TEST ARTICLE INGREDIENT LISTING

TEST ARTICLE 1 – Beet the sun SPF40 (Expected SPF 40)

Avobenzone: 3% Homosalate: 10% Octisalate: 5% Octocrylene: 3%

Water (Aqua/Eau), Propanediol, Pentylene Glycol, 1,2-Hexanediol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Beta Vulgaris Root Extract, Bisabolol, Caprylyl Glycol, Citric Acid, Ethylhexyl Methoxycrylene, Eugenia Caryophyllus Bud Extract, Hyaluronic Acid, Hydroxyacetophenone, Isohexadecane, Polysorbate 80, Salix Alba Bark Extract, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Hydroxide, Solidago Virgaurea Extract, Sorbitan Oleate, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Xanthan Gum