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FDA IN-VITRO BROAD SPECTRUM TEST

FINAL REPORT

August 24, 2016

SPONSOR: Taylor James, LTD DBA Supergoop!
200 E Grayson, Suite 112
San Antonio, TX 78215

TEST PRODUCT: Supergoop! Invincible Setting Powder SPF 45
CONFIDENTIAL

PROJECT -ACCESSION NUMBER: CONFIDENTIAL

RESEARCH STANDARD

This clinical study was conducted in accordance with BioScreen Testing Services standard practices and a modification of the broad spectrum testing method *(21 CFR 201.327.(j)) as defined by the Final Monograph; "Labeling and Effectiveness testing; Sunscreen Drug Products for Over-the-Counter Human Use", Final Rule, 21 CFR Parts 201 and 310, (FR Doc. 2011-14766 Filed 06/16/2011 at 8:45 am; Publication Date: 06/17/2011, Docket No. FDA-1978-N-0018, RIN 0910-AF43) using Labsphere's UV-2000S Benchtop Sunscreen Analyzer.*

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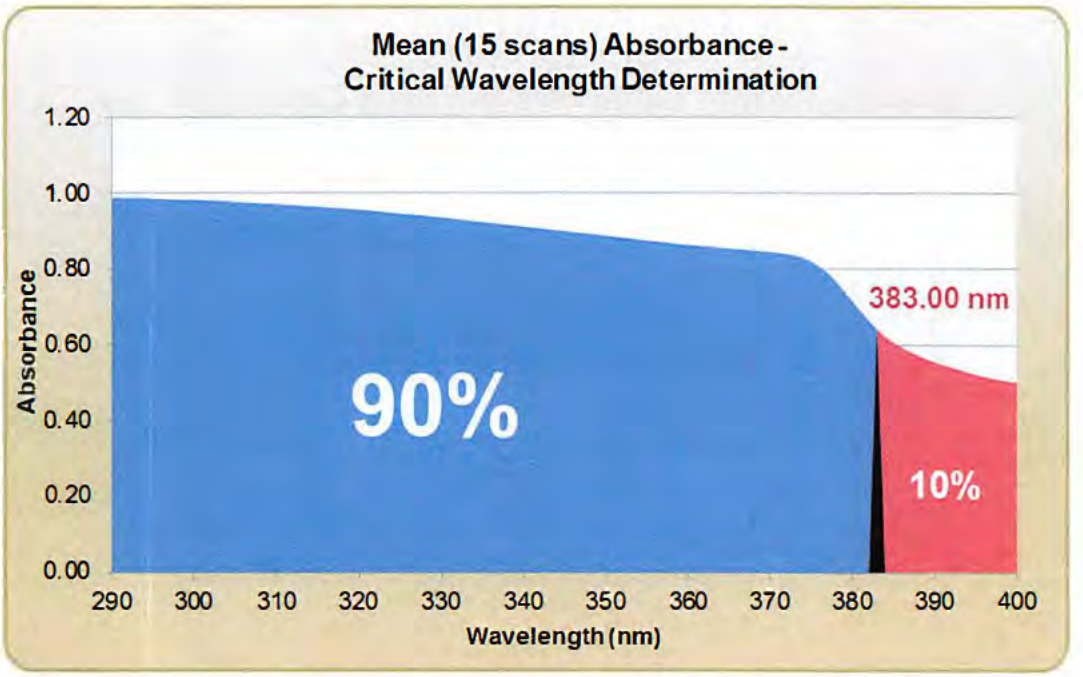
I. STUDY CONCLUSION AND RESULTS

The Critical Wavelength of the Supergoop! Invincible Setting Powder SPF 45 CONFIDENTIAL is 383.00nm.

Critical Wavelength Values After Pre-Irradiation Procedure					
UV Source Irradiance Output:				5.0 MED/h	
Irradiation Time (Single Plate):				2880 sec	
	Location 1	**Location 2**	**Location 3**	**Location 4**	**Location 5**
Plate 1	383	383	383	383	383
Plate 2	383	383	383	383	383
Plate 3	383	383	383	383	383
Average	**383.00 nm**				
Requirement	minimum λ_c = 370 nm				



II. STUDY OBJECTIVE

The study objective was to evaluate the critical wavelength of the test product according to a modification of the broad spectrum testing method published in *21 CFR 201.327(j).*

The Solar Light Xenon Arc Fade Test UV Simulator – Model 16S-300-003 V4.0 or LS1000-6S-UV was used as UV source of pre-irradiation.

III. TEST PRODUCT

Accession No. CONFIDENTIAL was assigned to Test Product: Supergoop! Invincible Setting Powder SPF 45 CONFIDENTIAL which was received from Taylor James, LTD DBA Supergoop! on July 7th, 2016.

IV. UV SOURCE (SOLAR SIMULATOR) EMISSION SPECTRUM

Solar simulator was filtered so that it provided a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,500 watts per square meter (W/m^2) on total solar simulator irradiance for all wavelengths between 250 and 1400 nm and the following percentage of erythema-effective radiation in each specified range of wavelengths:

Wavelength range (nm)	Erythemal Contribution (%)
<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

UVA II (320-340 nm) irradiance was ≥ 20% of the total UV (290-400 nm) irradiance.

UVA I (340-400 nm) irradiance was ≥ 60% of the total UV irradiance.

The emission spectrum of the solar simulator was determined using a radiometer with a response weighted to match the spectrum in *ISO 17166 CIE S 007/E entitled "Erythemal reference action spectrum and standard erythema dose,"* which was incorporated by reference in accordance with *5 U.S.C. 552(a) and 1 CFR part 51.*

V. PLATE (SUBSTRATE)

PMMA Plates Sa	6 µm	**Surface topography measurement (Sa)**
		Requirement: 2 to 7 µm
Application Area	5 cm x 5 cm = 25 cm^2	Area requirement: min 16cm^2
Manufacturer	HeliosScreen Laboratoire	
Designation	HD6 2015 000242	

PMMA = Polymethylmethacrylate

VI. PROCEDURE

1. The sunscreen product was applied to the PMMA plate using the roughened side upper-most by weight, at an application rate of 0.75mg/cm^2 using a positive-displacement automatic pipette.

2. The type of spreading action employed when applying the test product consisted of two phases.

    a. Phase 1: Spreading with a very light pressure for approximately 30 seconds.

    b. Phase 2: Spreading with greater pressure for approximately 30 seconds.

3. The treated sample was then allowed to equilibrate for 15 minutes in the dark at ambient temperature to help facilitate formation of a standard stabilized product film.

4. To account for lack of photostability, the test product was applied on the PMMA plate and irradiated with a fixed dose of UV radiation.

    a. The pre-irradiation dose was delivered and calculated as illustrated below.

$$Dose = 4\,MED = 4\,x\,200\,J/m^2 - eff\left(800\,J/m^2 - eff\right)$$

Where: MED - Minimal Erythemal Dose, the lowest UV dose that produces skin reddening.

$$1\,MED = 200\,J/m^2 - eff$$

VII. CALCULATIONS

A. Transmittance Measurements

The transmittance values were measured at 1 nanometer intervals on three different plates with a minimum of 5 measurements per plate.

Measurements of spectral irradiance transmitted for each wavelength λ through control PMMA plates coated with 15μL of glycerin (no sunscreen product) were obtained from 5 different locations on the PMMA plate [$C_1(\lambda)$, $C_2(\lambda)$, $C_3(\lambda)$, $C_4(\lambda)$, and $C_5(\lambda)$].

In addition, a minimum of 5 measurements of spectral irradiance transmitted for each wavelength λ through the PMMA plate covered with the sunscreen product were similarly obtained after pre-irradiation of the sunscreen product [$P_1(\lambda)$, $P_2(\lambda)$, $P_3(\lambda)$, $P_4(\lambda)$, and $P_5(\lambda)$].

The mean transmittance for each wavelength, $\overline{T(\lambda)}$ was the ratio of the mean of the C(λ) values to the mean of the P(λ) values, as follows:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

Where: $n \geq 5$

B. Mean Absorbance Values

Mean transmittance values, $\overline{T(\lambda)}$, were converted into mean absorbance values, $\overline{A(\lambda)}$, at each wavelength by taking the negative logarithm of the mean transmittance value as follows:

$$\overline{A(\lambda)} = -\log \overline{T(\lambda)}$$

C. Determination of Critical Wavelengths

Critical wavelength measurements were used to measure the breadth of the UV absorbance curve. Critical wavelength (λ_c) was the wavelength at which the area under the absorbance curve represented 90 percent of the total area under the curve in the UV region. This was expressed mathematically as:

$$\int_{290}^{\lambda c} \overline{A(\lambda)} d\lambda = 0.9 \int_{290}^{400} A(\lambda) d\lambda$$

Where: λ_c Critical wavelength

$\overline{A(\lambda)}$ Mean absorbance at each wavelength

$d\lambda$ Wavelength interval between measurements

A mean critical wavelength of λ_c = 370 nm or greater is classified as broad spectrum protection.

Jordan DeSantis
Clinical Supervisor

Steve Park
Clinical Quality Assurance Supervisor

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EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA) – 40 MINUTES WATER RESISTANT

FINAL REPORT

August 17, 2016

SPONSOR: Taylor James, LTD DBA Supergoop!
200 E Grayson, Suite 112
San Antonio, TX 78215

TEST PRODUCT: Supergoop! Invincible Setting Powder SPF 45
CONFIDENTIAL

PROJECT -ACCESSION NUMBER: CONFIDENTIAL

RESEARCH STANDARD

This clinical study was conducted in accordance with standard practices of BioScreen Testing Services and as defined by 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, Labeling 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] using Xenon arc solar simulator as the UV source.

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I. STUDY CONCLUSIONS

The Sun Protective Factor (SPF) of Supergoop! Invincible Setting Powder SPF 45 CONFIDENTIAL when tested on ten (10) subjects as described herein under static and 40 minute water resistant conditions yielded the mean SPF values of 49.73 and 48.38 and the label SPF's of 47 and 46, respectively.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.28 and was within the standard deviation range of the expected SPF of 16.3 ± 3.43. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.20.

II. RESULTS

Under conditions of the study a total of 10 healthy subjects, 24-59 years of age, completed the clinical study evaluating the Sun Protective Factor (SPF) of Supergoop! Invincible Setting Powder SPF 45 CONFIDENTIAL.

SUBJECT ID	SEX	MED/Hr	I (Amps)	SKIN TYPE	MED I J/M²	MED II J/M²	STD (7% PadO/3%Oxyb)	WR CONTROL	SPF VALUE STATIC	SPF VALUE WR
64 0424	F	127.1	6.1	II	28.44	28.44	18.75	18.00	51.75	51.75
74 2314	M	126.8	6.2	III	44.44	44.44	16.30	15.00	51.75	45.00
78 1833	F	126.8	6.0	II	35.55	35.55	16.30	15.00	51.75	51.75
60 0919	M	126.2	6.0	II	35.55	35.55	18.75	18.00	45.00	45.00
62 3569	F	128.8	6.0	II	55.55	55.55	16.30	15.00	51.75	51.75
76 1792	F	129.0	6.0	II	28.44	28.44	16.30	18.00	45.00	45.00
82 1509	F	128.1	6.4	III	44.44	44.44	16.30	15.00	51.75	51.75
50 1386	F	126.2	6.2	II	44.44	44.44	18.75	18.00	51.75	51.75
74 2693	M	128.0	6.7	II	35.55	35.55	16.30	15.00	51.75	45.00
96 0145	M	127.5	6.1	II	44.44	44.44	18.75	15.00	45.00	45.00
MEAN							**17.28**	**16.20**	**49.73**	**48.38**
STANDARD DEVIATION							**1.27**	**1.55**	**3.26**	**3.56**
STANDARD ERROR							**0.40**	**0.49**	**1.03**	**1.13**
STANDARD ERROR % OF MEAN							**2.31**	**3.02**	**2.07**	**2.34**
NUMBER OF SUBJECTS (N)							**10**	**10**	**10**	**10**
UPPER 5% t-DISTRIBUTION							**2.2622**	**2.2622**	**1.8331**	**1.8331**
A VALUES							**0.9085**	**1.1088**	**1.8898**	**2.0637**
LABEL SPF							**16**	**15**	**47**	**46**

F = Female, M = Male, MED = Minimal Erythema Dose, I = Intensity of Light Source, STD = Standard, SPF = Sun Protection Factor, WR = Water Resistant

III. STUDY OBJECTIVE

To evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as defined by 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, Labeling 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] using Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 40 minute water immersion experiment which was carried out under controlled conditions as described in the above mentioned FDA Sunscreen Final Rule and Section 6.0 herein.

IV. TEST PRODUCT

Accession No. CONFIDENTIAL was assigned to Supergoop! Invincible Setting Powder SPF 45 CONFIDENTIAL which was received from Taylor James, LTD DBA Supergoop! on July 7, 2016.

The study began on July 20, 2016 and was completed on August 2, 2016.

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

V. TEST PRODUCT HANDLING

Test product that had been reviewed and approved for use by the Regulatory and Safety representatives of Taylor James, LTD DBA Supergoop! was tested.

Upon arrival at BioScreen the test product was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested. Sample will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

VI. STUDY PARTICIPATION RECRUITMENT

Panel selection was accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

VII. INFORMED CONSENT AND MEDICAL HISTORY FORMS

Informed consent was obtained from each volunteer prior to initiating the study describing 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 form to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms will be available for inspection on the premises of BCS only. Reference 21 CFR Ch. 1 Part 50, Subpart B.

VIII. SUBJECT DEMOGRAPHICS

Number of subjects enrolled		10
Number of subjects completing study		10
Age Range		24-59
Sex	Male	4
	Female	6
Race	Caucasian	10
	Hispanic	0
	Asian	0

IX. INCLUSION CRITERIA

1. Sex: Male and Female
2. Age Range: 18-65
3. Race: Unrestricted
4. Fitzpatrick Skin Type I, II and III
5. Individuals who were free of any dermatological or systemic disorder, which could interfere with the results, at the discretion of the Investigator.
6. Individuals who were in good general health.
7. Individuals who completed a preliminary medical history.
8. Individuals who were free of any acute or chronic disease that might interfere with or increase the risk of study participation.
9. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in the test site areas that would interfere with SPF determination.
10. Individuals who read, understood and agreed to sign an informed consent document.
11. Individuals who were able to cooperate with the Investigator and research staff, were willing to have test materials applied according to the protocol, and completed the full course of the study.
12. Individuals who were willing to refrain from using any sunscreen products, sunbathing, or tanning bed use, 24 hours prior to study initiation and the for the entire duration of the study.
13. Individuals with excessive hair on their back who were willing to clip their hair.

X. EXCLUSION CRITERIA

1. Individuals who were under a Physician's care.
2. Individuals who were taking any medication (topical or systemic) that could mask or interfere with the test results.

3. Individuals with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes, or any disease that would increase the risk associated with study participation.
4. Individuals with an active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema).
5. Individuals with damaged skin at or in close proximity to test sites (e.g., sunburn, tattoos, scars, excessive hair or other disfigurations).
6. Individuals with a history of adverse effects upon sun exposure.
7. Individuals who had any history, which, in the Investigator's opinion, indicated the potential for harm to the subject or placed the validity of the study in jeopardy.
8. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
9. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions, or uneven pigmentation in the test sites.
10. Individuals who had a known history of hypersensitivity to any cosmetics, personal care products, fragrances and/or sunscreen products.

XI. ARTIFICIAL LIGHT SOURCE

The light source, a 150 watt Xenon Arc Solar Stimulator (Solar Light Co., Philadelphia, PA, Model 14S or 16S) with a continuous emission spectrum in the UVB range of 290 to 400 nm will be used. Xenon arc is selected on the basis of its black body radiation temperature of 6000° K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight.[1]

This device is equipped with a dichroic mirror (reflects all radiation below 400nm) and which works in conjunction with a 1mm thick Schott WG-320 filter (absorbs all radiation below 290 nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter is attached to remove reflected (infra-red, greater than 700nm) heat and remaining visible radiation. UVB radiation will be monitored continuously during exposure using a Model DCS-a 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 size of the exposure site was ≥ 1 cm^2. The solar stimulator was allowed a warm up time of at least 15 minutes before use and the power supply output was recorded.

[1]*Berger, D.S.: Specification and Design of Solar Ultraviolet Simulators. J. Invest. Dermatol. 53: 192-199, 1969.*

XII. PROCEDURE

1. Prospective subjects reported to the facility on the start of the study.
2. Prior to beginning all study related activities, prospective subjects completed an informed consent form, medical history form and a HIPPA form.
3. Subjects were screened based on the Federal Register Vol. 64, No. 98:27690,1999*:

   Type I – Always burns easily; never tans

   Type II – Always burns easily; tans minimally

   Type III – Burns moderately; tans gradually

   * Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.
4. Subjects with Fitzpatrick Skin Types greater than III were not enrolled in the study
5. The infrascapular area of the back to the right and left of the midline was used.
6. A trained staff member observed the test sites to ensure uniform pigmentation, skin tone, and texture, and absence of warts, moles, nevi, scars, blemishes, and active dermal lesions using a Woods Lamp
7. Any areas that could be expected to produce erratic results were not used for UV exposures.
8. A 30 cm^2 rectangular test site was wiped down and cleaned prior to delineation with a skin pen. This test site was used to determine the Minimal Erythema Dose (MED_u) of untreated and unprotected skin.
9. A minimum of five UV exposures were administered within this site to determine the subject's inherent MEDu. UV exposures were calculated using a geometric progression of 1.25^n.
10. Each exposure site was at least 0.5 cm^2 and was separated from the next exposure site by at least 0.8 cm.
11. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.
12. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.
13. Subjects returned the facility approximately 16 to 24 hours after UV exposure.
14. A trained staff member visually graded the exposure sites based on the following 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

15. All visual grading was conducted under same lighting conditions and in the same position in which the UV dose was given to the panelist.
16. The lowest UV dose producing perceptible erythema with clearly defined borders determined the individual's MED (grade 1). Any instance of painful erythema or severe erythema with a grade of 3 or greater was considered an adverse experience.
17. This MED was used in determination of the series of UV radiation exposures to be administered to the protected site in subsequent testing of standard, test sunscreens.
18. A series of 30 cm^2 rectangular test sites were wiped down and cleaned prior to delineation with a skin pen. A minimum distance of 1 cm will be maintained between the borders of adjacent test site application areas.
19. One rectangular test site served as the untreated and unprotected site.
20. A second rectangular test site served as the test product site and the third rectangular site served as the SPF Standard Sunscreen (7% Padimate O/3% Oxybenzone).
21. All products (oils, creams, and most lotions) were shaken and/or swirled with a glass rod before use. Products such as powders, pastes, and ointments that could not be drawn into a syringe, were weighed, and then applied by spreading on the test site.
22. The test product and 7% Padimate O/3% Oxybenzone standard sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites measuring 30 cm^2 in the amount of 2.0 mg/cm^2.
23. Evenness of application was verified by observation with a Wood's Lamp and the product(s) were allowed to dry at least 15 minutes prior to UV exposure.
24. The untreated and unprotected site received a series of minimum five UV exposures based upon previously determined MED_u such that the series of 5 doses included the previously determined MED_u in the center using a geometric progression of 1.25^n.
25. The UV exposures for SPF Standard, PADIMATE O.OXYBENZONE SPF STANDARD were calculated from the previously determined MED_u where a minimum of 5 doses were administered using a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X. X denotes the expected SPF.
26. The UV exposures for the test product was calculated from the previously

determined MED_u where a minimum of 5 doses were administered using a geometric progression of 25%, i.e. 0.64X, 0.80X, 1.00X, 1.25X and 1.56X for products with an expected SPF of 8, a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X for products with an expected SPF from 8 to 15 and a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X for products with an expected SPF higher than 15.

27. The middle dose in each of these dose series (i.e. the third dose) should equal the previously determined MED_u times the expected SPF.
28. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.
29. Following UV exposures to the test product site, untreated and unprotected site and the 7% Padimate O/3% Oxybenzone standard sunscreen site, two 50 cm^2 rectangular test sites were wiped down and cleaned before being delineated with a skin pen.
30. These test sites were selected to perform the 40 minute water resistant portion of the study.
31. The test product and in-house water resistant control sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites in the amount of 2.0 mg/cm^2.
32. Evenness of application was verified by observation with a Wood's Lamp and the product(s) were allowed to dry at least 15 minutes.
33. Following the 15 minute waiting period, a total of 40 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying).
34. Immersion was achieved indoors in a circulating whirlpool maintained at 23°C to 32°C where pool and air temperature and the relative humidity were recorded.
35. Following the 40 minute water immersion/rest period cycle, the test sites were allowed to air-dry without toweling prior to exposure from the solar simulator.
36. The UV exposures for in-house water resistant control were calculated from the previously determined MED_u where a minimum of 5 doses were administered using a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X. X denotes the expected SPF.
37. The UV exposures for the test product was calculated from the previously determined MED_u where a minimum of 5 doses were administered using a geometric progression of 25%, i.e. 0.64X, 0.80X, 1.00X, 1.25X and 1.56X for products with an expected SPF of 8, a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X for products with an expected SPF from 8 to 15 and a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X for products with an expected SPF higher than 15.

38. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.

39. Subjects returned to the facility approximately 16 to 24 hours after UV exposure.

40. A trained staff member visually graded the exposure sites based on the following scale. The technician who evaluated the MED did not know the identity of the test product application sites and UV exposures. Also he/she was not the same person to have applied the sunscreen product to the test site or administered the doses of UV radiation.

    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

41. Subjects were then dismissed from the study.

XIII. REJECTION CRITERIA

Panelist's results were rejected and the panelist was replaced if:

1. An exposure series failed to elicit an MED response on the untreated skin. The test was considered a technical failure even if the MED response was observed in the protected site.

2. The responses on the protected area were randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.

3. All exposures in a series elicited responses – thus prohibiting any MED calculation.

4. The subject was non-compliant (e.g. subject withdrew from the test due to illness or work conflicts or did not shield the exposed testing sites from further UV radiation until the MED was determined.)

XIV. SPF CALCULATIONS

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

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

The mean SPF, $(\overline{SPF})$ and standard deviation (s) value were calculated. The standard error (SE) was determined by the following:

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

Where n = the number of subjects.

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

$$A = t * SE$$

The labeled SPF for panels using a minimum of 10 evaluable subjects was the largest whole number less than the mean SPF minus A. This number should be rounded down to the nearest whole number.

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

For the study to be 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). Additionally, a minimum of 10 subjects must complete the study with valid data for analysis.

XV. ADVERSE EVENTS

There were no adverse events reported during study period.

Jordan DeSantis
Clinical Supervisor

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QA Analyst II