[redacted]

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

[redacted] **Ref. No.:** [redacted]

Date: February 12, 2020

Sponsor: [redacted]

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 January 9, 2020, one test sample labeled All of the lights facial sunscreen, Formula #[redacted] was received from [redacted] and assigned [redacted]

3.0 Test Material Handling:

Upon arrival at [redacted] 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 [redacted] 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 [redacted]

4.4 Panel Demographics:

Number of panelists enrolled		10
Number of panelists completed study		10
Age Range		28 – 65
Sex	Male	5
	Female	5
Race	Caucasian	7
	Hispanic	2
	Asian	0
	African American	1

5.0 Institutional Review Board (IRB):

The annual IRB of [redacted] 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 [redacted]

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). A minimum of 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 shaken and 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
S0109-B (SPF 32):	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 [redacted], executed ICFs, IRB approvals, AEs/SAEs associated with the study, etc. are maintained on the premises of [redacted] 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.

[redacted]

15.0 Conclusion:

The Sun Protection Factor (SPF) of the test material [redacted] Client No.: All of the lights facial sunscreen, Formula # [redacted] when tested on ten panelists as described herein under static conditions yielded the mean SPF value of 34.40, which can claim an SPF label of 32, according to the reference.

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

[redacted]
Principle Investigator

[redacted]
Technician

[redacted]
Technician

[redacted]
Laboratory Manager

[redacted]
Quality Assurance Supervisor

2/12/2020
Date

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Table

Sponsor: [redacted]
Lab No.: [redacted]
Client No.: All of the lights facial sunscreen, Formula #: [redacted]
Expected SPF: 30-35

Exp Date	Subject #	Subject ID #	Age	Sex	Race	Type	Lamp Output MED/Hr	Lamp Output I (Amps)	Minimal Erythemal Dose MEDu (J/M²)	Minimal Erythemal Dose MEDp (J/M²) STD (ssMEDp)	Minimal Erythemal Dose MEDp (J/M²) Product (tpMEDp)	SPF Value STD (ssMEDp)	SPF Value Product (tpMEDp)
1/20	1	03 9045	28	F	C	II	130.2	6.0	46.20	831.60	1700.16	18.00	36.80
1/21	2	03 8688	49	M	C	II	130.9	5.5	46.20	693.00	1478.40	15.00	32.00
1/21	3	03 9169	61	F	C	II	130.2	6.0	46.20	831.60	1700.16	18.00	36.80
1/28	4	03 9624	62	F	C	II	132.0	5.5	46.20	693.00	1478.40	15.00	32.00
1/29	5	03 9455	60	M	C	II	131.0	5.5	46.20	693.00	1700.16	15.00	36.80
1/29	6	03 8977	48	M	C	II	130.2	6.0	46.20	693.00	1478.40	15.00	32.00
1/30	7	03 9072	32	M	AA	III	132.0	5.5	56.69	1020.42	2086.19	18.00	36.80
2/3	8	03 9441	52	M	H	III	132.0	5.5	56.69	1020.42	2086.19	18.00	36.80
2/3	9	03 8700	58	F	C	II	131.2	5.0	46.20	693.00	1478.40	15.00	32.00
2/5	10	03 9527	65	F	H	II	130.2	6.0	46.20	693.00	1478.40	15.00	32.00
Mean SPF (x)												**16.20**	**34.40**
Standard Deviation (s)												**1.55**	**2.53**
Standard Error (SE)												**0.49**	**0.80**
Number of Subjects (n)												**10**	**10**
Upper 5% t DIST. (t)												**2.262**	**2.262**
Label SPF												**15**	**32**

< 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 January 16, 2020 through February 6, 2020.