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EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA 2011) STATIC AND VERY WATER RESISTANT (80 Minutes)

CR Ref. No.:

ALU.S1016-B.SF80WR10

Date:

December 7, 2020

Sponsor:



1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the static and very water resistant (80 minutes) 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. This test was conducted prior to and immediately following an immersion experiment which was carried out under controlled conditions [Very Water Resistant (80 minutes) Testing] as described in the above mentioned monograph.

2.0 Sample Description:

On October 16, 2020, one test sample labeled Sonrei Kids Zinq, received from and assigned CR Lab No. S1016-B.

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.
- i. 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 are 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		67
Sex		
	Female	
Race	Caucasian	7
	Hispanic	
	Asian	0
	African American	3

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:

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 0.8 cm 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.

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

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 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/cm². 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 S1016-B (SPF 60): 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 redetermine the MED. All immediate responses were recorded after UV radiation exposure from the solar simulator.

7.2 Very Water Resistant (80 minutes) SPF Determination:

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. Following the static test as previously described, one test area measuring 30cm^2 was assigned to serve as the site for test product for water resistant (80 minutes) SPF determination.

The test product was spread uniformly throughout the area at a concentration of 2.0mg/cm², and then allowed a fifteen minute drying period as before. Evenness of application was confirmed under a Wood's Lamp.

Immersion was achieved indoors in a whirlpool tub with circulating water. Each panelist spent twenty minutes in the water, immediately followed by a fifteen minute rest period out of the water until a total of eighty minutes in the water was achieved. The whirlpool bath was maintained at an average temperature of 74-89°F at moderate agitation.

After the last immersion, the test site was air dried without toweling for at least fifteen minutes prior to irradiation. The water and air temperatures were recorded. Evenness of the test material was confirmed under a Wood's Lamp after the panelist exited the tub.

After the fifteen minute dry time one test area measuring 30cm² was assigned to serve as the site for the Padimate O/Oxybenzone Standard after water immersion. The standard was spread uniformly throughout the area at a concentration of 2.0mg/cm², and then allowed a fifteen minute drying period as before. Evenness of each application was confirmed under a Wood's Lamp.

The second series of test material exposures was administered to the protected areas. The exact series of exposures given was determined by the MED and the expected SPF of the product as before.

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 = <u>Protected MED (MEDp)</u> Unprotected MED (MEDu)

9.2 Calculation of the mean SPF:

The mean SPF value (SPF) as well as the standard deviation (s) was calculated from the SPF_i values.

CR Laboratories, Inc.

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.: S1016-B; Client No.: Sonrei Kids Zinq, when tested on ten panelists as described herein under static and very water resistant (80 minutes) conditions yielded the mean SPF values of 67.20 and 64.50, respectively. The test material can claim an SPF label of 64 under static conditions and 61 under very water resistance (80 minute) conditions, according to the reference.

On the same panel, the mean SPF of the Padimate O/Oxybenzone Standard before water immersion was 15.60 and following water immersion was 15.60.

Principle investigator	recumician
Technician	Laboratory Manager
Quality Assurance Supervisor	

EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA 2011) STATIC AND VERY WATER RESISTANT (80 Minutes)

Table 1

Sponsor:

CR Lab No.:

S1016-B

Client No.:

Sonrei Kids Zinq,

Expected SPF:

60

Exp. Date	#	Subject					Lamp Output		MEDu -	SPF Values (MEDp)			
		ID#	Age	Sex	Race	Туре	MED/ Hr	I (Amps)	(J/M²)	STD (ssMEDp)		Product (tpMEDp)	
										(B.W.)	(A.W.)	(B.W.)	(A.W.)
10/21	1	03 8281	55	F	С	II	130.0	7.5	46.20	15.00	15.00	60.00	60.00
10/27	2	03 7523	42	M	C	II	132.0	6.5	46.20	15.00	15.00	69.00	60.00
10/28	3	03 6057	64	F	C	ΙÌ	131.2	6.5	46.20	15.00	15.00	69.00	60.00
11/10	4	03 9455	61	M	C	II	131.9	6.5	46.20	18.00	18.00	69.00	69.00
11/16	5	03 9130	59	M	AA	Ш	130.0	6.0	56.69	15.00	15.00	69.00	69.00
11/18	6	03 9463	46	M	C	II	130.0	6.0	56.69	18.00	18.00	69.00	69.00
11/24	7	03 9550	46	F	AA	Ш	131.0	6.5	56.69	15.00	15.00	69.00	69.00
11/30	8	03 9354	59	F	C	II	130.0	6.0	46.20	15.00	15.00	69.00	60.00
11/30	9	03 8404	67	F	C	1	130.0	6.0	46.20	15.00	15.00	60.00	60.00
12/1	10	03 9324	54	M	AA	III	129.9	6.5	56.69	15.00	15.00	69.00	69.00
Mean SPF (x)								15.60	15.60	67.20	64.50		
Standard Deviation (s)								1.26	1.26	3.79	4.74		
Standard Error (SE)							0.40	0.40	1.20	1.50			
Number of Subjects (n)						10	10	10	10				
Upper	Upper 5% t DIST. (t)						2.2622	2.2622	2.262	2.262			
Label	SPF									14	14	64	61

< Erythema in all subsites

1;

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

WR: B.W.: Water Immersion (80 minutes)

A.W.:

Before Water Immersion

After Water Immersion

STD:

2011 FDA Standard Padimate O/Oxybenzone

Study Period:

This study was conducted from October 20, 2020 through December 3, 2020.

^{*} Data not included in calculations

EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA 2011) STATIC AND VERY WATER RESISTANT (80 Minutes)

Table 2

Sponsor: CR Lab No.:

S1016-B

Client No.:

Sonrei Kids Zinq,

Exp. Date		Subject ID#	Lamp Output		MEDu _	Exposure Timings (MEDp)			
	#		MED/ Hr	I	(J/M²)	STD (s	sMEDp)	Product (tpMEDp)	
				(Amps)		(B.W.)	(A.W.)	(B.W.)	(A.W.)
10/21	1	03 8281	130.0	7.5	46.20	693.00	693.00	2772.00	2772.00
10/27	2	03 7523	132.0	6.5	46.20	693.00	693.00	3187.80	2772.00
10/28	3	03 6057	131.2	6.5	46.20	693.00	693.00	3187.80	2772.00
11/10	4	03 9455	131.9	6.5	46,20	831.60	831.60	3187.80	3187.80
11/16	5	03 9130	130.0	6.0	56.69	850.35	850.35	3911.61	3911.61
11/18	6	03 9463	130.0	6.0	56.69	1020.42	1020.42	3911.61	3911.61
11/24	7	03 9550	131.0	6.5	56.69	850.35	850.35	3911.61	3911.61
11/30	8	03 9354	130.0	6.0	46.20	693.00	693.00	3187.80	2772.00
11/30	9	03 8404	130.0	6.0	46.20	693.00	693.00	2772.00	2772.00
12/1	10	03 9324	129.9	6.5	56.69	850.35	850.35	3911.61	3911.61

< Erythema in all subsites

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

WR: Water Immersion (80 minutes)
B.W.: Before Water Immersion
A.W.: After Water Immersion

STD: 2011 FDA Standard Padimate O/Oxybenzone

^{*} Data not included in calculations