



EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 80 MINUTE WATER RESISTANT

Ref. No.: MS12.SPF.M5064.BTSI.80MINWR3

Date: May 18, 2012
Revision #1 Date: May 25, 2012

Sponsor: **CoreTex Products Inc.**
1850 Sunnyside Ct.
Bakersfield, CA 93308

1.0 Objective:

This panel has been convened 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 80 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.

Three subjects were tested instead of the minimum of ten cited in the reference.

2.0 Sample Description:

Received: 4/27/2012
Received From: **CoreTex Products Inc.**
Number Of Test Samples Received: 2
Label On Test Samples: Coretex Thick SPF 30 Sunscreen –
12B08C/COR05
Accession No.: 754843

3.0 Test Material Handling:

Upon arrival at the clinic, 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 tests requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

4.0 Panel Demographics:

Number of subjects enrolled	3
Number of subjects completing study	3
Age Range	50 - 56
Sex.....	Male
	Female
Race.....	Caucasian
	Hispanic
	Asian

4.1 Standards For Inclusion In A Study:

- a. Individuals eighteen years of age or older.
- b. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.
- c. Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.
- d. Individuals with Fitzpatrick Skin Type I, II, and III only.
- e. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with SPF determination.
- f. Individuals who complete a preliminary medical history form mandated by the clinic and are in general good health.
- g. Individuals who will read, understand and sign an informed consent document relating to the specific type of study they are subscribing. Consent forms are kept on file and are available for examination on the premises of the clinic only.
- h. Individuals able to cooperate with the Investigator and research staff, be willing to have test materials applied according to the protocol, and complete the full course of the study.
- i. Individuals willing to refrain from using any sunscreen products, sunbathing or tanning bed use, 24 hours prior to study initiation and the entire duration of the study.

- j. Individuals with excessive hair on their back who are willing to have hair removed by technicians prior to commencement of study.

4.2 Standards For Exclusion From The Study:

- a. Individuals who are under a doctor's care.
- b. Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results.
- c. Subjects 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.
- d. Individuals diagnosed with chronic skin allergies.
- e. Individuals with a history of adverse effects upon sun exposure.
- f. Female volunteers who indicate that they are pregnant or lactating.
- 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:

An 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 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.

A trained technician performed a physical examination of the panelist's back to determine if study eligibility criteria were satisfied.

The parties agree to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

4.4 Panel Composition:

Healthy volunteers over the age of 18 years were recruited for this study. The panel consisted of fair-skin individuals with Fitzpatrick Skin Types I, II or III defined as follows (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 the first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4.5 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of the clinic, consists of five or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file at the clinic and is available for inspection during the hours of operation.

5 Artificial Light Source:

The light source employed was a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S, Model 15S or Model 16S) having a continuous emission spectrum in the UVB range from 290 to 400 nm. Xenon arc was 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 sunlight¹.

This device was equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG-320 filter (which absorbs all radiation below 290nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remained 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 size of the exposure site is $\geq 1\text{cm}^2$. The solar simulator was allowed a warm up time of at least 15 minutes before use and power supply output was recorded.

Realignment of the Light Sources and calibration of the sunburn meters are conducted semi-annually by independent certification facilities and more often as necessary at the discretion of the operating technician or Investigator. A certificate for the Solar Simulator Emission Spectrum compliance is on file at the clinic. The spectroradiometric measurements are performed at least annually.

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

6 Procedure:

(A) **STATIC SPF DETERMINATION (INCLUDING 7% PADIMATE O/3% OXYBENZONE STANDARD)**

The infrascapular area of the back to the right and left side of the midline was used. Within this area, 30 cm² rectangular test sites were delineated with a gentian violet surgical skin marker. 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.

The procedure for this study is outlined in the Federal Register / Vol.76, No.117, 21 CFR Parts 201 and 310 published on Friday June 17, 2011. One test site area served to determine each subject's Minimal Erythema Dose (MED).

A minimum of five UV exposures was administered within this site. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation.

The test material and 7% Padimate O/3% Oxybenzone standard were shaken and/or swirled with a glass rod before use and were evenly applied using plastic volumetric syringes to rectangular areas measuring 3 cm x 10 cm (30 cm²) for a final concentration of 2.0 mg/cm². Evenness of application was verified by observation with a Wood's Lamp. An adjacent test site was then selected to perform a static determination on the test substance, as above, prior to the immersion test.

Fifteen minutes after application, a protected site received a series of five UV exposures based upon previously determined MED.

All immediate responses were recorded after UV radiation exposure from the solar simulator.

The UV exposures for 7% Padimate O/3% Oxybenzone, in-house water resistant control and test material were calculated from previously determined MED and the intended SPF as follows:

SPF 16.3: MED times 0.76x, 0.87x, 1.00x, 1.15x and 1.32x

SPF 15: MED times 0.69x, 0.83x, 1.00x, 1.20x and 1.44x

SPF 30: MED times 0.76x, 0.87x, 1.00x, 1.15x, and 1.32x where x equals the expected SPF of the product.

(B) 80 MINUTE WATER RESISTANT DETERMINATION (INCLUDING IN-HOUSE WATER RESISTANT CONTROL)

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. On the day of the test, following exposure of the 7% Padimate O/3% Oxybenzone standard, MED's and static determination, another test site was designated. One other adjacent site was selected to perform a water resistant determination of an in-house 80 minute water resistant standard with a known SPF as a control.

The water resistant SPF value was determined by the product's ability to resist an 80-minute period of water immersion, achieved through the following test regimen: After application of the sunscreen product followed by the waiting period, a total of 80 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying). Immersion was achieved indoors in a circulating whirlpool maintained at 23 to 32⁰C for these testing procedures. The pool and air temperature and the relative humidity were recorded. At the conclusion of the water immersion/rest period cycle, the test sites were allowed to air-dry without toweling prior to exposure from the solar simulator, as described.

7 Evaluation Of Responses:

Sixteen to twenty-four hours post exposure, the subjects are instructed to return to the testing facility for evaluation of delayed erythemic responses. The technician who evaluates 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.

$$SPF = \frac{\textit{Protected MED}}{\textit{Final unprotected MED}}$$

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

- 7.1 All technical employees of the clinic are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published; which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.

8.0 Determination of the Test Product's SPF Value and PCD:

Calculation of SPF– According to the reference, the mean SPF value (\bar{x}) is calculated using a minimum of 10 evaluable subjects per formulation. The standard deviation was determined (s). The upper 5% point was obtained from the t distribution table with $n-1$ degrees of freedom (t). The standard error (SE) was calculated by $(s)/\sqrt{n}$ (where n equals the number of subjects who provided valid test results).

Therefore, the label SPF value for panels using a minimum of 10 evaluable subjects is the largest whole number less than the mean SPF minus ($t \times SE$).

$$\text{Label SPF} = \text{Mean SPF} - (t \times SE)$$

Only three test panelists were included in this study.

9.0 Rejection Criteria:

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

1. An exposure series fails to elicit an MED response on the untreated skin. The test is considered a technical failure even if the MED response is observed in the protected site.
2. The responses on the protected area are randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.
3. All exposures in a series elicit responses – thus prohibiting any MED calculation.
4. The subject was non-compliant (e.g. subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined.)

10.0 Results:

**EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) -WATER RESISTANT - 80 MINUTE WATER IMMERSION**

Table

Sponsor: **CoreTex Products Inc.**
 Lab No.: M-5064
 Client No.: Accession No.: 754843, Coretex Thick SPF 30 Sunscreen – 12B08C/COR05

Subject ID #	Sex	MED/ Hr	I (Amps)	Skin Type	MED I J/M ²	MED II J/M ²	STD (7%PadO/ 3%Oxyb)	WR		SPF Values	
								Control	Static	Static	WR
50 3320	F	125.6	6.0	II	46.20	46.20	16.30	15.00	34.50	26.10	26.10
62 3368	F	126.5	6.0	II	30.33	30.33	16.30	15.00	30.00	26.10	26.10
94 7230	F	127.8	6.0	II	60.89	60.89	18.75	18.00	34.50	22.80	22.80
MEAN (x)							17.12	16.00	33.00	25.00	
STANDARD DEV (s)							1.41	1.73	2.60	1.91	
STD. ERROR							0.82	1.00	1.50	1.10	
S.E. % OF MEAN							4.79	6.25	4.55	4.40	
N							3	3	3	3	

MED: Minimal Erythema Dose
 I: Intensity of light source

Evaluation Period: This study was conducted from May 2, 2012 through May 8, 2012.

11.0 Observations:

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

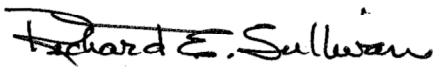
12.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of the clinic in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

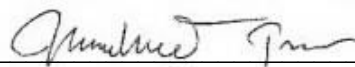
13.0 Conclusions:

The Sun Protection Factor (SPF) of the above test material (Lab No.: M-5064; Client No.: Accession No.: 754843, Coretex Thick SPF 30 Sunscreen – 12B08C/COR05C) when tested on three subjects as described herein under static and 80 minute water resistant conditions yielded the mean SPF values of 33.00 and 25.00 respectively.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.12. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.00.



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