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FDA IN-VITRO BROAD SPECTRUM TEST

FINAL REPORT

February 25, 2016

SPONSOR: Poofy Organics
6 Franklin Place
Rutherford, NJ 07070

TEST PRODUCT: Sunscreen

PROJECT –ACCESSION NUMBER: 938341 – 938341

RESEARCH STANDARD

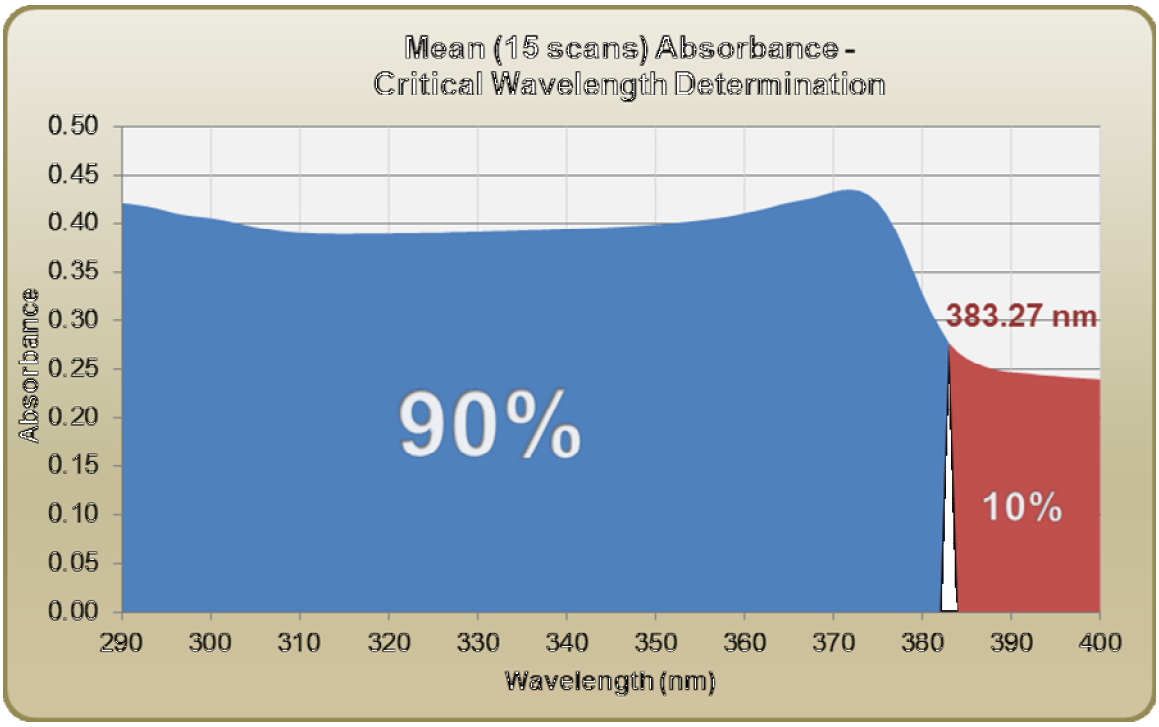
This clinical study was conducted in accordance with the International Conference of Harmonization Tripartite Guidelines on Good Clinical Practice, applicable FDA regulations/guidelines set forth in 21 CFR Parts 11, and 50 and standard practices of BioScreen Testing Services.

TABLE OF CONTENTS

I. STUDY CONCLUSION AND RESULTS

The Critical Wavelength of the Sunscreen is 383.27 nm, and **does satisfy** the required minimum of 370 nm for "Broad Spectrum" labeling.

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	384
Plate 2	383	383	383	383	383
Plate 3	383	384	383	384	384
Average	**383.27 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 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. 938341 was assigned to Test Product: Sunscreen which was received from Poofy Organics on February 23, 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 2009 000153	

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.

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