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FDA IN-VITRO BROAD SPECTRUM TEST

AMA Ref. No.: MS16.FDA.BRDSPCTRM.INVITRO.O6439.JSF

Date: April 18, 2016

Sponsor: Just Skin Food
[redacted]
Cape May, New Jersey 08204

Sample Description:

On April 18, 2016 one test sample labeled Sunscreen batch#132426A was received from Just Skin Food and assigned AMA Lab No.: O-6439.

Upon arrival at AMA Laboratories, Inc., the test material is 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.

Study Objectives:

The sample (AMA Lab No.: O-6439; Client No.: Sunscreen batch#132426A) was evaluated according to 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 06/14/2011 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 (S/N 1216135073). 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.

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 AMA Laboratories, Inc. in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

Plate (Substrate):

PMMA Plates Sa:	6µm	*(Sa requirement: 2 to 7 µm)*
Application Area:	5 cm x 5 cm = 25cm^2	*(Area requirement: min. 16 cm^2)*
Manufacturer:	HeliosScreen Laboratoire	
Designation:	HD6 2009 000153	

Methodology:

Quantity Applied:

Sunscreen product was applied to the roughened PMMA plate (roughened side uppermost) by weight, at an application rate of 0.75mg/cm^2 using a positive-displacement automatic pipette.

Spreading Technique:

The type of spreading action to be employed when applying the test product consists of two phases. Phase 1: Spreading with a very light pressure for approximately 30 seconds. Phase 2: Spreading with greater pressure for approximately 30 seconds.

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

Pre-Irradiation UV Dose (PID):

To account for lack of photostability, the test product is applied on the PMMA plate and irradiated with a fixed dose of UV radiation. The pre-irradiation dose to be delivered is calculated as follows:

$$Dose = 4\ MED = 4 \times 200\ J/m^2\ –eff\ (800\ J/m^2\ –eff)$$

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

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

UV Source (Solar Simulator) Emission Spectrum:

Solar simulator is filtered so that it provides 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 is ≥ 20% of the total UV (290-400 nm) irradiance. UVA I (340-400 nm) irradiance is ≥ 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," dated 1999 (First edition, 1999-12-15; corrected and reprinted 2000-11-15), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Transmittance Measurements:

The transmittance values are 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 15 microliters of glycerin (no sunscreen product) are 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 are 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, $\overline{T(\lambda)}$, is 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: $n \geq 5$

Calculation of mean absorbance values:

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

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

Determination of Critical Wavelength:

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

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

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.

Security Label Disclosure:

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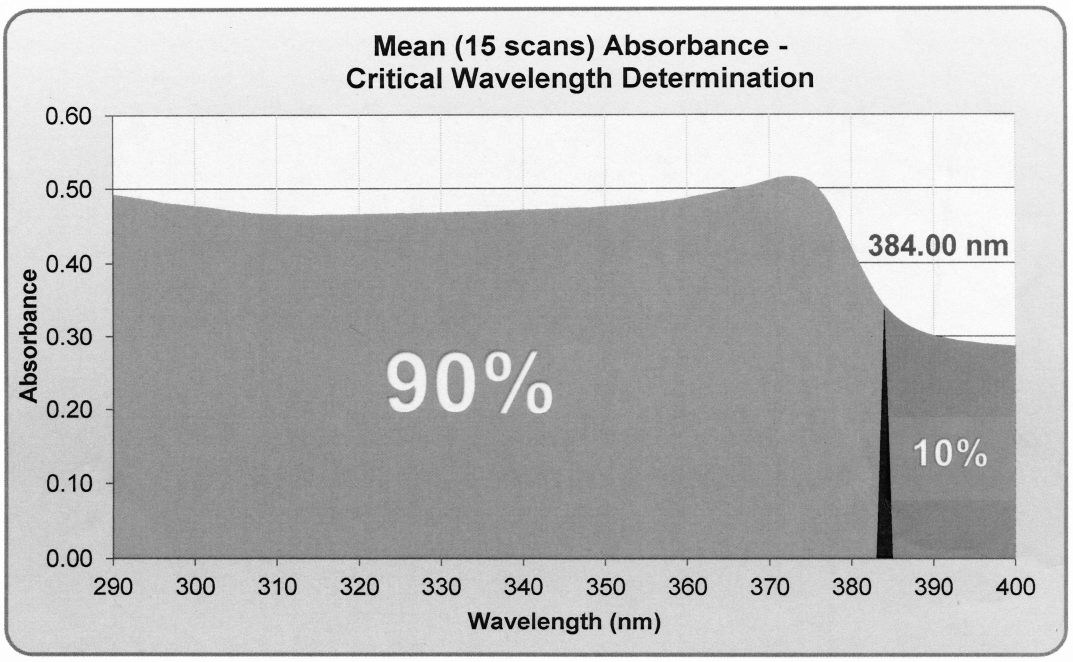
Results:

Critical Wavelength: (requirement: minimum λ_c = 370 nm)

Critical Wavelength Values After Pre-Irradiation Procedure					
UV Source (LS1000-6S-UV Solar Simulator) Irradiance				5.0 MED/h	
Irradiation Time (Single Plate):				2880 sec	
	Location	Location	Location	Location	Location
Plate 1	384	384	384	384	384
Plate 2	384	384	384	384	384
Plate 3	384	384	384	384	384
Average:	**384.00 nm**				



The Critical Wavelength of the above test material (AMA Lab No.: O-6439; Client No.: Sunscreen batch#132426A) is 384.00 nm, and satisfies the criteria for "Broad Spectrum" labeling (minimum of 370 nm required).

SIGNATURE PAGE

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Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Christian Gorglione, B.S.
Quality Assurance Supervisor

4/18/16
Date