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EVALUATION OF IN-VITRO BROAD SPECTRUM TEST FDA METHOD (2011 FINAL RULE)

CR Ref. No.: ALU.S1016-B.IVF

Date: November 11, 2020

Sponsor: [redacted]

1.0 Objective:

To measure the critical wavelength of a sunscreen product in accordance with the Broad Spectrum Test of 21 FDA CFR Parts 201 and 310; Sunscreen Drug Products for Over-the-Counter Human Use and Labeling and Effectiveness testing. Federal Register, Vol. 76, No. 117, June 17, 2011, using Labsphere's UV-2000S Benchtop Sunscreen Analyzer. Irradiation was done using the Solar Light Xenon Arc Fade Test UV Simulator – Model 16S-300-003 V4.0.

2.0 Test Material:

On October 16, 2020, one test sample labeled [redacted] Formula # 326-099/20384-01-02 was received from [redacted] 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 UV Spectrometry:

4.1 Light Source:

The light source employed is a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 16S) which has a continuous spectral distribution of UV radiation from 290 to 400nm.

Realignment and certification of the Light Source and calibration of the sunburn meter is 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 simulator used in this study is in compliance with the above mentioned monograph.

4.2 Substrate:

Optical-grade polymethyl methacrylate (PMMA) plates, manufactured by Helioscreen, were used for this test. Plates are designed to be roughened on one side to a three dimensional surface topography measure (Sa) of 6 micrometers (HD 6 µm). Plates have a rectangular application area of approximately 25 square centimeters (25 cm^2).

4.3 Spectrometer:

Labsphere's UV-2000S measures spectral transmittance across the 250-450 nm wavelength spectrum using an integrating sphere and two spectrometer instruments.

The sample holder (sample stage assembly) is equipped with an X-Y stage for positioning a sample plate with nine specific numbered sites to follow. Five sites are chosen. The stage incorporates a mask to ensure accurate and consistent sample test results.

4.4 Input Optics:

The UV-2000S optical components are housed in upper and lower optical chambers called the optics head and input optics. The UV-2000S is equipped with an integrating sphere constructed of Spectralon, a highly diffuse reflective material.

4.5 Dynamic range of the spectrometer:

The UV-2000S is equipped with two diode array spectrometers (Spectrometer No. 1 and Spectrometer No. 2). The spectrometers are identical except that operate one after the other during the scanning process so that data collection from the integrating sphere and lower chamber occurs simultaneously. UVB calculations are performed across the 290-450nm spectrum.

5.0 Procedure:

5.1 Test Material Application to PMMA Plate:

The test material was applied to the roughened side of three PMMA plates at 0.75 mg per square centimeters (0.75mg/cm^2) by a trained technician. The test material was evenly spread over each plate using a finger cot. The PMMA plates were then allowed to equilibrate for fifteen (15) minutes in the dark.

Additionally, 15 µl of glycerin (no sunscreen product) was evenly spread on a PMMA plate which was used as a reference plate.

5.2 Test Material Pre-Irradiation:

To account for the lack of photostability, the PMMA plates applied with the test material were irradiated with a solar simulator (described in section 4.1) at a fixed dose of UV irradiation of 4 MEDs (Minimal Erythema Dose) which is equivalent to an erythemal effective dose of 800 J/m^2 eff.

5.3 Calculation of Mean Transmittance Values:

After pre-irradiation the mean transmittance values were determined for each wavelength λ over the full UV spectrum (290 to 400 nm). Transmittance values were measured at 1nm intervals. Measurements of spectral irradiance transmitted for each wavelength through control PMMA plates (no test material applied) were obtained from at least five (5) [C1(λ), C2(λ), C3(λ), C4(λ) and C5(λ)]different locations on the plate.

Five (5) measurements of spectral irradiance transmitted for each wavelength through the PMMA plate applied with the test material were similarly obtained after the pre-irradiation of the test material [P1(λ), P2(λ), P3(λ), P4(λ) and P5(λ)].

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:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

5.4 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 values as follows:

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

5.5 Number of Plates:

Three (3) individual plates were used for each test material. Therefore a total of fifteen (15) measurements were used to determine the mean absorbance values for each test material.

5.6 Calculation of the critical wavelength:

The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.

6.0 Results:

Please see attached Table.

7.0 Archiving and Confidentiality:

Hard copies of records such as raw data sheets, correspondence between the sponsor and Cantor Research Laboratories, Inc., 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, instrumental reports, 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.

8.0 Conclusion:

The test material [CR Lab No.: S1016-B; Client No.: Sonre[redacted] Formula # 326-099/20384-01-02] when tested on three PMMA plates as described herein using Labsphere's UV-2000S for analysis yielded the mean critical wavelength value of 370.27, which may be classified as **Broad Spectrum Protection**, according to the reference.

[redacted]

Principle Investigator

[redacted]

Technician

[redacted]

Laboratory Manager

[redacted]

Quality Assurance Supervisor

11/11/2020

Date

EVALUATION OF IN-VITRO BROAD SPECTRUM TEST
FDA METHOD (2011 FINAL RULE)

Table

Sponsor: [redacted]
CR Lab No.: S1016-B
Client No.: [redacted] Formula # 326-099/20384-01-02

Plate 1 (avg. 5 sites)	Plate 2 (avg. 5 sites)	Plate 3 (avg. 5 sites)	Mean (avg. 3 plates)	*Pass/ **Fail
370.00	370.60	370.20	370.27	*PASS

* Pass (≥370nm)
** Fail (<370nm)

FDA Method (2011 Final Rule)
Results Report

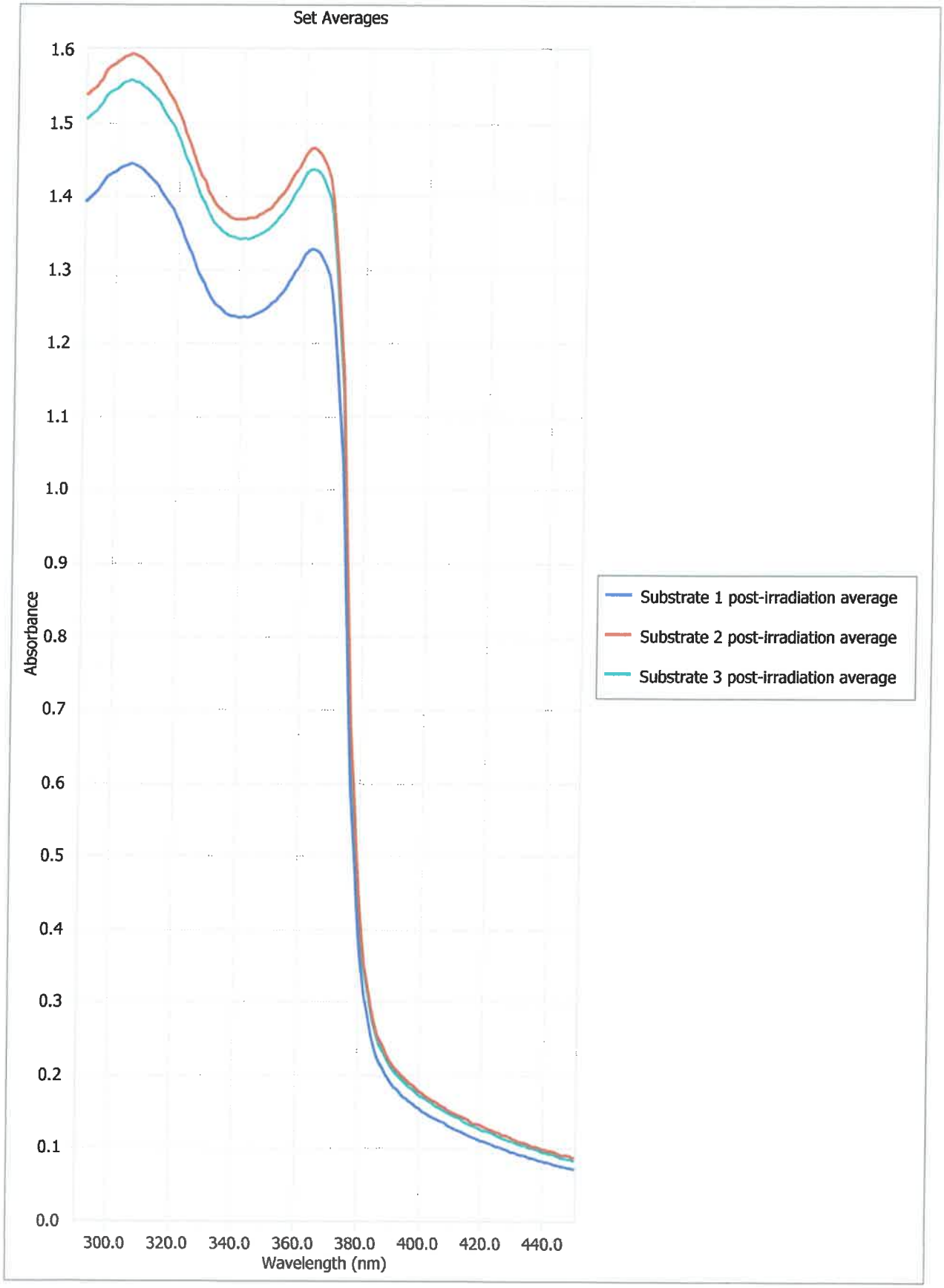
Sample:	S1016-B
Description:	[redacted] Formula #: 326-099/20384-01-02
Operator:	Cantor Research Laboratories, Inc.
Client:	[redacted]
Comment:	
Date:	11/9/2020 11:13:35 AM
Unit serial number:	0902118642

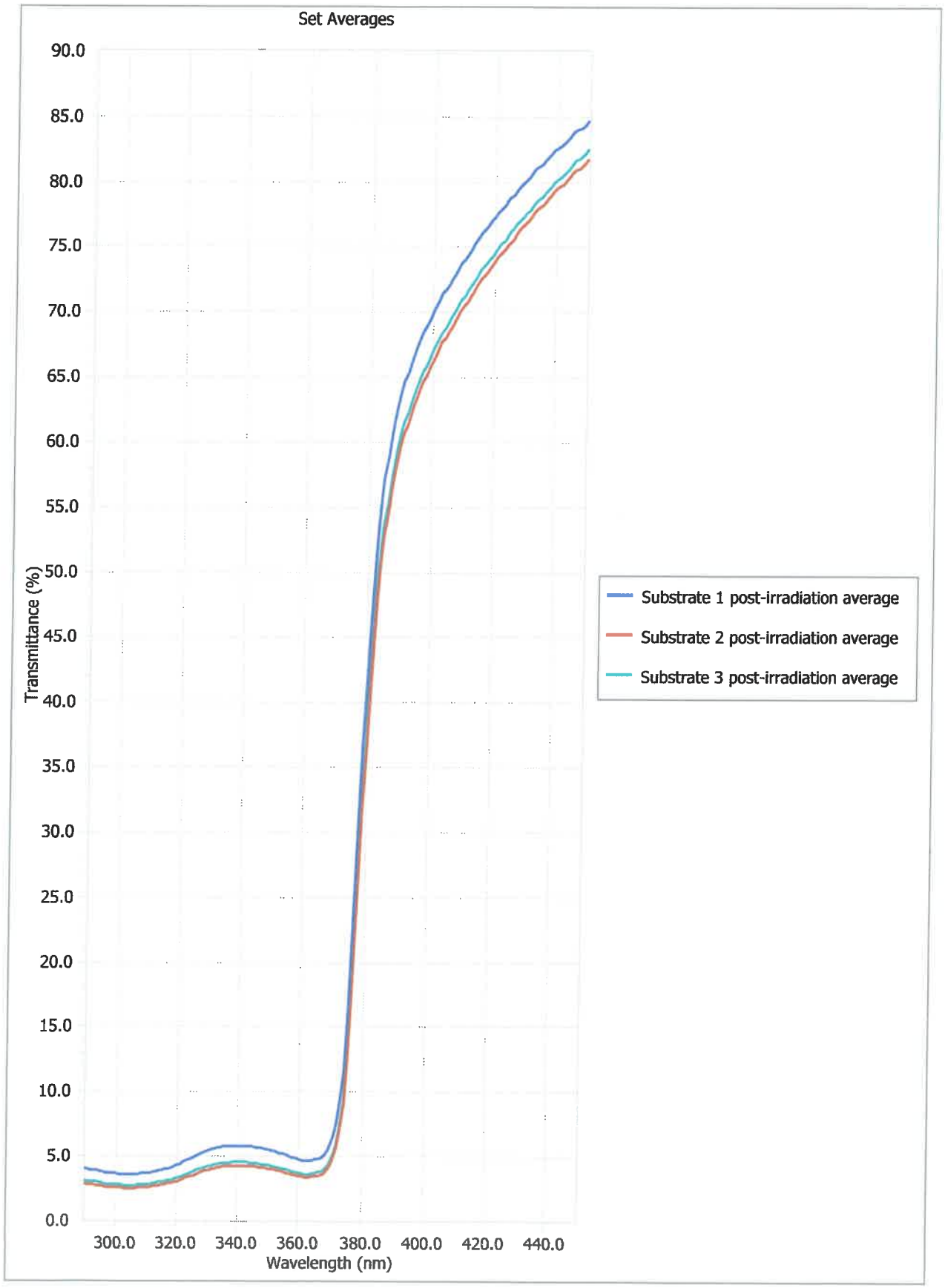
Product Results

Critical Wavelength Mean	370.27
Broad Spectrum Protection	Pass

Substrate Data

	Critical Wavelength	Broad Spectrum Protection
Substrate 1 post-irradiation	370.00	Pass
Substrate 2 post-irradiation	370.60	Pass
Substrate 3 post-irradiation	370.20	Pass


Set Averages
Absorbance
1.6
1.5
1.4
1.3
1.2
1.1
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
300.0
320.0
340.0
360.0
380.0
400.0
420.0
440.0
Wavelength (nm)
Substrate 1 post-irradiation average
Substrate 2 post-irradiation average
Substrate 3 post-irradiation average


Set Averages
90.0
85.0
80.0
75.0
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Transmittance (%)
300.0
320.0
340.0
360.0
380.0
400.0
420.0
440.0
Wavelength (nm)
Substrate 1 post-irradiation average
Substrate 2 post-irradiation average
Substrate 3 post-irradiation average