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FDA IN-VITRO BROAD SPECTRUM TEST

AMA Ref. No.: MS14.FDA.BRDSPCTRM.INVITRO.N8396.BELL

Date: January 13, 2015

Sponsor: Supergoop!

Sample Description:

On December 9, 2014 one test sample labeled SPF 50 Refresh Setting Mist; **Sample ID:** CONFIDENTIAL and assigned AMA Lab No.: N-8396.

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.: N-8396; Client No.: SPF 50 Refresh Setting Mist; **Sample ID:** CONFIDENTIAL) 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 06/16/2011 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.

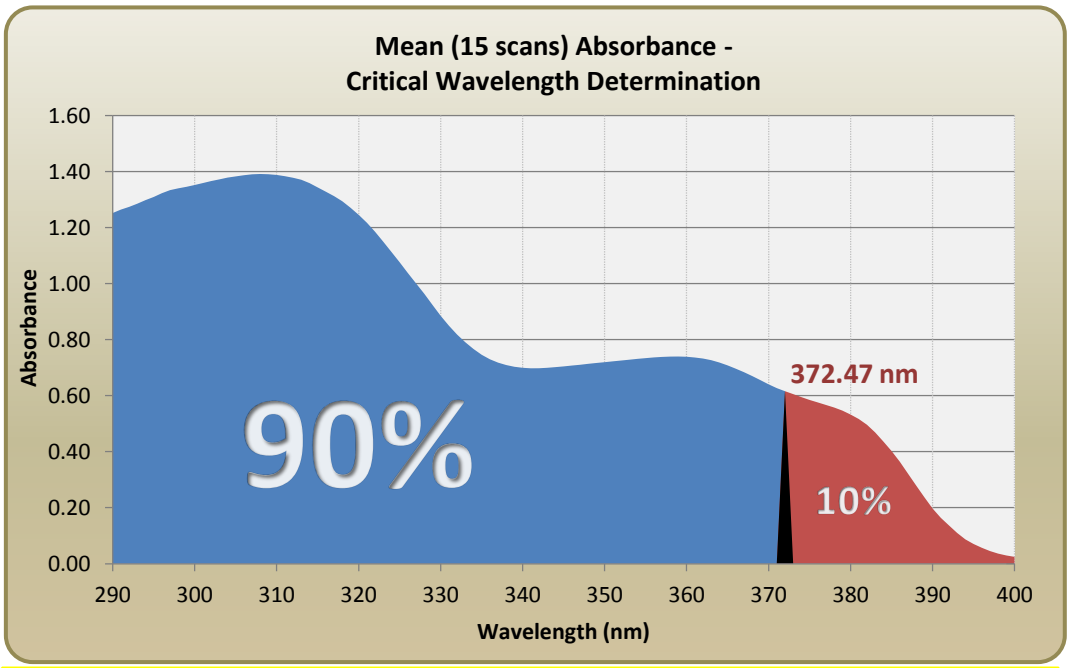
Plate (Substrate):

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	

Results:

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

Critical Wavelength Values After Pre-Irradiation Procedure					
UV Source (LS1000-6S-UV Solar Simulator) Irradiance Output:				4.0 MED/h	
Irradiation Time (Single Plate):				3600 sec	
	Location 1	Location 2	Location 3	Location 4	Location 5
Plate 1	372	372	372	372	372
Plate 2	373	373	373	372	372
Plate 3	372	373	373	373	373
Average:	**372.47 nm**				



The Critical Wavelength of the above test material (AMA Lab No.: N-8396; Client No.: SPF 50 Refresh Setting Mist; **Sample ID:** CONFIDENTIAL) is 372.47 nm, and satisfies the criteria for "Broad Spectrum" labeling (minimum of 370 nm required).

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Technician

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Technician

Donna Muratschew, M.D.
Study Director

David R. Winne, B.S.
Technical Director

1/13/15
Date

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EVALUATION OF SUN PROTECTION BY SPF DETERMINATION (FDA) – STATIC

AMA Ref. No.: MS14.SPF.N8396.BELL.FDAST10

Date: January 23, 2015

Sponsor: Supergoop!

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the static 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 a Xenon arc solar simulator as the UV source.

2.0 Sample Description:

On December 9, 2014 one test sample labeled SPF 50 Refresh Setting Mist, **Sample ID:** CONFIDENTIAL [redacted] and assigned AMA Lab No.: N-8396.

3.0 Test Material Handling:

Upon arrival at AMA 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 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.

EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) - STATIC

Table

Sponsor: Supergoop!
AMA Lab No.: N-8396
Client No.: SPF 50 Refresh Setting Mist, **Sample ID:** CONFIDENTIAL

Subject ID #	Sex	MED/ Hr	I (Amps)	Skin Type	MED I J/M^2	MED II J/M^2	STD (7%PadO/ 3%Oxyb)	SPF Value
68 2184	F	128.6	5.4	II	46.20	46.20	18.75	57.50
58 2460	F	128.9	6.1	III	46.20	46.20	16.30	57.50
52 9607	F	128.2	6.0	III	46.20	46.20	18.75	57.50
78 4237	M	129.4	6.3	II	46.20	46.20	16.30	50.00
62 5219	F	129.1	6.7	II	46.20	46.20	18.75	57.50
86 5052	M	125.8	6.0	II	30.33	30.33	16.30	57.50
76 6191	M	127.5	6.2	II	46.20	46.20	16.30	57.50
50 1810	M	128.1	6.0	II	30.33	30.33	18.75	50.00
68 3264	F	126.6	5.8	II	30.33	30.33	16.30	50.00
40 5720	F	126.6	6.3	II	46.20	46.20	18.75	57.50
MEAN (x)							**17.53**	**55.25**
STANDARD DEV (s)							**1.29**	**3.62**
STD. ERROR							**0.41**	**1.14**
S.E. % OF MEAN							**2.34**	**2.06**
N							**10**	**10**
UPPER 5% t DIST.							**2.2622**	**1.8331**
A VALUES							**0.9228**	**2.0984**
LABEL SPF							**16**	**53**

MED: Minimal Erythemal Dose
I: Intensity of light source

Evaluation Period: This study was conducted from December 9, 2014 through January 15, 2015.

14.0 Conclusions:

The Sun Protection Factor (SPF) of the above test material (AMA Lab No.: N-8396; Client No.: SPF 50 Refresh Setting Mist, **Sample ID:** CONFIDENTIAL CONFIDENTIAL when tested on ten subjects as described herein under static conditions yielded the mean SPF value of 55.25 and the label SPF of 53. The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.53 and was within the standard deviation range of the expected SPF of 16.3 +/- 3.43.

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1/23/15
Date