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Quality Assurance Audit Statement

Clinical Study Number: 2019-0006
Start Date: January 17, 2019
Completion Date: February 16, 2019
Sponsor: [redacted]
Study Type: SPF Water Resistant FDA 80 Minutes
Product Code: Sungel SPF 50+ 306-048
[redacted]

The clinical study listed above was conducted in accordance with the clinical study protocol, CRLS, LLC Standard Operating Procedures (SOPs), which incorporate the principles of applicable Good Clinical Practice (GCP) defined by applicable guidelines and regulations established by the International Council for Harmonization (ICH) and U.S. Regulatory Agencies. The clinical study master file was reviewed for compliance with the clinical study protocol, CRLS SOPs, and applicable guidelines and regulations by the Lab Manager and the Quality Assurance.

[redacted]

Signature **Date**

ECRLNC2019-0006: Evaluation of the 80-Minute Water Resistant Sun Protection Factor (SPF) of Sunscreen-Containing Formulas According to the FDA Final Rule [1]

March 05, 2019

Final Report

Objective: To measure the sun protection factor (SPF) of over-the-counter (OTC) sunscreen-containing formulas after 80 minutes of water immersion according to the FDA Final Rule [1]

Test Product: Sungel SPF 50+ 306-048

Study Dates: January 17, 2019 to February 16, 2019

Results: Thirteen subjects completed the test. The mean 80-Minute Water Resistant SPF of the test product, Sungel SPF 50+ 306-048, was 58.44 (n=10, SD=3.28). The test product meets FDA Final Rule requirements for labeling as 80-Minute Water Resistant SPF 50+. [1]

Sponsor: [redacted]

Investigator: Kacie Murdoch

Eurofins CRL Cosmetics, Inc.
533 N. Spring Street, Winston Salem, NC 27101
Phone: (336) 725-6501, Fax: (336) 725-6503

Summary:
On the first day of the study each subject received a series of UV doses from a xenon arc solar simulator to an unprotected site on the mid-back. The solar simulator was a single-port xenon arc lamp with a 1 mm WG320 UVC blocking filter, a 1 mm UG-11 visible and infrared blocking filter and a heat rejecting dichroic mirror (Model 16S, Solar Light Co., Philadelphia).

On the second day the minimal erythema dose (MED) was determined as the lowest UV dose which produced perceptible erythema with clearly defined borders. Then 100 mg of the test product was applied to a 50 cm^2 area of the mid-back. After a 15 minute drying period, the subject sat, submerged to the upper back, in gently moving, pool temperature water (25 to 32° C) for four, twenty-minute intervals for a total of 80 minutes of water immersion. After the subjects completed 80 minutes of water immersion, 100 mg of the 7% Padimate-O/3% Oxybenzone standard sunscreen was applied to an adjacent 50 cm^2 area of the mid-back (Standard provided by Cosmetech Laboratories, Inc., Fairfield, NJ). Each sunscreen-protected site was divided into five sub-site test areas that were at least 0.5 cm^2 in area for UV exposures.

The test product had an expected SPF of 60. The 7% Padimate-O/3% Oxybenzone standard sunscreen had an expected SPF of 16.3. After a 15-minute drying period, five UV doses increasing in geometric increments of 1.15 (0.76, 0.87, 1.00, 1.15 and 1.32) times the product of the MED and 60 were administered to the test sunscreen-protected area and five UV doses increasing in geometric increments of 1.15 (0.76, 0.87, 1.00, 1.15 and 1.32) times the product of the MED and 16.3 were administered to the standard sunscreen protected area. A series of five UV doses increasing in geometric increments of 1.25 (0.64, 0.80, 1.00, 1.25 and 1.56) times the Initial MEDu were also administered to a second unprotected site. On the third day the MED was determined for the sunscreen-protected sites (MEDp) and the unprotected sites (MEDu). The SPF of each sunscreen was calculated as the ratio of the MEDp for each sunscreen-protected site to the Final MEDu.

Details of calibrations for the Solar Simulators used in this testing are shown in the APPENDIX.

According to the FDA Final Rule [1], the labeled SPF must be calculated as follows:

SPF values for individual subjects (SPFi) will be calculated as:

$SPFi = MEDp/MEDu$

The mean SPF and standard deviation (SD) will be calculated from valid SPFi values.

The Standard Error (SE) will be calculated as:

$SE = SD/\sqrt{n}$

Where n equals the number of subjects who provided valid test results.

The t value from Student's t distribution table corresponding to the upper 5% point with n-1 degrees of freedom will be obtained.

The labeled SPF value will be determined as the largest whole number less than the following calculation after at least 10 subjects:

$Labeled\ SPF = Mean\ SPF - (t * SE)$

In order for the SPF determination of the test product to be valid, the SPF value of the 7% Padimate-O and 3% Oxybenzone Standard should fall within the standard deviation range of the expected SPF (i.e. 16.3 ± 3.43 or 12.87 to 19.73)

Results:
Thirteen subjects, five men and eight women, who provided written, informed consent, completed the study. Subjects included four with skin type I and nine with skin type II.[1] Ages ranged from 19 to 49 years and the mean age was 33.46 (n=13, SD=8.36). Subject demographic and 80-minute WR SPF results are listed in Table 1.

The mean 80-Minute WR SPF of the test product, Sungel SPF 50+ 306-048, was 58.44 (n=10, SD=3.28). The labeled SPF value, which is the mean SPF – (t * SE), rounded down to the nearest whole number, was 56.

The mean static SPF of the 7% Padimate-O/3% Oxybenzone standard was 16.29 (n=13, SD=0.02). The SPF value of the 7% Padimate-O/3% Oxybenzone standard was within the required range [1].

Protocol Deviations:
No protocol deviations were reported.

Enrollment:
Subjects 01-02 and 01-08 were unable to complete. Subject 01-14 was lost to follow up. All other subjects enrolled in the study completed all study procedures.

Data Exclusions:
Subjects 1-06, 1-10 and 01-12 did not yield evaluable SPF data for the test product. No other data were excluded from this report.

Adverse Events:
No adverse events were reported.

Table 1. Subject Demographic, 80-Minute Water Resistant SPF Results for 306-048 and Static SPF Results for 7% Padimate/3% Oxybenzone Standard

[redacted]

2011 FDA Final Rule 80-min WR

									306-048 Labeled SPF 60			7% Padimate-O/3% Oxybenzone Standard Labeled SPF 16.3	
Tech Initals	Panelist #	ECRLNC#	Age	Sex	FST	ITA	MED_{uI} (eff J/m^2)	MED_{uR} (eff J/m^2)	$tpMED_p$ (eff J/m^2)	**80-min WR Achieved SPF**	Expected SPF	$ssMED_p$ (eff J/m^2)	**Achieved SPF**
KRT/BRQ	01-01	3603	34	M	I	63.1	79.57	79.57	4774.00	**60.00**	60.00	1294.77	**16.27**
LGD/KRT	01-03	3774	38	M	II	48.4	101.27	101.27	6076.00	**60.00**	60.00	1649.20	**16.29**
LGD/KRT	01-04	4327	32	F	I	61.3	65.63	65.63	3937.50	**60.00**	60.00	1071.88	**16.33**
KRT/LGD	01-05	4785	19	M	II	53.6	101.27	101.27	6076.00	**60.00**	60.00	1649.20	**16.29**
RT/LGD/JL/CI	01-06	4753	49	F	II	42.6	122.97	122.97	<4238.73	**<34.47**	60.00	2003.63	**16.29**
LGD/JL/KRT	01-07	4185	38	F	II	43.2	122.97	122.97	7378.00	**60.00**	60.00	2003.63	**16.29**
LGD/JL/KRT	01-09	3930	32	M	I	60.6	79.57	79.57	4774.00	**60.00**	60.00	1294.77	**16.27**
KRT/LKQ	01-10	4160	47	M	II	46.5	122.97	122.97	<3689.00	**<30.00**	60.00	2003.63	**16.29**
KRT/LGD	01-11	4800	23	F	II	54.0	102.08	102.08	5330.21	**52.21**	60.00	1662.50	**16.29**
LGD/KRT/JL	01-12	4809	28	F	I	61.8	65.10	65.10	3399.67	**52.22**	60.00	1063.30	**16.33**
LGD/KRT/JL	01-13	1760	29	F	II	47.6	122.97	122.97	<3689.00	**<30.00**	60.00	2003.63	**16.29**
JL/LGD/KRT	01-15	4009	33	F	II	54.3	101.27	101.27	6076.00	**60.00**	60.00	1649.20	**16.29**
JL/KRT	01-16	4571	33	F	II	47.3	102.08	102.08	6125.00	**60.00**	60.00	1662.50	**16.29**

Mean=	33.46	Mean=	52.6
SD=	8.36	SD=	7.3
n=	13	n=	13

Mean=	**58.44**
SD=	3.28
n=	10
SE=	1.04
t=	1.83
Labeled SPF =	**56.54**

Mean=	**16.29**
SD=	0.02
n=	13
SE=	0.01
t=	1.78
Labeled SPF =	**16.28**
Mean: Valid (Y/N)	Yes
Labeled: Valid (Y/N)	Yes

Data Rejected / Disqualified

Panelist #	ECRLNC#	Date	Reason
01-02	3776	22-Jan-19	Unable to complete
01-08	4686	7-Feb-19	Unable to complete
01-14	4679	14-Feb-19	Lost to follow up

Conclusion:

The test product, Sungel SPF 50+ 306-048, meets the FDA Final Rule requirements for labeling as 80-Minute Water Resistant SPF 50+. [1]

[redacted] [redacted]

Kacie Murdoch – Investigator Date

References:

1. U. S. Food and Drug Administration. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Final Rule; 21 CFR Parts 201 and 310. Federal Register, Vol. 76, No. 117, June 17, 2011. pp. 35660-35665.
2. Guideline for the colorimetric determination of skin color typing and prediction of the minimal erythema dose (MED) without UV exposure. Colipa, 2007.