Quality Assurance Audit Statement

Clinical Study Number: 2019-0267
Start Date: October 15, 2019
Completion Date: December 04, 2019
Sponsor: [redacted]
Study Type: SPF ASNZ Water Resistant (4 hours)
Product Code: Sea Clearly Translucent Gel Sunscreen BS SPF 50

The clinical study listed above was conducted in accordance with the clinical study protocol, Eurofins CRL, Inc. 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, Eurofins CRL SOPs, and applicable guidelines and regulations by the Lab Manager and the Quality Assurance. Eurofins CRL, Inc. waives any responsibility as to how data is used by sponsors after it's reported by our lab.

[redacted]

Signature

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Protocol #ECRLNC-2019-3000, Project #ECRLNC2019-0267:
Evaluation of the Four Hour Water Resistant Sun Protection Factor (SPF) of Sunscreen Formulas According to AS/NZS 2604:2012

December 26, 2019

Final Report

Objective: To measure the Four Hour Water Resistant Sun Protection Factor (SPF) of Sunscreen Formulas According to AS/NZS 2604:2012 [1]

Test Product: Sea Clearly Translucent Gel Sunscreen BS SPF 50

Study Dates: October 15, 2019 to December 04, 2019

Results: Fourteen subjects completed the test. The mean 4-Hour Water Resistant SPF of the test product, Sea Clearly Translucent Gel Sunscreen BS SPF 50, was 60.72 (n=10, SD=2.28). [1]

Sponsor: [redacted]

Investigator: [redacted]

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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 up to 100 mg of the test product was applied to approximately 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 twelve, twenty-minute intervals for a total of 240 minutes of water immersion. After the subjects completed the water immersion, up to 100 mg of the P2 Standard sunscreen was applied to approximately a 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 P2 standard sunscreen had an expected SPF of 16.1. After a 15-minute drying period, five UV doses increasing in geometric increments of 1.12 (0.80, 0.89, 1.00, 1.12 and 1.25) times the product of the MED and 60 were administered to the test sunscreen-protected area. Then five UV doses increasing in geometric increments of 1.25 (0.64, 0.80, 1.00, 1.25 and 1.56) times the product of the MED and 16.1 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.

SPF Computation

The appropriate test product and the Standard Sunscreen SPF values were computed for each subject, as follows:

1. The MED was determined as the first exposure site in the series that produced an erythema grade of at least 2 (Mild erythema with clearly defined borders). The progression of erythema grades was consistent with the UV doses administered.

2. Test product and Standard Sunscreen SPF values were calculated as the ratio of the MED for sunscreen-protected sites to the MED for unprotected site.

3. The static SPF (SPF_s) was calculated as the mean of the total individual static SPF values (SPF_{is}), determined on all subjects completing the procedure. A corresponding 95% bilateral confidence interval (95%CI) was calculated. Both the SPF_s and the 95%CI were calculated according to the guidelines described in the ISO International Sun Protection Factor (SPF) Test Method. [1] The test is considered acceptable if the 95% confidence interval on the mean static SPF (SPF_s) is within $\pm$ 17% of the mean static SPF (SPF_s). The mean value of the P2 Standard was between 13.7 and 18.5.

Results:
Fourteen subjects seven male and seven female, who provided written, informed consent, completed the study. Subjects included seven with skin type I, five with skin type II and two with skin type III.[1] Ages ranged from 24 to 54 years and the mean age was 35.00 (n=14, SD=9.88). Subject demographic and 4-Hour WR SPF results are listed in Table 1.

The mean 4-Hour WR SPF of the test product, Sea Clearly Translucent Gel Sunscreen BS SPF 50, was 60.72 (n=10, SD=2.28). The 95% Confidence Interval was 2.69% of the mean SPF.

The mean SPF of the P2 standard was 16.08 (n=12, SD=0.02). The 95% Confidence Interval was 0.07% of the mean SPF. The SPF value of the standard was within the required range [1].

Protocol Deviations:
No protocol deviations were reported.

Enrollment:
Subjects 10 and 11 were lost to follow up. Subject 13 was dismissed due to and adverse event.

Data Exclusions:
Subject 02 did not yield evaluable SPF data for the test product. Subject 03 and 14 data was rejected due to an illogical progression of responses during the visual evaluation. All other obtained data are included in this report.

Adverse Events:
Panelist was coughing and wheezing, used two puffs of a Ventolin inhaler on site and was discontinued from the study. This is considered resolved as the panelist is under a physician's care.

Table 1. Four-Hour WR SPF Results forSea Clearly Translucent Gel Sunscreen BS SPF 50 and P2 Standard

ECRLNC2019-0267[redacted]
AS/NZS 2604:2012
4-Hour WR SPF

									Sea Clearly Translucent Gel Sunscreen BS SPF 50			**P2 Standard Labeled SPF 16.1**	
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)	**4-Hr WR Achieved SPF**	Expected SPF	$ssMED_p$ (eff J/m^2)	**Achieved SPF**
BRQ/JAL/KRT	01	4160	47	M	II	48.3	123.96	123.96	7437.50	**60.00**	60.00	1997.92	**16.12**
ANA/BRQ	02	3423	51	F	I	55.3	102.08	102.08	<3879.17	**<38.00**	60.00	1640.63	**16.07**
ANA/KRT/BR	03	4110	24	M	II	53.5	*	*	*	*	*	*	*
ANA/KRT	04	4539	37	M	II	51.2	102.08	102.08	6125.00	**60.00**	60.00	1640.63	**16.07**
ANA	05	5456	28	M	III	39.5	153.13	153.13	9187.50	**60.00**	60.00	2464.58	**16.10**
BRQ/AOS	06	5541	23	M	I	63.7	80.21	80.21	<3850.00	**<48.00**	60.00	1290.63	**16.09**
BRQ/ANA	07	5055	28	F	I	56.4	102.08	102.08	6125.00	**60.00**	60.00	1640.63	**16.07**
BRQ/ANA	08	3803	37	F	I	64.6	80.21	80.21	4812.50	**60.00**	60.00	1290.63	**16.09**
BRQ/ANA	09	4420	26	F	I	67.1	65.63	65.63	3937.50	**60.00**	60.00	1057.29	**16.11**
BRQ	12	4766	31	M	I	55.6	102.08	102.08	6861.46	**67.21**	60.00	1640.63	**16.07**
ANA/NLK	14	4974	39	F	III	37.3	**	**	**	**	**	**	**
ANA/BRQ	15	5412	30	F	I	57.1	102.08	102.08	6125.00	**60.00**	60.00	1640.63	**16.07**
ANA/AOS	16	4792	54	M	II	46.4	102.08	102.08	6125.00	**60.00**	60.00	1640.63	**16.07**
KRT/ANA	17	5569	35	F	II	50.4	102.08	102.08	6125.00	**60.00**	60.00	1640.63	**16.07**
		Mean=	35.00		Mean=	53.3							
		SD=	9.88		SD=	8.7							
		n=	14		n=	14							

Mean=	**60.72**
SD=	2.28
n=	10
t=	2.26
SEM=	0.72
c=	1.63
95% CI: Lower=	59.09
95% CI: Upper=	62.35
CI[%]	2.69%
CI[%} <17% = Pass	Pass

Mean=	**16.08**
SD=	0.02
n=	12
t=	2.20
SEM=	0.00
c=	0.01
95% CI: Lower=	16.07
95% CI: Upper=	16.09
CI[%]	0.07%
CI[%} <17% = Pass	Pass

Notes

Panelist #	ECRLNC #	Date	Reason
*03	4110	23-Oct-19	Data reject - illogical progression
10	2459	16-Nov-19	Lost to follow up
11	3186	20-Nov-19	Lost to follow up
13	4263	22-Nov-19	Disqualified due to AE
**14	4974	23-Nov-19	Data reject - illogical progression

Conclusion:

The mean 4-Hour Water Resistant SPF of the test product, Sea Clearly Translucent Gel Sunscreen BS SPF 50, was 60.72 (n=10, SD=2.28). [1]

[redacted]
[redacted] Investigator

References:

1. Australia/New Zealand Standard – Sunscreen Products – Evaluation and Classification, AS/NZS 2604:2012, APPENDIX B, 2012-05-30.
2. International Organization for Standardization (ISO), International Standard, ISO 24444:2010(E), Cosmetics – Sun Protection test methods – In Vivo Determination of SPF (Sun Protection Factor)