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

FINAL REPORT

April 4, 2016

SPONSOR: Poofy Organics
6 Franklin Place
Rutherford, NJ 07070

TEST PRODUCT: Sunscreen

PROJECT –ACCESSION NUMBER: 938340 - 938340

RESEARCH STANDARD

This clinical study was conducted in accordance with standard practices of BioScreen Testing Services and the International Conference of Harmonization Tripartite Guideline on Good Clinical Practice, applicable 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.

TABLE OF CONTENTS

	Page
I. STUDY CONCLUSIONS.....	4
II. RESULTS	4
III. STUDY OBJECTIVE.....	5
IV. TEST PRODUCT	5
V. TEST PRODUCT HANDLING	5
VI. STUDY PARTICIPATION RECRUITMENT.....	5
VII. INFORMED CONSENT AND MEDICAL HISTORY FORMS	5
VIII. SUBJECT DEMOGRAPHICS	6
IX. INCLUSION CRITERIA	6
X. EXCLUSION CRITERIA.....	6
XI. ARTIFICIAL LIGHT SOURCE	7
XII. PROCEDURE	8
XIII. REJECTION CRITERIA	10
XIV. SPF CALCULATIONS.....	11
XV. ADVERSE EVENTS.....	11

I. STUDY CONCLUSIONS

The Sun Protective Factor (SPF) of Sunscreen when tested on ten (10) subjects as described herein under static conditions yielded the mean SPF value of 30.00 and the label SPF of 30.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 16.54 and was within the standard deviation range of the expected SPF of 16.3 ± 3.43 .

II. RESULTS

Under conditions of the study a total of 10 healthy subjects, 21-61 years of age, completed the clinical study evaluating the Sun Protective Factor (SPF) of Sunscreen.

No.	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
1	2373	M	143	7	II	134.40	134.40	16.30	30.00
2	2489	F	155.3	7	I	107.10	107.10	16.30	30.00
3	7206	M	154.2	7	II	134.40	134.40	16.30	30.00
4	12937	F	139.1	7	I	134.40	134.40	16.30	30.00
5	15342	F	154.3	7	I	134.40	134.40	16.30	30.00
6	16272	M	153.6	7	II	134.40	134.40	16.30	30.00
7	17829	F	152.6	7	II	134.40	134.40	18.75	30.00
8	20555	M	154.3	7	II	134.40	134.40	16.30	30.00
9	20944	M	159.4	7	II	134.40	134.40	16.30	30.00
10	21387	F	157.3	7	II	134.40	134.40	16.30	30.00
MEAN								16.54	30.00
STANDARD DEVIATION								0.77	0.00
STANDARD ERROR								0.24	0.00
STANDARD ERROR % OF MEAN								1.48	0.00
NUMBER OF SUBJECTS (N)								10	10
UPPER 5% T DISTRIBUTION								1.883	1.883
A VALUES								0.448	0.000
LABEL SPF								16	30

F = Female, M = Male, MED = Minimal Erythema Dose, I = Intensity of Light Source, STD = Standard, SPF = Sun Protection Factor

III. STUDY OBJECTIVE

The objective of the study was to evaluate the effectiveness of the test material as a sunscreen product by determining the static Sun Protection Factor (SPF) on human skin employing the procedure 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 Dpc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011] using a Xenon arc solar stimulator as the UV source.

IV. TEST PRODUCT

Accession No. 938340 was assigned to Sunscreen which was received from Poofy Organics on February 23, 2016.

The study began on March 21, 2016 and was completed on March 30, 2016.

7% Padimate O/3% Oxybenzone Standard was used as the control.

V. TEST PRODUCT HANDLING

Test product that had been reviewed and approved for use by the Regulatory and Safety representatives of Poofy Organics was tested.

Upon arrival at BioScreen the test product 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.

VI. STUDY PARTICIPATION RECRUITMENT

Panel selection was accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

VII. INFORMED CONSENT AND MEDICAL HISTORY FORMS

Informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document form to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form.

Reference *21 CFR Ch. 1 Part 50, Subpart B.*

VIII. SUBJECT DEMOGRAPHICS

Number of subjects enrolled.....	10
Number of subjects completing study.....	10
Age Range.....	21-61
Sex.....	Male..... 5
	Female..... 5
Race.....	Caucasian..... 9
	Hispanic..... 1
	Asian..... 0

IX. INCLUSION CRITERIA

1. Sex: Male and Female
2. Individuals 18-65 years of age
3. Race: Unrestricted
4. Fitzpatrick Skin Type I, II and III
5. Individuals who were free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.
6. Individuals who were free of any acute or chronic disease that might interfere with or increased the risk of study participation.
7. Individuals with no uneven skin tones, pigmentation, scars, other irregularities, or hair in test site areas that would interfere with SPF determination.
8. Individuals with excessive hair on their back who were willing to have their hair clipped.
9. Individuals who completed a preliminary medical history form mandated by BioScreen Clinical Services and who were in general good health.
10. Individuals who read, understood, and signed an informed consent document relating to the specific type of study they were subscribing. Consent forms are kept on file and are available for examination on the premises of BioScreen Clinical Services only.
11. Individuals who were able to cooperate with the Investigator and research staff, were willing to have test materials applied according to the protocol, and completed the full course of the study.
12. Individuals who were willing to refrain from using any sunscreen products, spray tan products, sunbathing/tanning, or tanning bed use, 24 hours prior to study initiation and the entire duration of the study.
13. Individuals who had not participated in an SPF study in the past 2 weeks.
14. Individuals who were capable of sitting still for an extended amount of time (45 minutes).

X. EXCLUSION CRITERIA

1. Individuals who were under doctor's care.
2. Individuals who were currently taking any medication (topical or systemic) that may have masked or interfered with the test results.
3. Individuals who were currently taking any medication that increased sensitivity to sun exposure.

4. Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes, or any disease that would increase the risk associated with study participation.
5. Individuals diagnosed with chronic skin allergies, skin conditions, etc. (Rosacea, atopic dermatitis/eczema).
6. Individuals with a history of adverse effects upon sun exposure.
7. Female volunteers who indicated that they were pregnant, planning a pregnancy or nursing.
8. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions, or uneven pigmentation in the test sites.
9. Individuals with known hypersensitivity or allergies to any sunscreen products.

XI. ARTIFICIAL LIGHT SOURCE

The light source, a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, PA, Model 14S or 16S) with a continuous emission spectrum in the UVB range of 290 to 400 nm will be used. Xenon arc is selected on the basis of its black body radiation temperature of 6000° K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight.¹

This device is equipped with a dichroic mirror (reflects all radiation below 400nm) and which works in conjunction with a 1mm thick Schott WG-320 filter (absorbs all radiation below 290 nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter is attached to remove reflected (infra-red, greater than 700nm) heat and remaining visible radiation. UVB radiation will be monitored continuously during exposure using a Model DCS-a Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter).

Measurements were taken at a position within 8mm from the surface of the skin. The size of the exposure site was $\geq 0.5 \text{ cm}^2$. Each exposure site was separated from the next exposure site by at least 0.8 cm. The solar stimulator was allowed a warm up time of at least 15 minutes before use and the power supply output was recorded.

Realignment of the light sources and calibration of the sunburn meters are conducted annually by independent certification facilities and more often as necessary at the discretion of the operating technician or investigator. A certificate for Solar Simulator Emission Spectrum compliance is on file. The spectroradiometric measurements are performed at least annually.

¹*Berger, D.S.: Specification and Design of Solar Ultraviolet Simulators. J. Invest. Dermatol. 53: 192-199, 1969.*

XII. PROCEDURE

1. Prospective subjects reported to the facility on the start of the study.
2. Prior to beginning all study related activities, prospective subjects completed an informed consent form, medical history form and a HIPAA form.
3. Subjects were screened based on the *Federal Register Vol. 76, No. 117:35660,2011**:

Type I – Always burns easily; never tans (sensitive)

Type II – Always burns easily; tans minimally (sensitive)

Type III – Burns moderately; tans gradually (light brown) (normal)

* Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4. Subjects with Fitzpatrick Skin Types greater than III were not enrolled in the study
5. The infrascapular area of the back to the right and left of the midline was used.
6. A trained staff member observed the test sites to ensure uniform pigmentation, skin tone, and texture, and absence of warts, moles, nevi, scars, blemishes, active dermal lesions, and excessive hair using a Wood's Lamp.
7. If necessary, excessive hair was clipped by a staff member.
8. Any areas that could be expected to produce erratic results were not used for UV exposures.
9. A 50 cm² rectangular test site was wiped and cleaned prior to delineation with a skin pen. This test site was used to determine the Minimal Erythema Dose (MED_u¹) of untreated and unprotected skin.
10. A minimum of five UV exposures were administered within this site to determine the subject's inherent MED_u. UV exposures were calculated using a geometric progression of 1.25ⁿ.
11. Each exposure site was at least 0.5 cm² and was separated from the next exposure site by at least 0.8 cm.
12. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.
13. Subjects were instructed to avoid UV exposure, tanning, sunscreen products, spray tans, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.
14. Subjects returned the facility approximately 16 to 24 hours after UV exposure.
15. A trained staff member visually graded the exposure sites based on the following scale:

- 0 = No Erythema
- ? = Questionable Erythema
- 1 = Perceivable Erythema
- 2 = Moderate Erythema
- 3 = Well-Defined Erythema with Edema
- 4 = Painfully Sensitive & Well Defined Erythema and/or Severe Edema

16. All visual grading was conducted under same lighting conditions and in the same position in which the UV dose was given to the panelist.
17. The lowest UV dose producing perceptible erythema with clearly defined borders determined the individual's MED_u¹ (grade 1). Any instance of painful erythema or severe erythema with a grade of 4 was considered an adverse experience.
18. This MED_u was used to determine the series of UV radiation exposures to be administered to the protected site in subsequent testing of standard and test sunscreens.
19. A series of 50 cm² rectangular test sites were wiped and cleaned prior to delineation with a skin pen.
20. One rectangular test site served as the untreated and unprotected site.
21. A second rectangular test site served as the test product site and the third rectangular site served as the SPF Standard Sunscreen (7% Padimate O/3% Oxybenzone).
22. All products (oils, creams, and most lotions) were shaken or swirled before use. Products such as powders, pastes, and ointments that could not be drawn into a syringe, were weighed, and then applied by spreading on the test site.
23. The test product and 7% Padimate O/3% Oxybenzone standard sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites measuring 50 cm² in the amount of 2 mg/cm².
24. Evenness of application was verified by observation with a Wood's Lamp and the product(s) were allowed to dry at least 15 minutes prior to UV exposure.
25. **Control:** The untreated and unprotected site received a series consisting of a minimum of five UV exposures based upon previously determined MED_u¹ such that the series of 5 doses included the previously determined MED_u¹ in the center using a geometric progression of 1.25ⁿ.
26. **Standard:** The UV exposures for SPF Standard, PADIMATE O.OXYBENZONE SPF STANDARD were calculated from the previously determined MED_u¹ where a minimum of 5 doses were administered using a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X. X denotes the expected SPF.
27. **Test Products:** The UV exposures for the test product was calculated from the previously determined MED_u¹ where a minimum of 5 doses were administered using:

- a. A geometric progression of 25%, i.e. 0.64X, 0.80X, 1.00X, 1.25X and 1.56X for products with an expected SPF of less than 8,
 - b. A geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X for products with an expected SPF from 8 to 15 or,
 - c. A geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X for products with an expected SPF higher than 15.
28. The middle dose in each of these dose series (i.e. the third dose) was equal to the previously determined MED_u^1 multiplied by the expected SPF.
 29. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.
 30. Subjects were instructed to avoid UV exposure, tanning, sunscreen products, spray tans, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.
 31. Subjects returned to the facility approximately 16 to 24 hours after UV exposure.
 32. A trained staff member visually graded the exposure sites based on the following scale. The technician who evaluated the MED did not know the identity of the test product application sites and UV exposures. Also he/she was not the same person to have applied the sunscreen product to the test site or administered the doses of UV radiation.
 - 0 = No Erythema
 - ? = Questionable Erythema
 - 1 = Perceivable Erythema
 - 2 = Moderate Erythema
 - 3 = Well-Defined Erythema with Edema
 - 4 = Painfully Sensitive & Well Defined Erythema and/or Severe Edema
 33. Subjects were then dismissed from the study.

XIII. REJECTION CRITERIA

Panelist's results were rejected and the panelist was replaced if:

1. An exposure series failed to elicit an MED response on the untreated skin. The test was considered a technical failure even if the MED response was observed in the protected site.
2. The responses on the protected area were randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.
3. All exposures in a series elicited responses – thus prohibiting any MED calculation.
4. The subject was non-compliant (e.g. subject withdrew from the test due to illness or work conflicts or did not shield the exposed testing sites from further UV radiation until the MED was determined.)

A maximum of three subjects may be rejected from the panel based on the above-listed criteria. If more than 3 subjects are rejected based on the criteria above, then the study is invalid.

XIV. SPF CALCULATIONS

SPF value for each test subject (SPF_i) will be calculated as follows:

$$SPF_i = \frac{MED_p}{MED_u}$$

The mean SPF (\overline{SPF}) and standard deviation (s) value will be calculated.

The standard error (SE) will be determined by the following:

$$SE = \frac{s}{\sqrt{n}}$$

Where n = the number of subjects.

The upper 5% point (A) will be obtained from the Student's t distribution table with $n - 1$ degrees of freedom (t). A will be calculated as follows:

$$A = t * SE$$

The labeled SPF for panels using a minimum of 10 evaluable subjects will be the largest whole number less than the mean SPF minus A . This number will be rounded down to the nearest whole number.

$$SPF = \overline{SPF} - A$$

For the study to be valid, the SPF value of the SPF Standard should fall within the standard deviation range of the expected SPF (i.e., 16.3 ± 3.43).

A minimum of 10 subjects must complete the study with valid data for analysis.

XV. ADVERSE EVENTS

There were no adverse events reported during study period.



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