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**EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 80 MINUTES WATER RESISTANT**

FINAL REPORT

December 28, 2015

SPONSOR: Kabana Skin Care
470 Cougar Ct.
Lafayette, CO 80026

TEST PRODUCT: Zinc Oxide Stick Sunscreen

PROJECT -ACCESSION NUMBER: 925795 – 925795

RESEARCH STANDARD

This clinical study was conducted in accordance with standard practices of BioScreen Testing Services and 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 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	7
XIII. REJECTION CRITERIA.....	11
XIV. SPF CALCULATIONS	11
XV. ADVERSE EVENTS.....	12

I. STUDY CONCLUSIONS

The Sun Protective Factor (SPF) of Zinc Oxide Stick Sunscreen when tested on ten (10) subjects as described herein under static and 80 minute water resistant conditions yielded the mean SPF values of 36.03 and 33.15 and the label SPF's of 34 and 31, respectively.

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 . The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.20.

II. RESULTS

Under conditions of the study a total of 10 healthy subjects, 19-52 years of age, completed the clinical study evaluating the Sun Protective Factor (SPF) of Zinc Oxide Stick Sunscreen.

SUBJECT ID	SEX	MED/Hr	I (Amps)	SKIN TYPE	MED I J/M ²	MED II J/M ²	STD (7% PadO/3%Oxyb)	WR CONTROL	SPF VALUE STATIC	SPF VALUE WR
90 5572	M	127.2	6.0	I	28.44	28.44	16.30	15.00	34.50	30.00
80 7036	F	126.8	6.0	II	44.44	44.44	16.30	15.00	34.50	34.50
82 4249	F	129.3	6.2	II	44.44	44.44	18.75	18.00	34.50	34.50
62 3906	F	126.7	6.1	II	35.55	35.55	18.75	18.00	34.50	34.50
58 3948	M	126.9	6.4	II	44.44	44.44	18.75	18.00	34.50	30.00
76 8076	M	126.5	6.2	II	44.44	44.44	18.75	15.00	39.60	34.50
62 0890	F	128.6	6.0	II	35.55	35.55	16.30	15.00	34.50	34.50
76 5957	F	126.1	6.0	II	35.55	35.55	16.30	18.00	39.60	30.00
86 5052	M	125.9	6.3	II	28.44	28.44	18.75	15.00	39.60	34.50
86 6126	F	127.8	5.6	III	55.55	55.55	16.30	15.00	34.50	34.50
MEAN							17.53	16.20	36.03	33.15
STANDARD DEVIATION							1.29	1.55	2.46	2.17
STANDARD ERROR							0.41	0.49	0.78	0.69
STANDARD ERROR % OF MEAN							2.34	3.02	2.16	2.08
NUMBER OF SUBJECTS (N)							10	10	10	10
UPPER 5% t-DISTRIBUTION							2.2622	2.2622	1.8331	1.8331
A VALUES							0.9237	1.1082	1.4281	1.2601
LABEL SPF							16	15	34	31

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

III. STUDY OBJECTIVE

To evaluate the effectiveness of a test material as a sunscreen product by determining the 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 Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 80 minute water immersion experiment which was carried out under controlled conditions as described in the above mentioned FDA Sunscreen Final Rule and Section 6.0 herein.

IV. TEST PRODUCT

Accession No. 925795 was assigned to Zinc Oxide Stick Sunscreen which was received from Kabana Skin Care on November 16, 2015.

The study began on December 4, 2015 and was completed on December 16, 2015.

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 Kabana Skin Care 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. Sample will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

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. These forms along with the signed consent forms will be available for inspection on the premises of BCS only. 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.....	19-52
Sex.....	Male..... 4
	Female..... 6
Race.....	Caucasian..... 10
	Hispanic..... 0
	Asian..... 0

IX. INCLUSION CRITERIA

1. Sex: Male and Female
2. Age Range: 18-65
3. Race: Unrestricted
4. Fitzpatrick Skin Type I, II and III
5. Individuals who were free of any dermatological or systemic disorder, which could interfere with the results, at the discretion of the Investigator.
6. Individuals who were in good general health.
7. Individuals who completed a preliminary medical history.
8. Individuals who were free of any acute or chronic disease that might interfere with or increase the risk of study participation.
9. Individuals with uneven skin tones, pigmentation, scars, other irregularities or hair in the test site areas that would interfere with SPF determination.
10. Individuals who read, understood and agreed to sign an informed consent document.
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, sunbathing, or tanning bed use, 24 hours prior to study initiation and the for the entire duration of the study.
13. Individuals with excessive hair on their back who were willing to clip or shave their hair.

X. EXCLUSION CRITERIA

1. Individuals who were under a Physician's care.
2. Individuals who were taking any medication (topical or systemic) that could mask or interfere with the test results.
3. Individuals 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.
4. Individuals with an active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema).
5. Individuals with damaged skin at or in close proximity to test sites (e.g., sunburn,

- tattoos, scars, excessive hair or other disfigurements).
6. Individuals with a history of adverse effects upon sun exposure.
 7. Individuals who had any history, which, in the Investigator's opinion, indicated the potential for harm to the subject or placed the validity of the study in jeopardy.
 8. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
 9. Individuals who used injectable insulin to control their diabetes.
 10. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions, or uneven pigmentation in the test sites.
 11. Individuals who had a known history of hypersensitivity to any cosmetics, personal care products, fragrances and/or sunscreen products.

XI. ARTIFICIAL LIGHT SOURCE

The light source, a 150 watt Xenon Arc Solar Stimulator (Solar Light Co., Philadelphia, PA, Model 14S or 16S) with a continuous emission spectrum in the UVB range of 290 to 320 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 semi-annually by independent certification facilities and more often as necessary at the discretion of the operating technician or investigator. A certificate for Solar Stimulator Emission Spectrum compliance is on file. The spectroradiometric measurements are performed at least annually.

¹Berger, 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 HIPPA form.
3. Subjects were screened based on the Federal Register Vol. 64, No.

98:27690,1999*:

Type I – Always burns easily; never tans

Type II – Always burns easily; tans minimally

Type III – Burns moderately; tans gradually

* 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, and active dermal lesions using a Woods Lamp
7. Any areas that could be expected to produce erratic results were not used for UV exposures.
8. A 50 cm² rectangular test site was wiped down and cleaned prior to delineation with a skin pen. This test site was used to determine the Minimal Erythema Dose (MED₀) of untreated and unprotected skin.
9. A minimum of five UV exposures were administered within this site to determine the subject's inherent MED₀. UV exposures were calculated using a geometric progression of 1.25ⁿ.
10. Each exposure site was at least 0.5 cm² and was separated from the next exposure site by at least 0.8 cm.
11. 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.
12. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.
13. Subjects returned the facility approximately 16 to 24 hours after UV exposure.
14. A trained staff member visually graded the exposure sites based on the following scale:

0 = No Erythema
? = Questionable Erythema
1 = Minimal Erythema
2 = Slight Erythema
3 = Well-Defined Erythema
4 = Erythema and Edema
5 = Erythema and Edema in vesicles

15. All visual grading was conducted under same lighting conditions and in the same position in which the UV dose was given to the panelist.
16. The lowest UV dose producing perceptible erythema with clearly defined borders determined the individual's MED (grade 1). Any instance of painful erythema or severe erythema with a grade of 3 or greater was considered an adverse experience.
17. This MED was used in determination of the series of UV radiation exposures to be administered to the protected site in subsequent testing of standard, test sunscreens.
18. A series of 50 cm² rectangular test sites were wiped down and cleaned prior to delineation with a skin pen. A minimum distance of 1 cm will be maintained between the borders of adjacent test site application areas.
19. One rectangular test site served as the untreated and unprotected site.
20. 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).
21. All products (oils, creams, and most lotions) were shaken and/or swirled with a glass rod 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.
22. 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 2.0 mg/cm².
23. 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.
24. The untreated and unprotected site received a series of minimum five UV exposures based upon previously determined MED_u such that the series of 5 doses included the previously determined MED_u in the center using a geometric progression of 1.25ⁿ.
25. The UV exposures for SPF Standard, PADIMATE O.OXYBENZONE SPF STANDARD were calculated from the previously determined MED_u 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.
26. The UV exposures for the test product was calculated from the previously determined MED_u where a minimum of 5 doses were administered using 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 8, 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 and 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.
27. The middle dose in each of these dose series (i.e. the third dose) should equal the

previously determined MED_u times the expected SPF.

28. 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.
29. Following UV exposures to the test product site, untreated and unprotected site and the 7% Padimate O/3% Oxybenzone standard sunscreen site, two 50 cm² rectangular test sites were wiped down and cleaned before being delineated with a skin pen.
30. These test sites were selected to perform the 80 minute water resistant portion of the study.
31. The test product and in-house water resistant control sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites in the amount of 2.0 mg/cm².
32. Evenness of application was verified by observation with a Wood's Lamp and the product(s) were allowed to dry at least 15 minutes.
33. Following the 15 minute waiting period, a total of 80 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying).
34. Immersion was achieved indoors in a circulating whirlpool maintained at 23°C to 32°C where pool and air temperature and the relative humidity were recorded.
35. Following the 80 minute water immersion/rest period cycle, the test sites were allowed to air-dry without toweling prior to exposure from the solar simulator.
36. The UV exposures for in-house water resistant control were calculated from the previously determined MED_u where a minimum of 5 doses were administered using a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X. X denotes the expected SPF.
37. The UV exposures for the test product was calculated from the previously determined MED_u where a minimum of 5 doses were administered using 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 8, 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 and 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.
38. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.
39. Subjects returned to the facility approximately 16 to 24 hours after UV exposure.
40. 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 = Minimal Erythema
- 2 = Slight Erythema
- 3 = Well-Defined Erythema
- 4 = Erythema and Edema
- 5 = Erythema and Edema in vesicles

41. 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.)

XIV. SPF CALCULATIONS

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

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

The mean SPF, \overline{SPF} and standard deviation (s) value were calculated. The standard error (SE) was determined by the following:

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

Where n = the number of subjects.

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

$$A = t * SE$$

The labeled SPF for panels using a minimum of 10 evaluable subjects was the largest whole number less than the mean SPF minus A. This number should 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). Additionally, 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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