J. Cosmet. Sci., **63,** 255–258 (July/August 2012)

Sand resistance of sunscreens

MICHAEL CASWELL, CARYL WOOD, and ALEXA MARTINEZ,
Consumer Product Testing Company, Inc., 70 New Dutch Lane, Fairfield, NJ 07004.

Accepted for publication November 30, 2011. A portion of this data was presented at the 2011 Sunscreen Symposium, Orlando, Florida, September 15-18, 2011.

Synopsis

Like water resistance in sunscreens, sand resistance in sunscreens is the ability of the sunscreen to retain its effectiveness while undergoing sand treatment. The influence of the type of sand on the sand resistance of sunscreens has not been described. The sand resistance of a control standard sunscreen, P2, and data on three grades of Quickrete® commercial grade sand, #1961, #1962, and #1152, are described. These sands represent a fine sand, a medium sand, and an all-purpose sand. Using the methodology described in the 2007 proposed amendment of the Final Monograph (1) with one exception, we obtained an SPF of 16.5 (1.6) for the control standard, compared to the expected SPF of 16.3 (3.4). After a five-minute treatment of sand #1961, #1962, or #1151, the SPF of the control standard was 18.3 (1.6), 18.4 (2.0), and 17.5 (2.2), respectively. Thus, all three sands exhibited a similar sand-resistance response. Thus, there was no significant difference in the average SPF with and without sand. The medium grade sand, Quickrete® commercial grade #1962, was preferred for sand-resistance testing because the fine sand was difficult to remove from the subject's backs and the coarse sand was unpleasant to the subjects.

INTRODUCTION

Typical sunscreen formulations leave on the skin a film that is frequently tacky. As sunscreens are frequently used on sandy beaches, the sand may be held to the skin, causing an unpleasant experience by the consumer. The consumer may brush off the sand with unknown consequences to the efficacy of the sunscreen.

Water-resistance SPF testing according to the Final Monograph (1) is a method to determine the SPF of a sunscreen drug product after a defined period of water exposure. Similarly, sand-resistance SPF testing is a method to determine the SPF of a sunscreen drug product after a defined period of sand exposure.

This clinical trial was designed to determine if the grade of the sand that is poured onto the sunscreen-treated skin and brushed off has a statistically significant effect on the SPF of a control standard sunscreen.

Address all correspondence to Michael Caswell at mcaswell@cptclabs.com.

MATERIALS AND METHODS

Multi-port 300-watt xenon arc solar simulators equipped with WG320 and UG11 filters were used as the source of full-spectrum UV radiation (Solar Light Company, Philadelphia, PA). These instruments provide a spectral output in both the UVB range (290 nm–320 nm) and the UVA range (320 nm–400 nm) that is similar to that of sunlight (2).

The solar simulators provided an appropriate warm-up period of approximately 30 minutes after which their output was measured with a UV intensity meter (Model PMA2100, Solar Light Company). Measurement of output was also measured at the end of the day to ensure that there were no fluctuations in radiation emission. To ensure that the solar simulators deliver the appropriate spectrum of UV radiation, their spectral output is measured semi-annually with an accurately calibrated spectroradiometer.

Three different grades of Quickrete® commercial sand was obtained from Quickrete®, Flanders, NJ. Grade #1961 is a fine sand with a US sieve number of 30–70 (0.2–0.6 mm), grade #1962 is a medium sand with a US sieve number of 20–50 (0.5–0.3 mm), and grade #1152 is a coarse sand that meets ASTM C33 specifications. The exact US sieve number is unknown. Each grade of sand was dried for approximately 24 hours in a 90°C oven and then allowed to cool to room temperature prior to use.

A control standard sunscreen (lot #CLI740901) was obtained from Cosmetech Laboratories, Inc. (Fairfield, NJ). The actives were padimate O (7.0%) and oxybenzone (3.0%).

The trial was conducted between February 4 and November 10, 2010, according to the World Medical Association Declaration of Helsinki. Potential subjects were recruited from the database at Consumer Product Testing Company, Inc., which currently contains information on more than 60,000 potential subjects. Potential subjects had the benefits and risks of the clinical trial described to them and they were allowed an opportunity to ask any questions. Once they signed the informed consent and became subjects, they were evaluated for qualification into the trial. The inclusion criteria included Fitzpatrick skin phototypes I, II or III, the previous reliability of the subject, and an age of 18 to 65 years (inclusive). The exclusion criteria included ill health, medications that would interfere with the trial, recent overexposure to UV, a history of adverse reactions to cosmetics or OTC drugs, and pregnancy or nursing. All 20 subjects completed the trial without any adverse event.

All procedures were conducted in ambient conditions (18°–26°C) while the subject was in the prone position. Each subject had five 50-cm^2 test sites outlined with a surgical marking pen on the subject's back between the scapulae and the beltline, lateral to the midline. One site was for determining the unprotected MED, one site was for determining the protected MED, and the other three sites were for determining the protected MED after treatment with one of the three grades of sand. The control standard sunscreen was applied and spread evenly over each of four test sites with a finger wearing a fingercot to provide a film of approximately 2.0 mg/cm^2.

Approximately five minutes after completion of the control standard application, approximately 30 ml of one grade of sand was poured from a height of approximately four inches over a time period of approximately 15 seconds. The sand remained on the sunscreen film for five minutes before being gently brushed off with a one-inch paintbrush. The brushing was conducted in a manner similar to that used when painting.

At least 15 minutes after completion of the control standard application, each test site was divided into five subsites, which were used for a progressive sequence of timed UV exposures, each of which was graduated incrementally by 15% over that of the previous exposure.

All sites were evaluated between 22 and 24 hours after exposure by an evaluator who did not apply the control standard or sand or irradiate the subsites. The MED for each test site is that quantity of erythema effective energy, expressed in seconds, required to produce mild but definite erythema with clearly defined borders. Data were recorded onto case report forms.

The SPF for each protected test site is that quantity of erythema effective energy, expressed in seconds, required to produce mild but definite erythema with clearly defined borders for the protected test site divided by that quantity of erythema effective energy, expressed in

Table I
Individual SPF Values

Subject		Skin			Control	Fine	Medium	All-purpose
No.	ID	type	Age	Gender	standard	sand	sand	sand
1	51970	II	57	M	14.2	12.4	14.2	14.2
2	11701	II	32	M	18.8	18.8	18.8	18.8
3	47003	III	34	M	18.8	18.8	18.8	18.8
4	15423	II	26	M	18.8	18.8	18.8	18.8
5	60245	III	44	F	18.8	21.6	18.8	18.8
6	66522	II	50	M	18.4	18.4	18.4	16.0
7	66400	III	45	M	16.0	21.2	21.2	21.2
8	47964	II	30	M	13.9	21.2	21.2	21.2
9	36939	II	29	F	16.0	16.0	21.2	18.4
10	57810	II	41	M	16.0	18.4	18.4	18.4
11	58977	III	39	M	16.0	18.4	18.4	18.4
12	67597	II	43	M	16.0	18.4	18.4	16.0
13	65072	III	33	F	16.0	16.0	16.0	16.0
14	64564	II	21	M	16.0	18.4	18.4	16.0
15	63032	III	36	F	16.0	16.0	16.0	16.0
16	64637	III	18	M	16.0	16.0	16.0	16.0
17	11735	II	49	M	18.4	21.2	21.2	21.2
18	7329	II	34	M	13.9	18.4	16.0	13.9
19	38010	II	29	M	16.0	18.4	18.4	16.0
20	65721	II	25	M	16.0	18.4	18.4	16.0
Average SPF (n = 20)					16.5	18.3	18.4	17.5
Standard deviation					1.62	2.21	1.96	2.20
Standard error					0.36	0.49	0.44	0.49
t (one-tail)					1.729	1.729	1.729	1.729
A					0.63	0.85	0.76	0.85
SPF label					15	17	17	16

seconds, required to produce mild but definite erythema with clearly defined borders for the unprotected test site. More simply,

$$\text{SPF} = \frac{\text{MED protected site}}{\text{MED unprotected site}}$$

RESULTS

The panel of subjects had 16 males (80%) and 4 females (20%), and had 13 Fitzpatrick skin phototype II (65%) and 7 Fitzpatrick skin phototype III (35%) subjects. There were no Fitzpatrick skin phototype I subjects. The subjects' mean age was 36 years (minimum = 18 years; maximum = 57 years).

The SPF values obtained in this clinical trial are shown in Table I. The control standard exhibited an SPF of 16.5 (StDev = 1.62), which is consistent with the expected SPF of 16.3. The test site that had been treated with the control standard followed by sand #1961 exhibited an SPF of 18.3 (StDev = 2.2). The test site that had been treated with the control standard followed by sand #1962 exhibited an SPF of 18.4 (StDev = 2.0). The test site that had been treated with the control standard followed by sand #1152 exhibited an SPF of 17.5 (StDev = 2.2). Thus, the SPF for each test site treated with the control standard followed by sand was essentially the same as the test site treated only with the control standard. There is no significant difference in the average SPF with or without sand.

CONCLUSIONS

Under the conditions of this clinical trial, there is no significant difference in the average SPF with or without sand. However, the fine sand was difficult to remove and the coarse sand was unpleasant to the subjects. Thus, our data suggests that Quickrete® commercial sand grade #1962 is preferred for sand-resistance testing.

The next step should be the assessment of sand resistance in commonly used sunscreens, especially those with water-resistance claims. However, the Final Rule (3) does not allow for a sand-resistance SPF related claim, which suggests that additional research might first require regulatory review.

REFERENCES

(1) Sunscreen drug products for over-the-counter human use, Final Monograph, *Federal Register,* **64,** 27666–27693 (1999).
(2) D. S. Berger, Specification and design of solar ultraviolet simulators, *J. Invest. Dermatol.,* **53,** 192–199 (1969).
(3) Labeling and effectiveness testing; sunscreen drug products for over-the-counter human use, *Federal Register,* **76,** 35620–35665 (2011).