

## Suncare Research Laboratories, LLC

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### SRL2006-004: FINAL REPORT

February 27, 2006

- Title:** Evaluation of the Static Sun Protection Factor (SPF) of a Sunscreen Formula
- Objective:** To measure the Static SPF of an over-the-counter (OTC) sunscreen formula and the 8% Homosalate Standard (HMS) in human volunteers according to the FDA Final Monograph<sup>1</sup>
- Test Product:** Formula 26 – Expected SPF 15
- Study Design:** Non-randomized, with blinded evaluations
- Study Dates:** February 2, 2006 to February 25, 2006
- Results:** Twenty subjects completed the test. The mean SPF of the test product, Formula 26, was 16.5 (n=20, SD=1.7). This product meets FDA Final Monograph labeling requirements for Static SPF 15.<sup>1</sup>
- Adverse Experiences:** No Adverse Experiences were reported
- Sponsor:** Kabana Skin Care, LLC  
3235 Wright Avenue  
Boulder, CO 80301  
  
Erik Kreider, CEO  
(888) 517-0414  
[erik@kabanaskincare.com](mailto:erik@kabanaskincare.com)
- Investigator:** Joseph W. Stanfield, M. S.

**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. On the second day the minimal erythema dose (MED) was determined as the lowest UV dose which produced mild erythema reaching the borders of the exposure site. Then 100 mg of the test product and 100 mg of the HMS standard were applied to separate, adjacent 50 cm<sup>2</sup> areas of the mid-back (8% Homosalate (HMS) Standard provided by Cosmetech Laboratories, Inc., Fairfield, NJ. Batch #106).

The test product had an expected SPF of 15 and the HMS standard sunscreen had an expected SPF of 4. After a 15-minute drying period UV doses ranging from 0.76 to 1.32 times the product of the MED and 15 were administered to the test sunscreen-protected areas. UV doses ranging from 0.64 to 1.56 times the product of the MED and 4 were administered to the HMS standard sunscreen-protected area. A series of UV doses were also administered to a second unprotected site. On the third day the MED was determined for the sunscreen-protected sites and the unprotected site. The SPF of each sunscreen was calculated as the ratio of the MED for each sunscreen-protected site to the final MED.

Detailed procedures for determining the Static Sun Protection Factor according to the FDA Sunscreen Monograph<sup>1</sup> are described in the protocol in APPENDIX 1.

Details of calibrations for Lamps 1, 2, 7 and 8 are shown in APPENDIX 2.

According to the FDA Final Monograph<sup>1</sup>, the labeled SPF must be calculated as follows:

Labeled SPF = Mean SPF Value – A  
Rounded down to the nearest whole number

Where A =  $t_s/\sqrt{n}$  and represents the 95% confidence interval.

t = upper 5% of student's t distribution  
s = Standard Deviation  
n = Number of Subjects

For the panel to be valid, the SPF of the HMS standard sunscreen must fall within the standard deviation range of the expected SPF (i.e.  $4.47 \pm 1.279$ ) and the 95% confidence interval for the mean SPF of the HMS standard sunscreen must contain the value 4.

**Results:**

Twenty subjects, 8 men and 12 women, who provided written, informed consent, completed the study. Subjects 16 and 18 were disqualified due to history. Subjects who completed the test included 4 with skin type I, 10 with skin type II and 6 with skin type III.<sup>1</sup> Ages ranged from 18 to 67 years and the mean age was 34.7 years (n=20, SD=14.2). Subject demographic and static SPF results are listed in Table 1.

Formula 26

The mean static SPF of the test product, Formula 26, was 16.5 (n=20, SD=1.7). The mean static SPF – A, rounded down to the nearest whole number was 15.

HMS Standard

The mean SPF of the HMS standard was 4.6 (n=20, SD=0.4). The 95% Confidence interval included the value 4.

Table 1. Subject Demographic and Static SPF Data for Formula 26 and HMS Standard

<b>SRL2006-004: Kabana Skin Care LLC</b>									<b>Formula 26</b>	<b>HMS Standard</b>	
Subject #	SRL ID#	Initials	Age	Sex	Skin Type	Lamp	Eff mW/cm <sup>2</sup>	Final MED (sec)	SPF	SPF	
01	977	TBB	41	F	III	1	0.654	16	16.06	5.06	
02	976	LJL	20	F	II	1	0.654	13	17.23	4.38	
03	863	RET	36	M	II	2	0.734	10	17.30	4.40	
04	979	CJT	48	M	III	8	1.500	13	17.23	4.38	
05	215	RGG	67	F	II	1	0.654	13	17.23	4.38	
06	693	BSI	42	M	I	1	0.654	13	13.31	4.77	
07	464	RCH	43	F	I	1	0.654	10	17.30	5.00	
08	995	TLP	44	M	I	2	0.734	8	21.63	5.50	
09	1000	CVN	20	M	II	1	0.654	13	17.23	4.38	
10	138	CB	46	F	II	8	1.500	10	14.00	4.40	
11	844	CGC	39	M	III	1	0.654	13	16.08	4.38	
12	1004	TDS	19	F	II	7	1.514	10	18.10	5.20	
13	1005	HPB	23	F	III	2	0.734	13	16.08	4.00	
14	936	CDS	37	F	III	8	1.500	13	16.08	4.38	
15	895	SGM	35	F	I	7	1.514	10	16.10	4.40	
17	173	JRK	23	M	II	1	0.654	10	16.10	4.40	
19	195	GGH	56	F	III	1	0.654	16	16.06	5.06	
20	1018	JMB	19	F	II	2	0.734	10	15.00	4.40	
21	1017	ADM	18	F	II	1	0.654	10	16.10	5.00	
22	1020	JAJ	18	M	II	7	1.514	13	16.08	4.38	
Mean=			34.7	Mean=			16.5	Mean=			4.6
SD=			14.2	SD=			1.7	SD=			0.4
n=			20	n=			20	n=			20
A=				A=			0.6	Mean+95% CI=			5
Mean-A=				Mean-A=			15	Mean-95%CI=			4

Subject 16 disqualified - history

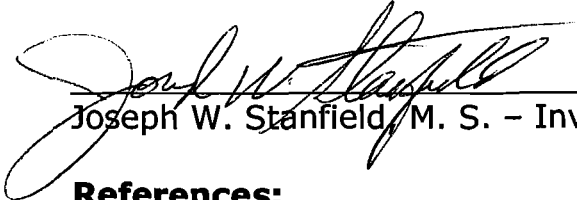
Subject 18 disqualified - history

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**Conclusion:**

The test product, Formula 26, meets the labeling requirements for Static SPF 15 according to the FDA Final Monograph.<sup>1</sup>

  
\_\_\_\_\_  
Joseph W. Stanfield, M. S. - Investigator

  
\_\_\_\_\_  
Date

**References:**

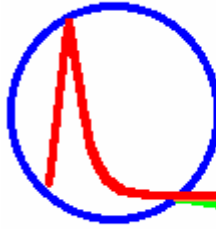
1. U. S. Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; 21CFR Parts 310, 352, 700 and 740. Federal Register 64 (98) May 21, 1999. pp. 27666-27693

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## **APPENDIX 1**

## **PROTOCOL**



**Suncare Research Laboratories, LLC**

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**SRL2006-004: Evaluation of the Static Sun Protection Factor (SPF)  
of a Sunscreen Formula**

January 3, 2006

- Objective:** To measure the Static SPF of an over-the-counter (OTC) sunscreen formula according to the FDA Final Monograph<sup>1</sup>
- Test Product:** Green Screen™ (active is a 40nm Zinc Oxide in a tropical butter water in oil emulsion)
- Study Design:** Non-randomized, with blinded evaluations
- Subjects:** Up to 25 qualified male and/or female volunteers with the skin types I, II and/or III.<sup>1</sup>
- Sponsor:** Kabana Skin Care LLC  
3235 Wright Avenue  
Boulder, CO 80301  
  
Erik Kreider, CEO  
888 517 0414  
erik@kabanaskincare.com
- Investigator:** Joseph W. Stanfield, M. S.  
Suncare Research Laboratories, LLC

**Introduction:**

The FDA Final Monograph<sup>1</sup> describes the procedures for determining the Static sun protection factor. The Static SPF is defined by the ratio of the minimal erythema dose of ultraviolet radiation for sunscreen-protected skin to that for unprotected skin. The minimal erythema dose (MED) is the dose of ultraviolet (UV) radiation that produces mild erythema (sunburn) with clearly defined borders, 22 to 24 hours after administration. Timed UV radiation doses are administered using a xenon arc lamp that simulates solar radiation. The technician will monitor the output of the solar simulator using a calibrated radiometer to insure that the erythemally effective irradiance is constant. Readings of erythemally effective irradiance will be recorded.

**Objective:**

The objective of this test is to measure the Static SPF of an over-the-counter (OTC) sunscreen formula according to the FDA Final Monograph<sup>1</sup>.

**Test Product:**

Green Screen™ (active is a 40nm Zinc Oxide in a tropical butter water in oil emulsion)

**Study Design:**

This is a non-randomized study with blinded evaluations.

**Subjects:**

Subjects will include up to 25 healthy male and female volunteers with skin types I, II and/or III<sup>1</sup> (See below).

<b>Skin Type</b>	<b>Erythema and Tanning Reactions to First Sun Exposure in Spring*</b>
I	Always burns easily; never tans
II	Always burns easily; tans minimally
III	Burns moderately; tans gradually
IV	Burns minimally; always tans well

\*Subject-reported responses to 1 hour of summer sun exposure

Subjects must report any OTC or prescription medication used within the week before and during study participation. Subjects must also satisfy the following criteria:

Inclusion Criteria:

- At least 18 years old, providing legally effective, written informed consent
- Willing and able to keep study appointments and follow instructions
- Good general health
- Willing to avoid sun and tanning lamp exposure during the study

Exclusion Criteria:

- History of abnormal response to UV radiation or sensitivity to any ingredient of the test products
- Sunburn, suntan, active dermal lesions, uneven skin tones or any condition such as nevi, blemishes or moles that might interfere with study procedures
- Use of any medication that might affect study results, e.g. photosensitizers, antihistamines, analgesics or anti-inflammatory drugs
- Pregnancy, nursing or any condition that might increase the risk of study participation
- Tanning bed or tanning lamp exposure in the last 3 months

**Study Procedures:**

Following is a schematic of the study:

<b>Subject Requirements</b>	<b>Before Study</b>	<b>During Study</b>		
No tanning lamp exposure	3 months			
Report all medication	1 week			
<b>Study Procedures</b>		<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>
Informed Consent		X		
Determine if subject qualified by medical history		X		
Administer UV doses for MED		X		
Evaluate responses; Determine MED			X	
Apply test product for Static SPF			X	
Apply HMS Standard for static SPF			X	
Administer UV doses to protected and unprotected sites			X	
Evaluate UV responses; Determine SPFs				X
<b>Identify concomitant medications</b>		X	X	X
<b>Assess compliance</b>			X	X
<b>Monitor for Adverse Experiences</b>		X	X	X

All procedures (product application, UV doses and evaluations) will be performed with the subjects in a seated position.

## **Day 1**

### Subject Enrollment

Prospective subjects will report to the testing laboratory and receive a complete explanation of study procedures. If they desire to participate and agree to the conditions of the study, subjects will sign a written, witnessed consent form and a permission to release personal health information form, and will provide a brief medical history. The back, between the belt-line and shoulder blades, will be examined for uneven skin tones and blemishes, using a Woods lamp. The technician will complete the Subject History Form and qualified subjects will be enrolled in the study. Subject numbers will be assigned in the order of study enrollment.

### MED Dose Administration

A timed series of 5 UV doses, increasing in 25 percent increments, will be administered to the mid-back, just below the shoulder blades and above the belt-line, with subjects in a seated position. UV doses for the MED, the time doses are completed and lamp readings will be recorded on the MED form.

Subjects will be instructed to avoid UV exposure, photosensitizers, analgesics, antihistamines and anti-inflammatory medications and to return to the testing laboratory 22 to 24 hours after completion of UV doses.

## **Day 2**

### MED Determination

Subjects will return to the testing laboratory within 22 to 24 hours after completion of MED doses for evaluation of responses and will be questioned non-directively to assess compliance, to identify concomitant medications and to monitor for adverse experiences. All evaluations will be performed with subjects in a seated position. A trained evaluator will grade responses of the UV exposed sites, under warm fluorescent or tungsten illumination of 450 to 550 lux, using the grading scale shown in Table 1.

Table 1. Grading Scale for Erythema Responses to UV Doses Administered to Untreated Sites and Sunscreen Treated Sites

0	No erythema response
1	Minimally perceptible erythema
2	Mild erythema with clearly defined borders
3	Moderate erythema with sharp borders*
4	Dark red erythema with sharp borders*
5	Dark red erythema with sharp borders and possible edema*
6	Intense erythema with sharp borders and edema*

\*If moderate, dark red or intense erythema does not reach borders of exposed site, an explanation will be provided in the comments section of evaluation forms

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

If there are pronounced tanning responses, the subject is probably Type IV and not qualified for the study. In this case the subject will be dropped from the study and replaced. Grades for each UV-exposed site, any comments and the evaluation time will be recorded.

If required for practical scheduling, the subject may leave the testing laboratory at this point and return within one week for completion of Day 2 procedures.

#### Application of Product for SPF Determination

If the study participation of the subject has been interrupted, the subject will be questioned non-directively to assess compliance, identify concomitant medications and monitor for adverse experiences.

With the subject in a seated position, the study technician will draw two 50 cm<sup>2</sup> rectangles in the designated locations on the subject's back between the belt-line and shoulder blades using a template and an indelible marker. The technician will then apply 100 mg of the test product in its designated rectangle and 100 mg of the HMS standard in an adjacent rectangle. The products will be applied by "spotting" the material across the area and gently spreading, using a finger cot, until a uniform film is applied to the entire area.

The technician will document product formula designation, test site location and application time.

UV Doses for Static SPF Determinations

After at least 15 minutes, the technician will administer a series of 7 progressively increasing, timed UV doses to the site treated with the test product. The dose series will be determined by the product of the expected SPF of the test product, the subject's MED and the following number:

Multiple of Subject's MED and Expected SPF (SPF <sub>≥</sub> 15)						
0.76	0.87	0.93	1.00	1.07	1.15	1.32

The technician will document UV doses, times completed and lamp effective irradiance readings for each test product.

UV Doses for the HMS Standard

At least 15 minutes after the application of the HMS standard, the technician will administer 7 progressively increasing timed UV doses to the HMS standard site. The dose series will be determined by the product of the HMS standard SPF (4), the subject MED and the following numbers:

Multiple of Subject MED and HMS Standard (SPF=4)						
0.64	0.80	0.90	1.00	1.10	1.25	1.56

The technician will document the UV doses for the HMS standard, time completed and the lamp effective irradiance reading.

UV Doses for Repeat MED Determination

The technician will administer a timed series of 5 UV doses, increasing by 25 percent increments, to an unprotected area of the mid-back. The series of 5 doses will include the original MED in the center as follows:

Multiple of Original MED				
0.64	0.80	1.00	1.25	1.56

UV doses for the repeat MED, time completed and the lamp effective irradiance reading will be recorded.

The technician will instruct subjects to return to the testing laboratory for evaluation within 22 to 24 hours after completion of the UV doses for the static SPF, HMS standard SPF and the repeat MED.

### **Day 3**

#### Evaluation of Responses to UV Doses for Static SPF and Repeat MED

Subjects will return to the testing laboratory and will be questioned non-directively to assess compliance, to identify concomitant medications and to monitor for adverse experiences. A trained evaluator, who did not participate in product applications or administration of UV doses will grade all sites that received UV doses, using the scale shown in Table 1. All evaluations will be performed with the subject in a seated position. The technician who applied the test product and administered the UV doses may assist the evaluator, but the technician may not influence the evaluator in the grading of UV responses. Grades of the responses of all sunscreen-treated sites will be recorded.

#### **SPF Computation:**

The technician will determine the repeat MED as above and compute the SPF values for each subject.

The final MED will be the repeat MED, unless the repeat MED cannot be determined. In that case the initial MED will be used as the final MED.

SPF values will be calculated as the ratio of the MED for sunscreen-protected sites to the final MED.

The labeled SPF must be calculated as follows, based on 20 subjects:

Mean SPF Value – A  
(rounded down to nearest whole number)

Where  $A = ts/\sqrt{n}$

t = upper 5% of student's t distribution

s = Standard Deviation

n = Number of Subjects

For the panel to be valid the SPF of the HMS standard sunscreen must fall within the standard deviation range of the expected SPF (i.e.  $4.47 \pm 1.279$ ) and the 95% confidence interval for the mean SPF of the HMS standard sunscreen must contain the value 4.

**Adverse Experiences:**

Any adverse experiences will be documented in the subject file and immediate medical attention will be obtained if appropriate. Any serious adverse experience defined as life-threatening or requiring emergency measures will be reported to the sponsor within 24 hours. All adverse experiences will be reported to the sponsor.

**Replacement of Subjects:**

Any subject who is disqualified due to non-compliance or adverse experience will be replaced. Subjects whose data do not permit successful computation of SPF values will be replaced.

**Indemnification**

The Sponsor agrees to indemnify, defend, and hold harmless Suncare Research Laboratories, LLC, from any demands, costs, or judgements arising out of or connected with the non-negligent use of the test material or performance of activities to be carried out pursuant to this Protocol. Suncare Research Laboratories, LLC shall notify the Sponsor within 10 working days after receipt of notice of injury, claim or lawsuit.

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**Study Fee:**

The fee for the above testing will be \$150 per subject completed per test product. The fee for this test will be invoiced upon completion of the test and submission of the final report. Payment terms will be Net 30 days.

**Investigator's Report:**

At the completion of the study, the investigator will provide the sponsor a tabulation of subject demographics; erythema grades; MEDs; SPF values; descriptive and inferential statistics and conclusions.

**Protocol Approval:**

Suncare Research Laboratories, LLC, certifies that this protocol meets FDA requirements for SPF labeling as specified in the Final Sunscreen Monograph (Reference 1 below).

**For Suncare Research Laboratories, LLC**

Joseph W. Stanfield 01/03/06  
Joseph W. Stanfield, M. S. - Investigator Date

**For Sponsor:**

Erik Kreider 2/2/06  
Erik Kreider, CEO Date

for formula 26 - test which tested SPF 14 in in vitro study.

**Reference:**

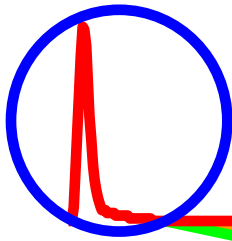
1. U. S. Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; 21CFR Parts 310, 352, 700 and 740. Federal Register 64 (98) May 21, 1999. pp. 27666-27693

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## **APPENDIX 2**

### **LAMP CALIBRATIONS**



## Suncare Research Laboratories, LLC

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### Calibration of Lamp 1

Lamp 1 (S/N 4533) is a 150 watt xenon arc solar simulator (Solar Light Company, Philadelphia, PA), equipped with a Schott WG320 UVC blocking filter, a heat-rejecting dichroic mirror and a visible and infrared blocking UG-11 filter. A UVB blocking filter is used for UVA doses. The lamp beam is uniform, as evidenced by uniform erythema across exposed sites, with a continuous spectrum that is free from substantial peaks. Less than 0.01% of total lamp energy is contributed by wavelengths shorter than 290 nm.

Lamp 1 was calibrated on January 8, 2006, using an Optronic Laboratories spectroradiometer Model OL754, which was calibrated inhouse using an NIST traceable source on November 9, 2005 (Calibration file J222F17.cal) and at Optronic Laboratories on April 12, 2005. Percent effective power and the permitted ranges according to the International SPF Test Method<sup>1</sup> are shown in the table below. As shown, the lamp spectrum is compliant with these spectral requirements.

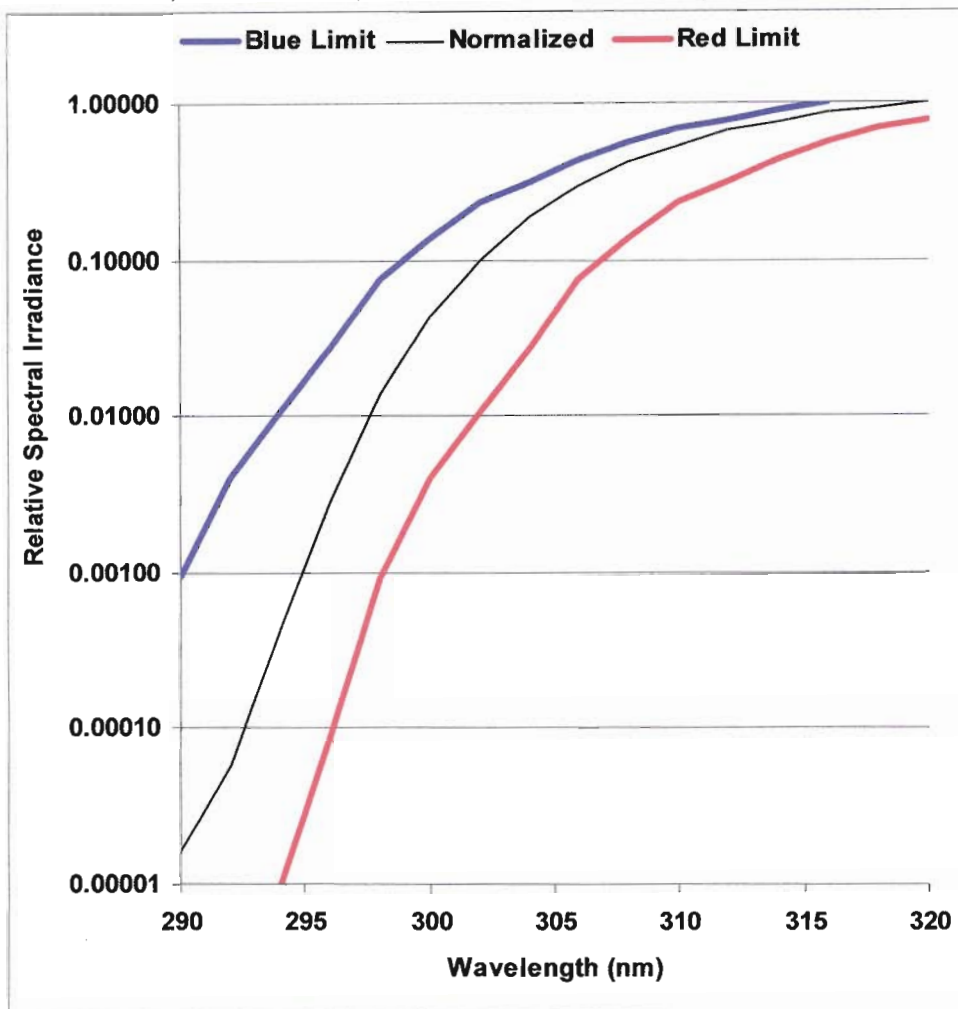
Range (nm)	Lamp 1 Bulb S/N 316625 WG-320 Filter#010806	International SPF Test Method %
<290	0.02%	<0.1
290-300	5.5%	1.0-11.0
290-310	63.2%	49.0-65.0
290-320	89.7%	85.0-90.0
290-330	94.5%	91.5-95.5
290-340	96.3%	94.0-97.0
290-350	97.7%	95.5-98.5
290-400	100.0%	99.9-100.0

At a setting of 7.0 amps and 22.6 Volts (158.2 Watts), total effective power was 0.91 effective  $\text{mw/cm}^2$  and total power from 250 to 800 nm was 108.7  $\text{mw/cm}^2$ .

With a 3 mm WG335 UVB blocking filter in place, the total UVA power was 58  $\text{mw/cm}^2$  and the ratio of UVAII power to total UVA power was 12.33%.

Figure 1 shows normalized lamp spectra compared to blue (short wavelength) and red (long wavelength) limits as described in Reference 2.

Figure 1. Normalized Spectrum of Lamp 1 Compared to Red and Blue Limits (Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.)



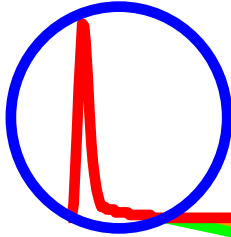
As shown in Figure 1, the lamp spectrum falls within the prescribed limits.

*Joseph W. Stanfield*  
 Joseph W. Stanfield  
 President, Suncare Research Laboratories, LLC

*1/8/06*

#### References

1. Cosmetic, Toiletries and Fragrances Association of South Africa, The European Cosmetic, Toiletry and Perfumery Association (COLIPA), Japan Cosmetics Industry Association (JCIA), International Sun Protection Factor (SPF) Test Method, October, 2005.
2. Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.



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### Calibration of Lamp 2

Lamp 2 (S/N 4534) is a 150 watt xenon arc solar simulator (Solar Light Company, Philadelphia, PA), equipped with a Schott WG320 UVC blocking filter, a heat-rejecting dichroic mirror and a visible and infrared blocking UG-11 filter. A UVB blocking filter is used for UVA doses. The lamp beam is uniform, as evidenced by uniform erythema across exposed sites, with a continuous spectrum that is free from substantial peaks. Less than 0.01% of total lamp energy is contributed by wavelengths shorter than 290 nm.

Lamp 2 was calibrated on January 17, 2006, using an Optronic Laboratories spectroradiometer Model OL754, which was calibrated inhouse using an NIST traceable source on November 9, 2005 (Calibration file J222F17.cal) and at Optronic Laboratories on April 12, 2005. Percent effective power and the permitted ranges according to the International SPF Test Method<sup>1</sup> are shown in the table below. As shown, the lamp spectrum is compliant with these spectral requirements.

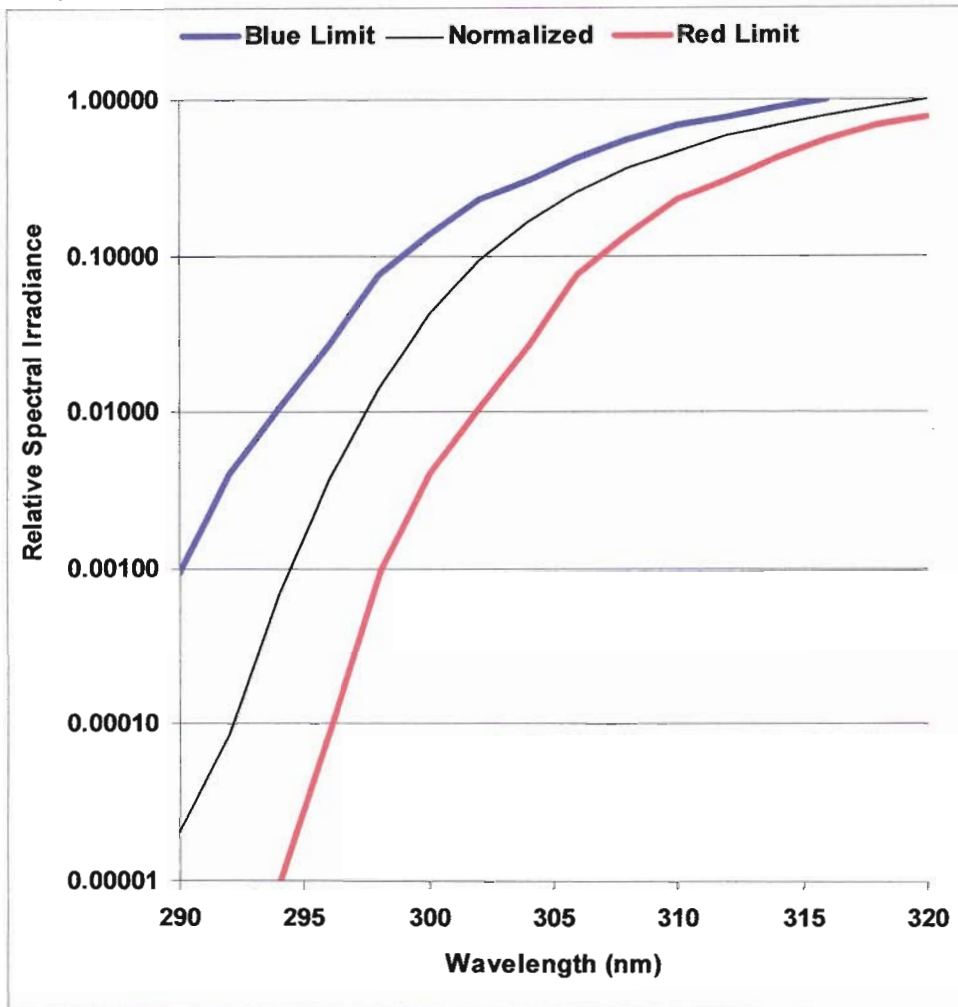
Range (nm)	Lamp 2 Bulb S/N 311844 WG-320 Filter#50419	International SPF Test Method 2005 %
<290	0.02%	<0.1
290-300	8.0%	1.0-11.0
290-310	61.0%	49.0-65.0
290-320	86.5%	85.0-90.0
290-330	91.7%	91.5-95.5
290-340	94.1%	94.0-97.0
290-350	96.1%	95.5-98.5
290-400	100.0%	99.9-100.0

At a setting of 6.0 amps and 24.7 Volts (150 Watts), total effective power was 0.51 effective mw/cm<sup>2</sup> and total power from 250 to 800 nm was 91 mw/cm.<sup>2</sup>

With a 3 mm WG335 UVB blocking filter in place, the total UVA power was 56 mw/cm<sup>2</sup> and the ratio of UVAII power to total UVA power was 9.7%.

Figure 1 shows normalized lamp spectra compared to blue (short wavelength) and red (long wavelength) limits as described in Reference 2.

Figure 1. Normalized Spectrum of Lamp 2 Compared to Red and Blue Limits (Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.)



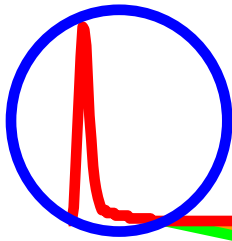
As shown in Figure 1, the lamp spectrum falls within the prescribed limits.

*Joseph W. Stanfield*  
 Joseph W. Stanfield  
 President, Suncare Research Laboratories, LLC

*1/17/06*

## References

1. CTFA of South Africa, The European Cosmetic, Toiletry and Perfumery Association (COLIPA), Japan Cosmetics Industry Association (JCIA), International Sun Protection Factor (SPF) Test Method, December 2005.
2. Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.



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### Calibration of Lamp 7

Lamp 7 (Model 16S-150, S/N 9533) is a 150 watt xenon arc solar simulator (Solar Light Company, Philadelphia, PA), equipped with a Schott WG320 UVC blocking filter, a heat-rejecting dichroic mirror and a visible and infrared blocking UG-11 filter. A UVB blocking filter is used for UVA doses. The lamp beam is uniform, as evidenced by uniform erythema across exposed sites, with a continuous spectrum that is free from substantial peaks. Less than 0.01% of total lamp energy is contributed by wavelengths shorter than 290 nm.

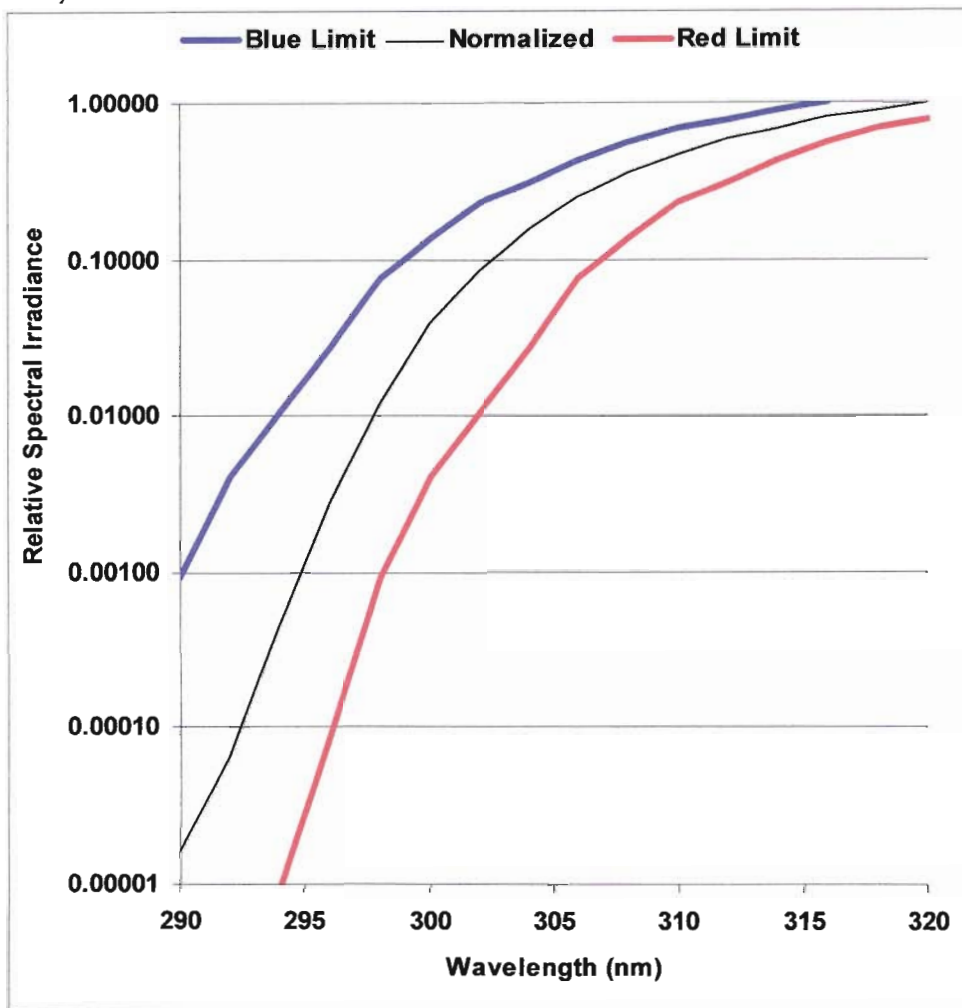
Lamp 7 was calibrated on December 19, 2005, using an Optronic Laboratories spectroradiometer Model OL754, which was calibrated inhouse using an NIST traceable source on November 9, 2005 (Calibration file J222F17.cal) and at Optronic Laboratories on April 12, 2005. Percent effective power and the permitted ranges according to the International SPF Test Method<sup>1</sup> are shown in the table below. As shown, the lamp spectrum is compliant with these spectral requirements.

Range (nm)	Lamp 7 Bulb S/N 312503 WG-320 Filter#080105	International SPF Test Method %
<290	0.01%	<0.1
290-300	6.3%	2.0-8.0
290-310	60.9%	49.0-65.0
290-320	89.3%	85.0-90.0
290-330	94.2%	91.5-95.5
290-340	96.1%	94.0-97.0
290-350	97.6%	95.5-98.5
290-400	100.0%	99.9-100.0

At a setting of 5.47 amps and 22.3 Volts (122.0 Watts), total effective power was 1.09 effective  $\text{mw}/\text{cm}^2$  and total power from 250 to 800 nm was 137  $\text{mw}/\text{cm}^2$ .

Figure 1 shows normalized lamp spectra compared to blue (short wavelength) and red (long wavelength) limits as described in Reference 2.

Figure 1. Normalized Spectrum of Lamp 7 Compared to Red and Blue Limits (Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.)



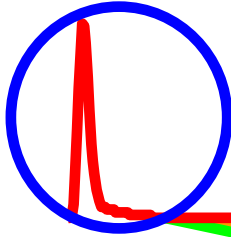
As shown in Figure 1, the lamp spectrum falls within the prescribed limits.

*Joseph W. Stanfield*  
 Joseph W. Stanfield  
 President, Suncare Research Laboratories, LLC

12/19/05

#### References

1. Cosmetic, Toiletries and Fragrances Association of South Africa, The European Cosmetic, Toiletry and Perfumery Association (COLIPA), Japan Cosmetics Industry Association (JCIA), International Sun Protection Factor (SPF) Test Method, October, 2005.
2. Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.



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### Calibration of Lamp 8

Lamp 8 (S/N 9560) is a 150 watt xenon arc solar simulator (Solar Light Company, Philadelphia, PA), equipped with a Schott WG320 UVC blocking filter, a heat-rejecting dichroic mirror and a visible and infrared blocking UG-11 filter. A UVB blocking filter is used for UVA doses. The lamp beam is uniform, as evidenced by uniform erythema across exposed sites, with a continuous spectrum that is free from substantial peaks. Less than 0.01% of total lamp energy is contributed by wavelengths shorter than 290 nm.

Lamp 8 was calibrated on January 16, 2006, using an Optronic Laboratories spectroradiometer Model OL754, which was calibrated inhouse using an NIST traceable source on November 9, 2005 (Calibration file J222F17.cal) and at Optronic Laboratories on April 12, 2005. Percent effective power and the permitted ranges according to the International SPF Test Method<sup>1</sup> are shown in the table below. As shown, the lamp spectrum is compliant with these spectral requirements.

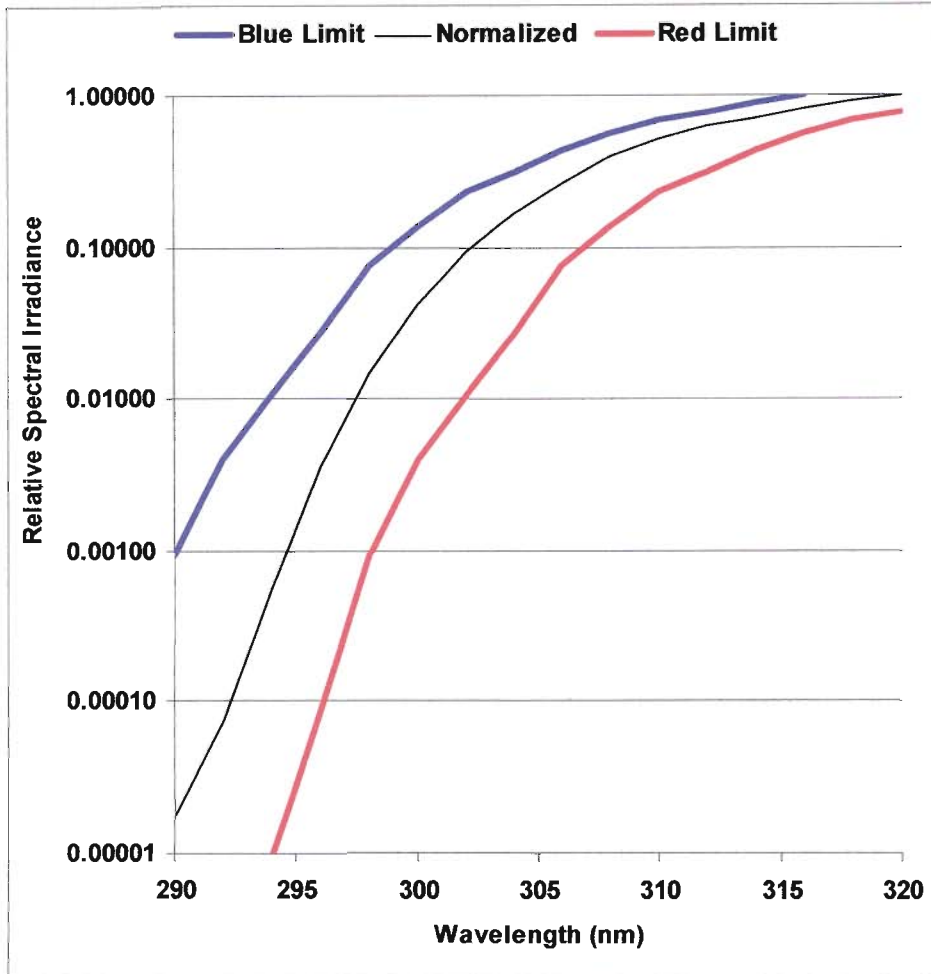
Range (nm)	Lamp 8 Calibration File: J222F17.cal Filter 050408+1 0.15 mm glass cover slip Bulb 316632	International Test Method, 2005
<290	0.02%	<0.1
290-300	8.08%	1.0-11.0
290-310	61.98%	49.0-65.0
290-320	88.91%	85.0-90.0
290-330	93.91%	91.5-95.5
290-340	95.90%	94.0-97.0
290-350	97.43%	95.5-98.5
290-400	99.98%	99.9-100.0

At a setting of 7.1 amps and 22.2 Volts (156.7 Watts), total effective power was 1.15 effective mw/cm<sup>2</sup> and total power from 250 to 800 nm was 150.1 mw/cm.<sup>2</sup>

With a 3 mm WG335 UVB blocking filter in place, the total UVA power was 76 mw/cm<sup>2</sup> and the ratio of UVAII power to total UVA power was 10.72%.

Figure 1 shows normalized lamp spectra compared to blue (short wavelength) and red (long wavelength) limits as described in Reference 2.

Figure 1. Normalized Spectrum of Lamp 8 Compared to Red and Blue Limits (Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.)



As shown in Figure 1, the lamp spectrum falls within the prescribed limits.

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#### References

1. Cosmetic, Toiletries and Fragrances Association of South Africa, The European Cosmetic, Toiletry and Perfumery Association (COLIPA), Japan Cosmetics Industry Association (JCIA), International Sun Protection Factor (SPF) Test Method, October 2005.
2. Freeman SE, Ley RD. Sunscreen protection against UV-induced pyrimidine dimers in DNA of human skin in situ. Photodermatol, Photoimmunol, Photomed 1988; 5:243-247.