



## Suncare Research Laboratories, LLC

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### **SRL2010-108: FINAL REPORT**

March 22, 2010

- 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:** EF5-21 - Expected Static SPF 20
- Study Design:** Non-randomized, with blinded evaluations
- Study Dates:** February 25, 2010 to March 19, 2010
- Results:** Twenty subjects completed the test. The mean SPF of the test product, EF5-21, was 21.38 (n=20, SD=1.7). This product meets FDA Final Monograph labeling requirements for Static SPF 20.<sup>1</sup>
- Adverse Experience:** One Adverse Experience was reported that was not related to the test product
- Sponsor:** Mineral Evolution, LLC  
1117 E. Putnam Ave #230  
Riverside, CT 06878
- 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)).

The test product had an expected SPF of 20 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 25 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.

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 =  $ts/\sqrt{n}$  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, 10 men and 10 women, who provided written, informed consent, completed the study. Subjects included 10 with skin type II and 10 with skin type III.<sup>1</sup> Ages ranged from 18 to 67 years and the mean age was 45.3 years (n=20, SD=15.5). Subject demographic and static SPF results are listed in Table 1.

EF5-21

The mean static SPF of the test product, EF5-21, was 21.38 (n=20, SD=1.7). The mean static SPF - A, rounded down to the nearest whole number was 20.

HMS Standard

The mean SPF of the HMS standard was 4.6 (n=20, SD=0.5). The 95% Confidence interval included the value 4.

**Adverse Experience:**

None Reported.

Table 1. Subject Demographic and Static SPF Data for EF5-21 and HMS Standard

<b>SRL2010-108: Mineral Evolution, LLC</b>									<b>EF5-21</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	1199	PDR	29	M	II	8	1.500	10	20.00	3.20		
02	1325	KSS	25	F	II	10	1.632	10	21.38	4.37		
03	1324	DN	38	M	III	10	1.632	10	21.38	4.20		
04	1013	KMM	64	M	III	8	1.500	13	21.44	4.50		
05	1236	JMW	47	M	II	10	1.632	13	21.44	5.06		
06	1192	KSJ	39	M	III	2	0.734	13	26.00	5.60		
07	1191	HWN	66	M	III	10	1.632	13	23.00	4.80		
08	976	LJL	21	F	III	10	1.632	13	21.38	4.38		
09	1108	JCR	43	M	II	10	1.632	13	21.38	4.48		
10	284	GDB	66	F	III	10	1.632	13	23.00	5.00		
11	915	KGH	47	F	II	10	1.632	13	21.44	5.06		
12	1008	LAB	45	F	III	10	1.632	13	21.44	4.60		
13	378	RJV	34	M	II	2	0.734	13	20.00	5.00		
14	1348	JTJ	18	M	III	2	0.734	13	21.38	5.00		
15	398	JMC	51	F	II	2	0.734	10	21.38	5.00		
16	612	RAL	66	F	II	10	1.632	10	23.00	4.38		
17	626	JHL	67	M	II	2	0.734	13	21.38	4.38		
18	924	SSB	39	F	III	10	0.734	13	18.59	3.56		
19	69	BSB	56	F	II	8	1.500	13	17.32	4.38		
20	694	TJP	45	F	III	2	0.734	13	21.30	5.00		
		Mean=	45.3						Mean=	21.38	Mean=	4.6
		SD=	15.5						SD=	1.70	SD=	0.5
		n=	20						n=	20	n=	20.0
									A=	0.5	Mean+95% CI=	5.0
									Mean-A=	20.88	Mean-95%CI=	4.0

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SRL2010-108  
EF5-21

**Conclusion:**

The test product, EF5-21, meets the labeling requirement for Static SPF 20 according to the FDA Final Monograph.<sup>1</sup>

  
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Joseph W. Stanfield, M. S. – Investigator

03/22/10  
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