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SRL2010-111: FINAL REPORT

March 05, 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[1]
Test Product:	EF1-35 - Expected Static SPF 20
Study Design:	Non-randomized, with blinded evaluations
Study Dates:	February 16, 2010 to March 03, 2010
Results:	Twenty subjects completed the test. The mean SPF of the test product, EF1-35, was 22.3 (n=20, SD=2.6). This product meets FDA Final Monograph labeling requirements for Static SPF 20.[1]
Adverse Experience:	None reported
Sponsor:	Mineral Evolution, LLC 1117 E. Putnam Ave #230 Riverside, CT 06878
Investigator:	Joseph W. Stanfield, M. S.

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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^2 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[1], 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

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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 ± 1.279) and the 95% confidence interval for the mean SPF of the HMS standard sunscreen must contain the value 4.

Results:
Twenty subjects, 7 men and 13 women, who provided written, informed consent, completed the study. Subjects included 2 with skin type I, 13 with skin type II and 5 with skin type III.[1] Ages ranged from 19 to 63 years and the mean age was 40.4 years (n=20, SD=14.7). Subject demographic and static SPF results are listed in Table 1.

EF1-35
The mean static SPF of the test product, EF1-35, was 22.3 (n=20, SD=2.6). The mean static SPF - A, rounded down to the nearest whole number was 22.

HMS Standard
The mean SPF of the HMS standard was 4.5 (n=20, SD=0.4). The 95% Confidence interval included the value 4.

Adverse Experience:
None Reported.

Table 1. Subject Demographic and Static SPF Data for EF1-35 and HMS Standard

SRL2010-111: Mineral Evolution, LLC

Subject #	SRL ID#	Initials	Age	Sex	Skin Type	Lamp	Eff mW/cm2	Final MED (sec)	EF1-35 SPF	HMS Standard SPF
1	409	BAL	62	F	III	1	0.654	10	20.0	4.1
2	408	BHL	63	M	III	8	1.5	16	21.5	4.5
3	1023	CBB	44	F	I	1	0.654	13	17.0	4.4
4	915	KGH	47	F	III	1	0.654	16	18.5	4.1
5	653	CKB	40	F	II	2	0.734	16	22.8	4.4
6	446	LAH	61	F	II	2	0.734	10	23.6	5.0
7	1105	TMC	19	F	I	2	0.734	10	21.2	4.4
8	327	WVH	42	M	II	2	0.734	16	20.4	4.4
9	110	LKM	42	M	II	8	1.5	13	24.6	4.4
10	741	TIJ	33	F	II	2	0.734	13	23.0	5.0
11	235	KAO	63	F	II	2	0.734	16	25.0	5.1
12	1109	LLL	22	M	II	8	1.5	16	19.9	4.1
13	621	ADW	49	M	III	1	0.654	13	22.6	5.0
14	496	MSP	26	M	II	2	0.734	13	20.1	5.0
15	1062	LND	41	F	III	1	0.654	13	25.4	5.0
16	1111	SKB	45	F	II	8	1.5	13	23.8	4.4
17	268	SNM	41	F	II	2	0.734	13	23.5	4.4
18	896	RKP	23	F	II	8	1.5	16	21.3	3.6
19	897	DMP	20	M	II	1	0.654	13	27.0	4.4
20	564	BDL	24	F	II	1	0.654	13	25.6	5.0
		Mean=	40.4					mean=	22.3	Mean= 4.5
		SD=	14.7					SD=	2.6	SD= 0.4
		N=	20.0					n=	20.0	n= 20.0
								A	0.6	Mean+95%CI 5
								Mean-A	21.7	Mean-95%CI 4

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Conclusion:

The test product, EF1-35, meets the labeling requirement for Static SPF 20 according to the FDA Final Monograph.[1]

Joseph W. Stanfield, M. S. – Investigator

03/05/10
Date

References:

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