

NOTE TO FILE

Product Name Change

Applies to assorted records associated with Formula # B02512

During the product development process Formula # B02512, was described as Elta MD UV Essential or "Elta MD Rosacea Sunscreen." The name for the product was changed to Elta MD UV Elements on May 18, 2016. The change took place prior to introducing the Item # 02512 Elta MD UV Elements 2 oz tube into interstate commerce. No commercial product was produced under the new "elements" name. The name change was undertaken due to marketing considerations. The listed documentation and test reports apply to activities undertaken for Formulation B02512, Bulk – Elta MD UV Essential SPF 44 and packaged products utilizing said formulation:

SPF Test Report

Broad Spectrum Test Report

Phototoxicity Report

Repeat Insult Patch Test Report (RIPT)


CMP-16005 (Compounding Validation B02512)

STB-16007 (Stability Protocol 02512)

SLG-16011 (Sealing Qualification 02512)

PKG-16008 (Packaging Validation 02512)


Reviewed By/Date


Approved By/Date



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**EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 40 MINUTE WATER RESISTANT**

AMA Ref. No.: MS16.SPF.O6007.SAP.40MINWR10

Date: April 7, 2016

Sponsor: Swiss-American Products, Inc.
2055 Luna Road
Carrollton, Texas 75006

1.0 Objective:

This panel has been convened 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 06/14/2011; Publication Date: 06/17/2011] using a Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 40 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.

2.0 Sample Description:

On March 29, 2016 one test sample labeled EltaMD UV Essential Sunscreen (Lot J1603221) was received from Swiss-American Products, Inc. and assigned AMA Lab No.: O-6007.

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material 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.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

4.0 Panel Demographics:

Number of subjects enrolled.....	10	
Number of subjects completing study.....	10	
Age Range	20 - 50	
Sex.....	Male	4
	Female	6
Race	Caucasian	10
	Hispanic	0
	Asian	0

4.1 Standards for Inclusion in the Study:

- a. Individuals eighteen years of age or older.
- b. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.
- c. Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.
- d. Individuals with Fitzpatrick Skin Type I, II, and III only.
- e. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with SPF determination.
- f. Individuals who complete a preliminary medical history form mandated by AMA Laboratories, Inc. and are in general good health.
- g. Individuals who will read, understand and sign an informed consent document relating to the specific type of study they are subscribing. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc. only.
- h. Individuals able to cooperate with the Investigator and research staff, be willing to have test materials applied according to the protocol, and complete the full course of the study.
- i. Individuals willing to refrain from using any sunscreen products, sunbathing or tanning bed use, 24 hours prior to study initiation and the entire duration of the study.
- j. Individuals with excessive hair on their back who are willing to have hair removed by AMA technicians prior to commencement of study.

4.2 Standards for Exclusion from the Study:

- a. Individuals who are under a doctor's care.
- b. Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results.
- c. Subjects 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.
- d. Individuals diagnosed with chronic skin allergies.
- e. Individuals with a history of adverse effects upon sun exposure.
- f. Female volunteers who indicate that they are pregnant or lactating.
- g. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions or uneven pigmentation in the test sites.
- h. Individuals with known hypersensitivity to any sunscreen products.

4.3 Informed Consent and Medical History Forms:

An 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 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 are available for inspection on the premises of AMA Laboratories, Inc. only. Reference 21 CFR Ch. 1 Part 50, Subpart B.

A trained technician performed a physical examination of the panelist's back to determine if study eligibility criteria were satisfied.

The parties agreed to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

4.4 Panel Composition:

Healthy volunteers over the age of 18 years were recruited for this study. The panel consisted of fair-skin individuals with Fitzpatrick Skin Types I, II or III defined as follows (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 the first 30 to 45 minutes of sun exposure after a winter season without sun exposure.

4.5 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc., consists of five or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file at AMA Laboratories, Inc. and is available for inspection during the hours of operation.

5.0 Artificial Light Source:

The light source employed is a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S, Model 15S or Model 16S) having a continuous emission spectrum from 290 to 400 nanometers. A 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 sunlight¹.

This device is equipped with a dichroic mirror (which reflects all radiation below 400 nm) and works in conjunction with a 1 mm thick Schott WG-320 filter (which absorbs all radiation below 290 nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter (black lens) is added to remove reflected (infra-red, greater than 700 nm) heat and remained visible radiation. UVB radiation is monitored continuously during exposure using a Model DCS-1 Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter). Measurements are taken at a position within 8mm from the surface of the skin. The size of the exposure site is $\geq 1 \text{ cm}^2$. The solar simulator is allowed a warm up time of at least 15 minutes before use and power supply output is 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 the Solar Simulator Emission Spectrum compliance is on file at AMA Laboratories, Inc. The spectroradiometric measurements are performed at least annually.

1/ Berger, D.S.: Specification and Design of Solar Ultraviolet Simulators. J. Invest. Dermatol. 53: 192-199, 1969.

6.0 Procedure:

(A) STATIC SPF DETERMINATION (INCLUDING 7% PADIMATE O / 3% OXYBENZONE STANDARD)

The infrascapular area of the back to the right and left side of the midline was used. Within this area, 30 cm² rectangular test sites were delineated with a gentian violet surgical skin marker. Sites were observed to ensure uniform pigmentation, skin tone and texture, and absence of warts, moles, nevi, scars, blemishes and active dermal lesions. Any areas that might be expected to produce erratic results were not used for UV exposures.

The procedure for this study is outlined in the Federal Register / Vol.76, No.117, 21 CFR Parts 201 and 310 published on Friday June 17, 2011. One test site area served to determine each subject's Minimal Erythema Dose (MED).

A minimum of five UV exposures were administered within this site. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation.

The test material and 7% Padimate O / 3% Oxybenzone standard were shaken and/or swirled with a glass rod before use and were evenly applied using plastic volumetric syringes to rectangular areas measuring 3 cm x 10 cm (30 cm²) for a final concentration of 2.0 mg/cm². Evenness of application was verified by observation with a Wood's Lamp. An adjacent test site was then selected to perform a static determination on the test substance, as above, prior to the immersion test.

Fifteen minutes after application, a protected site received a series of five UV exposures based upon previously determined MED.

All immediate responses were recorded after UV radiation exposure from the solar simulator.

The UV exposures for 7% Padimate O / 3% Oxybenzone, in-house water resistant control and test material were calculated from previously determined MED and the intended SPF as follows:

SPF 16.3: MED times 0.76x, 0.87x, 1.00x, 1.15x and 1.32x

SPF 15: MED times 0.69x, 0.83x, 1.00x, 1.20x and 1.44x

SPF 45: MED times 0.76x, 0.87x, 1.00x, 1.15x, and 1.32x where x equals the expected SPF of the product.

(B) 40 MINUTE WATER RESISTANT DETERMINATION
(INCLUDING IN-HOUSE WATER RESISTANT CONTROL)

This test is employed to determine the substantivity of a test product and its ability to resist 40 minutes of water immersion. On the day of the test, following exposure of the 7% Padimate O / 3% Oxybenzone standard, MED's and static determination, another test site was designated. One other adjacent site was selected to perform a water resistant determination of an in-house 40 minute water resistant standard with a known SPF as a control.

The water resistant SPF value was determined by the product's ability to resist a 40-minute period of water immersion, achieved through the following test regimen: After application of the sunscreen product followed by the waiting period, a total of 40 minutes water immersion was scheduled; 20 minutes in the water, 15 minute rest (without towel drying), 20 minutes in the water. Immersion was achieved indoors in a whirlpool tub with water circulating by a 1 h.p. pump at 3450 RPM. Each panelist spent twenty minutes in the water, immediately followed by a fifteen minute rest period out of the water until a total of forty minutes in the water were achieved. The whirlpool bath was set at 23°C to 32°C at moderate agitation. The water and air temperatures and relative humidity were recorded. After the last immersion, the test sites were air dried without toweling for at least fifteen minutes prior to exposure of treated areas to the solar simulation. The protected sites received a series of five UV exposures based upon previously determined MED.

7.0 Evaluation of Responses:

Sixteen to twenty-four hours post exposure, the subjects were instructed to return to the testing facility for evaluation of delayed erythemic responses. 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. All erythemic response evaluations are performed in an area where the lighting provides at least 450 lux of illumination and with the test subjects in the same position as when the test site was irradiated.

$$SPF = \frac{\text{Protected MED}}{\text{Final unprotected MED}}$$

Visual grading 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

7.1 All technical employees of AMA Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.

8.0 Determination of the Test Product's SPF Value:

Calculation of SPF— According to the reference, the mean SPF value (\bar{x}) is calculated using a minimum of 10 evaluable subjects per formulation. The standard deviation was determined (s). The upper 5% point was obtained from the t distribution table with $n-1$ degrees of freedom (t). The standard error (SE) was calculated by $(s)/\sqrt{n}$ (where n equals the number of subjects who provided valid test results).

Therefore, the label SPF value for panels using a minimum of 10 evaluable subjects is the largest whole number less than the mean SPF minus ($t \times SE$).

$$\text{Label SPF} = \text{Mean SPF} - (t \times SE)$$

9.0 Rejection Criteria:

Panelist's results were rejected and the panelist 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 is 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 withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined.)

10.0 Results:

Please see attached Table.

11.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

12.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

13.0 Security Label Disclosure:

To prevent loss of and protect intellectual property, original, certified documents issued by AMA Laboratories Inc. can be identified by a proprietary, tamper evident security hologram affixed to all Conclusion/Signature pages on final reports. Any attempt to remove the hologram will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the AMA LABS, INC. hologram intact will be recognized by AMA Laboratories Inc. as a certified original.

14.0 Conclusions:

The Sun Protection Factor (SPF) of the test material (AMA Lab No.: O-6007; Client No.: EltaMD UV Essential Sunscreen (Lot J1603221)) when tested on ten subjects as described herein under static and 40 minute water resistant conditions yielded the mean SPF values of 49.05 and 47.70 and the label SPF's of 47 and 45, 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.

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**EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) - WATER RESISTANT - 40 MINUTE WATER IMMERSION**

Table

Sponsor: Swiss-American Products, Inc.
 AMA Lab No.: O-6007
 Client No.: EltaMD UV Essential Sunscreen (Lot J1603221)

Subject ID #	Sex	MED/ Hr	I (Amps)	Skin Type	MED I J/M ²	MED II J/M ²	STD (7%PadO/ 3%Oxyb)	SPF Values		
								WR Control	Static	WR
72 0561	M	126.7	6.1	II	44.44	44.44	18.75	15.00	51.75	51.75
72 4447	M	126.2	6.1	II	44.44	44.44	16.30	18.00	51.75	45.00
54 7248	F	127.3	6.2	II	44.44	44.44	18.75	15.00	51.75	45.00
72 4379	F	125.3	6.1	II	44.44	44.44	16.30	18.00	45.00	45.00
54 4408	F	127.4	6.4	II	35.55	35.55	16.30	15.00	45.00	45.00
84 2976	M	127.6	6.0	II	35.55	35.55	18.75	18.00	51.75	51.75
82 6930	F	128.6	6.0	II	35.55	35.55	16.30	18.00	51.75	51.75
90 0774	F	125.8	6.1	II	28.44	28.44	18.75	15.00	45.00	45.00
74 6499	M	127.6	6.0	II	28.44	28.44	16.30	15.00	45.00	45.00
58 9967	F	126.2	6.0	III	55.55	55.55	18.75	15.00	51.75	51.75
MEAN (x)							17.53	16.20	49.05	47.70
STANDARD DEV (s)							1.29	1.55	3.49	3.49
STD. ERROR							0.41	0.49	1.10	1.10
S.E. % OF MEAN							2.34	3.02	2.24	2.31
N							10	10	10	10
UPPER 5% t DIST.							2.2622	2.2622	1.8331	1.8331
A VALUES							0.9228	1.1088	2.0231	2.0231
LABEL SPF							16	15	47	45

MED: Minimal Erythema Dose

I: Intensity of light source

Evaluation Period: This study was conducted from March 29, 2016 through April 6, 2016.

15.0 Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Report reviewed by:



Tasmiya Masud, B.A.
Quality Assurance Supervisor

4/7/16

Date