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AN INVESTIGATION INTO THE EFFICACY OF TOPICALLY APPLIED ANTI-INFLAMMATORY PRODUCT

AMA Ref. No.: MS11.ERYTHSUPP.REP.M1006.BIOV

Date: September 13, 2011

Sponsor: Biovelop AB
Älvåsvägen 1
61020 Kimstad
Sweden

1.0 Objective:

This panel has been convened to evaluate the effectiveness of test material intended to reduce, prevent and treat UV induced erythema using a Xenon arc solar simulator as the UV source. Efficacy was evaluated objectively via grading performed by the trained technician.

2.0 Test Material:

2.1 Test Sample Description:

On July 13, 2011 one test sample labeled Avenacare™ Oat Beta Glucan was received from Biovelop AB and assigned AMA Lab No.: M-1006.

2.2 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 test 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.

2.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, toxicology, microbiology or in-vitro performance spectra may be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in Section 3.0.

2.3.1 Sponsor purports that prior to sample submission to AMA the following tests were conducted with no adverse results and that the test data are on file at their premises and have not been made available to AMA personnel:

- USP or CTFA Preservative Efficacy Test or equivalent
- 90 Day Accelerated Stability and Container Compatibility Study
- Fifty (50) person Repeat Insult Patch Test (RIPT) or equivalent

3.0 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc. consists of 5 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.

4.0 Panel Selection:

4.1 Standards for Inclusion in a Study:

1. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.
2. Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.
3. Individuals with Fitzpatrick skin type I, II, and III only.
   Type I - Always burn easily; never tans
   Type II - Always burn easily; tans minimally
   Type III- Burns moderately; tans gradually
4. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with the study conduct.
5. Individuals who will complete a preliminary medical history form mandated by AMA Laboratories, Inc. and are in general good health.
6. 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.

7. Individuals able to cooperate with the Investigator and research staff, willing to have test material applied according to the protocol, and complete the full course of the study.
8. Individuals willing to refrain from using any sunscreen products, sunbathing or tanning bed use, 7 days prior to study initiation and the entire duration of the study.
9. Individuals with excessive hair on their back who are willing to clip or shave their hair.

4.2 Standards for Exclusion from a Study:

1. Individuals who are under the care of a physician.
2. Individuals currently taking medication that may mask or interfere with the test results.
3. Individuals diagnosed with chronic skin allergies.
4. Females who are pregnant, lactating, have been pregnant, or given birth within the six month period immediately preceding study commencement.
5. 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.
6. Individuals who have experienced irritation or sensitivity to lotion products.
7. Individuals with known allergies or skin and/or eye conditions, which would interfere with the study at the discretion of the Study Director.
8. Individuals with a history of adverse effects upon sun exposure.
9. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions or uneven pigmentation in the test sites.

4.3 Panel Composition:

Healthy volunteers between the age of 23 and 55 years old were recruited for this study. The panel consisted of fair-skin individuals with skin types I, II, III defined as follows (Federal Register Vol. 64, No. 98:27690,1999)*:

Type I - Always burn easily; never tans
Type II - Always burn easily; tans minimally
Type III- Burns moderately; tans gradually

* Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4.4 Recruitment:

Panel selection is accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

4.4 Informed Consent Document:

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 panelist was also given a copy of the informed consent for his records. Each subject was assigned a permanent identification number and completed an extensive medical history form and screening 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.

5.0 Population Demographics:

Number of subjects enrolled		5
Number of subjects completing study		5
Age Range		23 - 55
Sex	Female	5
Race	Caucasian	5

6.0 Artificial Light Source:

The light source, a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S or 16S) with a continuous emission spectrum in the DVB range of 290 to 320 nm was used. Xenon arc was 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 sunlight[1].

This device was equipped with a dichroic mirror (reflects all radiation below 400nm) and which works in conjunction with a 1 mm thick Schott WG-320 filter (absorbs all radiation below 290 nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter was attached to remove reflected (infra-red, greater than 700 nm) heat and remaining visible radiation. UVB radiation was 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 were taken at a position within 8 mm from the surface of the skin. The field of irradiation was a circle 1 cm in diameter. The solar simulator was allowed a warm up time of at least 15 minutes before use and the power supply output was 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.

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

7.0 Test Site Selection:

The infrascapular area of the back to the right and left of the midline was used. Within this area one 30 cm^2 (10 cm by 3 cm) rectangular test site and seven 9 cm^2 (3 cm by 3 cm) 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 may have been expected to produce erratic results were used for UV exposures.

8.0 MED Determination on Unprotected Skin [MED(US)]:

One site (30 cm^2 rectangle) was used to determine Minimal Erythema Dose [MED(US)] of untreated and unprotected skin. A minimum of five UV exposures were administered within this site to determine the subject's inherent MED(US). UV exposures were calculated using a geometric progression of 1.25^n. The MED was determined within one week prior to testing. This MED was used in determination of the series of UV radiation exposures to be administered to the test sites.

Visual grading was done at 22 to 24 hours post irradiation according to the following 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

The series of UV-exposures should produce at least a first subsite without erythema (grade of <1) and one or more sites with responses ranging from minimal erythema to well-defined erythema. The lowest UV dose producing the endpoint of minimal erythema determines the individual's MED (grade 1).

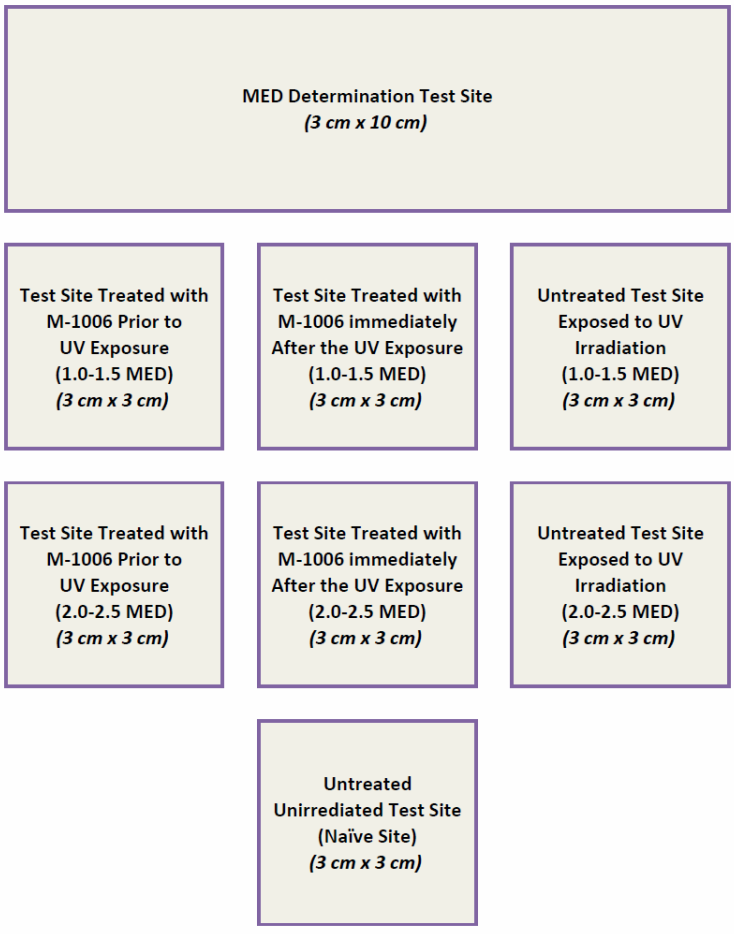
Any instance of painful erythema or severe erythema with a grade of 3 or greater was considered an adverse experience. Erythema grades were recorded on a case report form provided by the Investigator.

All immediate responses (if any) were recorded after UV radiation exposures from the solar simulator were completed. These responses included several types of typical responses such as immediate darkening or tanning in 30 to 60 minutes and/or immediate reddening with rapid fading.

All technical employees of AMA laboratories, Inc. were required to take and pass a visual discrimination examination conducted by a board certified ophthalmologist using the Farnsworth-Munsell 100 Hue Test. This test, which determines a persons ability to discern color against black background, was modified to incorporate a flesh tone background (instead of black) to simulate the actual use conditions.

9.0 Procedure:

As a condition of enrollment, subjects were instructed to abstain from using of any lightening/brightening and sunscreen product and refrain from sunbathing or tanning bed use for a period of at least 7 days prior to study commencement. The infrascapular area of the back to the right and left side of the midline was used. Within this area the test sites were delineated with a gentian violet surgical skin marker according to following schedule:



The test material was shaken and/or mixed thoroughly before use and was dispensed to the test site via volumetric syringe at a concentration of 2 mg/cm^2.

Test was conducted according to the following schedule:

Day 1		● MED Determination - UV Exposures
Day 2		● MED Determination - Erythematic Responses Grading (24 Hours post Exposures)
		● *AM Test Product Application* and UV Exposures
	● *PM Test Product Application*	
Day 3	● *AM Test Product Application*	
	BASELINE	● Skin Erythema Scoring
		● Lab Scale Photography
	● *PM Test Product Application*	
Day 4	● *AM Test Product Application*	
	24 HOURS	● Skin Erythema Scoring
	● *PM Test Product Application*	
Day 5	● *AM Test Product Application*	
	48 HOURS	● Skin Erythema Scoring
	● *PM Test Product Application*	
Day 6	● *AM Test Product Application*	
	72 HOURS	● Skin Erythema Scoring
		● Lab Scale Photography

Delayed erythematic responses were recorded for each of the test sites at 24h post exposure and then approximately every 24 hours until dispensation of the erythema (return of homoestasis).

Visual grading was conducted according to following scale:

0.0 = No Erythema
0.5 = Questionable Erythema
1.0 = Minimal Erythema
2.0 = Slight Erythema
3.0 = Well-Defined Erythema
4.0 = Erythema and Edema
5.0 = Erythema and Edema in vesicles

All subjects were inducted in additional investigation where the Lab Scale Photographs were taken prior to the initial application (at Baseline) and again after 72 hours after initial application.

10.0 Results:

Please refer to attached tables and charts.

11.0 Observations:

Test results were not accepted if:

1. An exposure series fails to elicit an MED response on the untreated skinsite. The test was considered a technical failure even if the MED response was observed in the protected site.
2. All exposures in a series elicit responses - thus prohibiting any MED calculation.

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

12.0 Statistical Source Data:

The source data are the visual erythema grading scores and the time scale for erythema dispensation.

13.0 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.

14.0 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 will be recognized by AMA Laboratories Inc. as a certified original.

15.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, the test material (AMA Lab No.: M-1006, Client No.: Avenacare™ Oat Beta Glucan) was reported to be effective in reducing, preventing and treating UV induced erythema.

Further, these phenomena were documented and confirmed by the photographic record made during the course of this study.

Mayya Tatsene, M.D.
Study Director

Patrycja Wojtowicz, M.S.
Technician

Kaitlyn Callaghan, B.S. (Candidate)
Technician

Jason Berke, A.A.S. Candidate
Photo Technician

David R. Winne, B.S.
Technical Director

9/13/11
Date

Note: All Services Undertaken Subject to the following General Policy: AMA Laboratories, Inc. Reports are submitted for exclusive use of the clients to whom they are addressed. Their significance is subject to the adequacy and representative character of the samples and to the comprehensiveness of the test, examination or surveys made. No quotations from AMA Laboratories, Inc., reports, or use of AMA Laboratories, Inc., name or names of staff members or sub-contractors is permitted except as expressly authorized in writing. The liability of AMA Laboratories, Inc. with respect to services rendered shall in no event exceed the amount of one hundred dollars. Any indemnification agreement attached to or included in the embodiment of this report shall, if sent by certified mail, return receipt requested, be deemed to be properly served, executed, notarized and accepted by virtue of the signature appearing on the return certified claim. Wherein this report is used to support commercial claims, the Sponsor is directed to provide said report in its entirety.

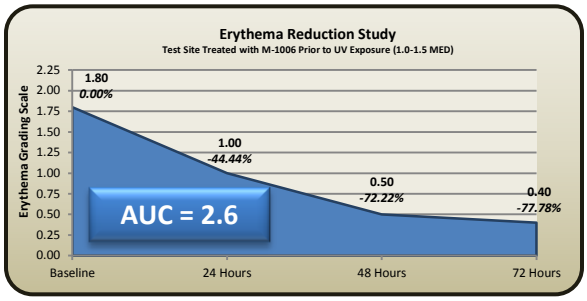
Erythema Suppression Study - SUMMARY	
AMA Lab No.:	M-1006
Client No.:	Avenacare™ Oat Beta Glucan

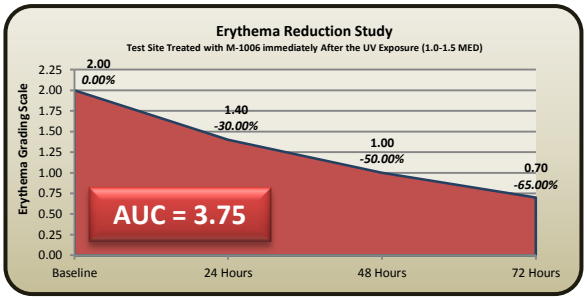
Test Site Treated with M-1006 Prior to UV Exposure (1.0-1.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	2.0	1.0	0.5	0.5
74 0188	2.0	1.0	0.5	0.5
72 6793	2.0	1.0	0.5	0.5
76 2801	2.0	1.0	0.5	0.5
50 1729	1.0	1.0	0.5	0.0
Mean:	1.80	1.00	0.50	0.40
% Difference:		-44.44%	-72.22%	-77.78%
AUC (Area Under Curve):		2.60		

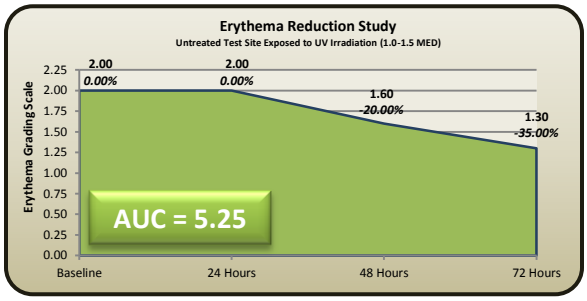
Test Site Treated with M-1006 immediately After the UV Exposure (1.0-1.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	2.0	2.0	1.0	1.0
74 0188	2.0	2.0	1.0	1.0
72 6793	2.0	1.0	1.0	0.5
76 2801	2.0	1.0	1.0	0.5
50 1729	2.0	1.0	1.0	0.5
Mean:	2.00	1.40	1.00	0.70
% Difference:		-30.00%	-50.00%	-65.00%
AUC (Area Under Curve):		3.75		

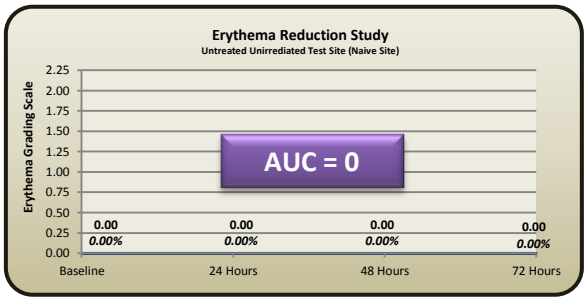
Untreated Test Site Exposed to UV Irradiation (1.0-1.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	2.0	2.0	2.0	2.0
74 0188	2.0	2.0	2.0	2.0
72 6793	2.0	2.0	2.0	1.0
76 2801	2.0	2.0	1.0	1.0
50 1729	2.0	2.0	1.0	0.5
Mean:	2.00	2.00	1.60	1.30
% Difference:		0.00%	-20.00%	-35.00%
AUC (Area Under Curve):		5.25		

Untreated Unirradiated Test Site (Naive Site)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	0.0	0.0	0.0	0.0
74 0188	0.0	0.0	0.0	0.0
72 6793	0.0	0.0	0.0	0.0
76 2801	0.0	0.0	0.0	0.0
50 1729	0.0	0.0	0.0	0.0
Mean:	0.00	0.00	0.00	0.00
% Difference:		0.00%	0.00%	0.00%
AUC (Area Under Curve):		0.00		







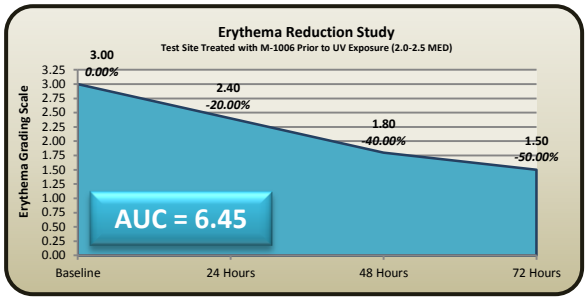


Visual grading was conducted according to following scale:

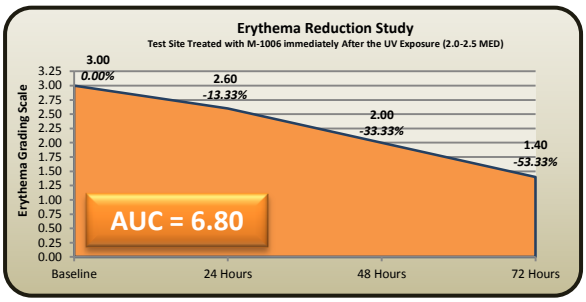
0.0 = No Erythema
0.5 = Questionable Erythema
1.0 = Minimal Erythema
2.0 = Slight Erythema
3.0 = Well-Defined Erythema
4.0 = Erythema and Edema
5.0 = Erythema and Edema in vesicles

Erythema Suppression Study - SUMMARY	
AMA Lab No.:	M-1006
Client No.:	Avenacare™ Oat Beta Glucan

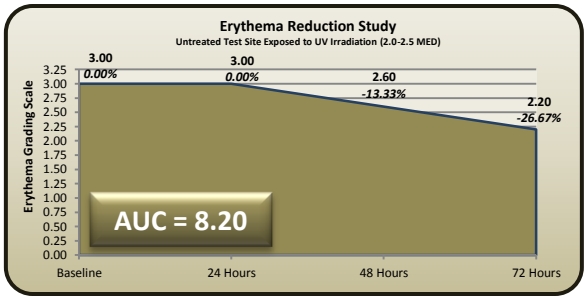
Test Site Treated with M-1006 Prior to UV Exposure (2.0-2.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	3.0	3.0	2.0	2.0
74 0188	3.0	3.0	2.0	2.0
72 6793	3.0	2.0	2.0	1.0
76 2801	3.0	2.0	1.0	0.5
50 1729	3.0	2.0	2.0	2.0
Mean:	3.00	2.40	1.80	1.50
% Difference:		*-20.00%*	*-40.00%*	*-50.00%*
AUC (Area Under Curve):		6.45		



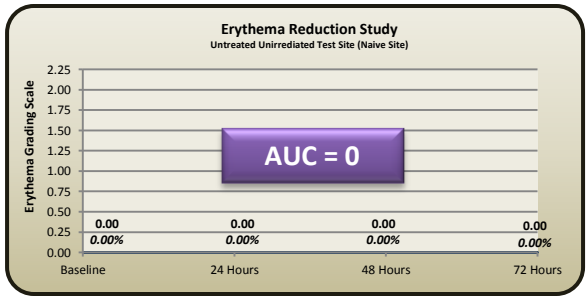
Test Site Treated with M-1006 immediately After the UV Exposure (2.0-2.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	3.0	3.0	2.0	1.0
74 0188	3.0	2.0	2.0	2.0
72 6793	3.0	2.0	2.0	1.0
76 2801	3.0	3.0	2.0	1.0
50 1729	3.0	3.0	2.0	2.0
Mean:	3.00	2.60	2.00	1.40
% Difference:		*-13.33%*	*-33.33%*	*-53.33%*
AUC (Area Under Curve):		6.80		



Untreated Test Site Exposed to UV Irradiation (2.0-2.5 MED)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	3.0	3.0	3.0	2.0
74 0188	3.0	3.0	3.0	3.0
72 6793	3.0	3.0	2.0	2.0
76 2801	3.0	3.0	2.0	2.0
50 1729	3.0	3.0	3.0	2.0
Mean:	3.00	3.00	2.60	2.20
% Difference:		*0.00%*	*-13.33%*	*-26.67%*
AUC (Area Under Curve):		8.20		



Untreated Unirradiated Test Site (Naïve Site)				
Subject ID Nos.:	Baseline	24 Hours	48 Hours	72 Hours
54 2735	0.0	0.0	0.0	0.0
74 0188	0.0	0.0	0.0	0.0
72 6793	0.0	0.0	0.0	0.0
76 2801	0.0	0.0	0.0	0.0
50 1729	0.0	0.0	0.0	0.0
Mean:	0.00	0.00	0.00	0.00
% Difference:		*0.00%*	*0.00%*	*0.00%*
AUC (Area Under Curve):		0.00		



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2.0 = Slight Erythema
3.0 = Well-Defined Erythema
4.0 = Erythema and Edema
5.0 = Erythema and Edema in vesicles

16.0 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

9/13/11
Date