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# EVALUATION OF PHOTOTOXICITY POTENTIAL BY UV-A IRRADIATION ON 20 HUMAN SUBJECTS

AMA Ref. No.: MS12.PHT.M7609O.20.AHI

Date: December 19, 2012

Sponsor: AUTUMN HARP INC.
26 Thompson Drive
Essex Junction, Vermont 05452

## 1.0 Objective:

This panel has been convened to assess the contact phototoxic potential of a test material on twenty human subjects.

## 2.0 Sample Description:

On November 20, 2012 one test sample labeled AH Lot # 125-281, Badger Kids SPF30 Lotion SF2 Autumn Harp Laboratory 11/12/2012 was received from AUTUMN HARP INC. and assigned AMA Lab No. M-7609.

## 3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material is 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 | | 20 |
| Number of subjects completing study | | 20 |
| Age Range | | 21-55 |
| Sex | Male | 3 |
| | Female | 17 |
| Race | Caucasian | 19 |
| | Hispanic | 1 |
| | Asian | 0 |

4.1 Standards for Inclusion in a Study:

- Individuals eighteen years of age or older.
- Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
- Individuals who have completed a preliminary medical history mandated by AMA Laboratories, Inc.
- Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc., only.
- Individuals with no known abnormal response to sunlight.

4.2 Standards for Exclusion from a Study:

- Individuals who are under doctor's care.
- Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
- Individuals with chronic skin allergies.
- Individuals with suntan or sunburn.
- Individuals with abnormal reaction to the sun.
- Pregnant or lactating females.

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.

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 sun exposure after a winter season of no 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 Procedure:

A bank of four 40 W fluorescent bulbs (Sylvania, 350 Blacklight, F40/350BL) with a continuous long-wave UV-A spectrum ranging between 320 and 400 nm (peak 365 nm) was used. Prior to initiation of screening, the intensity of the light source was determined by using an IL 1700 Research Radiometer; SED 038 detector, with a W Diffuser and a UV-A Filter.

The inner left arm is designated as the control (non-irradiated) site and the inner right arm as the test site. On the initial day of the study, the test sites are tape stripped with hypo-allergenic tape 3 times to remove several layers of cornified epithelium. Two-tenths of a milliliter (0.2 ml or 0.2 g) of test material is placed onto a 2 cm x 2 cm Parke-Davis Readi Bandage occlusive patch or the equivalent, then applied to the non-irradiated control site (left arm) and allowed to remain in place for 24 hours.

Concurrently the test material is applied to the right arm directly onto the skin. The site is then irradiated with non-erythemogenic ultraviolet (UV-A) irradiation at a distance of 10 cm from the source and receiving a UV-A light dosage of greater than 4.4 J/cm$^2$. The test site is then covered with a Parke-Davis Readi-Bandage type occlusive patch containing additional test material (0.2 ml or 0.2 g) for a period of 24 hours, then removed. Hydrophilic ointment USP serves as the negative control (irradiated and non-irradiated). Immediately following and at approximately twenty four, forty eight hours and 1 week post removal all sites are scored as follows:

0 - No evidence of any effect
? - Minimal, faint, uniform or spotty erythema
1 - Pink uniform erythema covering most or the entire contact site
2 - Pink-red erythema visibly uniform in entire contact site
3 - Bright red erythema with or without petechiae or papules
4 - Deep red erythema with or without vesiculation or weeping
T - Tan

6.0 Results:

Please refer to attached Tables.

7.0 Observations:

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

8.0 Archiving:

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

9.0 Reference:

1. Kaidbey, K.H. and Kligman, A.M.: Identification of topical photosensitizing agents in humans. J. Invest. Dermatol., 70: 149-151, 1978.
2. Kaidbey, K.H. and Kligman, A.M.: Identification of contact photosensitizers by human assay. In "Current concepts in cutaneous toxicity", edited by V.A. Drill and P. Lazar Academic Press, Inc., pp. 55-68, 1980.

10.0 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.

11.0 Conclusions:

The test material (AMA Lab No.: M-7609; Client No.: AH Lot # 125-281, Badger Kids SPF30 Lotion SF2 Autumn Harp Laboratory 11/12/2012) when tested as described herein, may be considered to be **NON-PHOTOTOXIC** according to the reference.

Mayya Tatsene, M.D.
Study Director

Breanna Wanamaker, A.A. (Candidate)
Technician

David R. Winne, B.S.
Technical Director

12/19/12
Date

## TABLE 1

AMA Lab. No.: M-7609
Client No.: AH Lot # 125-281, Badger Kids SPF30 Lotion SF2
Autumn Harp Laboratory 11/12/2012

| Subject ID | RACE | Sex | UV-A Light Dosage ($J/cm^2$) | Exposure (Min) | 0 Hour Reading of Site | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Right Arm | | Left Arm | |
| | | | | | Control* | Test | Control* | Test |
| 00 0002 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 08 4686 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 21 1413 | H | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 44 7118 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 48 0738 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 52 5216 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 56 1117 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 60 2057 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 2435 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 3596 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 7431 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 9835 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 66 8507 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 0500 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 2480 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 72 6793 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 1783 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 4376 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 76 2719 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 80 4036 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |

## TABLE 2

AMA Lab. No.: M-7609
Client No.: AH Lot # 125-281, Badger Kids SPF30 Lotion SF2
Autumn Harp Laboratory 11/12/2012

| Subject ID | RACE | Sex | UV-A Light Dosage ($J/cm^2$) | Exposure (Min) | 24 Hour Reading of Site | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Right Arm | | Left Arm | |
| | | | | | Control* | Test | Control* | Test |
| 00 0002 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 08 4686 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 21 1413 | H | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 44 7118 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 48 0738 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 52 5216 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 56 1117 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 60 2057 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 2435 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 3596 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 7431 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 9835 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 66 8507 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 0500 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 2480 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 72 6793 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 1783 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 4376 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 76 2719 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 80 4036 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |

## TABLE 3

AMA Lab. No.: M-7609
Client No.: AH Lot # 125-281, Badger Kids SPF30 Lotion SF2
Autumn Harp Laboratory 11/12/2012

| Subject ID | RACE | Sex | UV-A Light Dosage ($J/cm^2$) | Exposure (Min) | 48 Hour Reading of Site | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Right Arm | | Left Arm | |
| | | | | | Control* | Test | Control* | Test |
| 00 0002 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 08 4686 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 21 1413 | H | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 44 7118 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 48 0738 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 52 5216 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 56 1117 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 60 2057 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 2435 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 3596 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 7431 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 9835 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 66 8507 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 0500 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 2480 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 72 6793 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 1783 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 4376 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 76 2719 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 80 4036 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |

## TABLE 4

AMA Lab. No.: M-7609
Client No.: AH Lot # 125-281, Badger Kids SPF30 Lotion SF2
Autumn Harp Laboratory 11/12/2012

| Subject ID | RACE | Sex | UV-A Light Dosage ($J/cm^2$) | Exposure (Min) | 7 Day Reading of Site | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Right Arm | | Left Arm | |
| | | | | | Control* | Test | Control* | Test |
| 00 0002 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 08 4686 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 21 1413 | H | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 44 7118 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 48 0738 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 52 5216 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 56 1117 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 60 2057 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 2435 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 3596 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 7431 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 62 9835 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 66 8507 | C | M | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 0500 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 70 2480 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 72 6793 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 1783 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 74 4376 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 76 2719 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |
| 80 4036 | C | F | 4.60 | 15 | 0 | 0 | 0 | 0 |

* - Hydrophilic Ointment USP
0 - No evidence of any effect
? - Minimal, faint, uniform or spotty erythema
1 - Pink uniform erythema covering most or the entire contact site
2 - Pink-red erythema visibly uniform in entire contact site
3 - Bright red erythema with or without petechiae or papules
4 - Deep red erythema with or without vesiculation or weeping
T - Tan

Evaluation Period:

This study was conducted from December 11, 2012 through December 18, 2012.

12.0 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

12/19/12
Date