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## AN INVESTIGATION INTO THE SKIN MOISTURIZATION EFFICACY OF TOPICALLY APPLIED TEST MATERIAL

AMA Ref. No.:

MS07.MOIST.L1358.REP.PSO

Date:

November 12, 2007

Sponsor:

Pure Source, Inc. 9750 NW 17th Street Miami, Florida 33172

1.0 Objective: The purpose of this study was to evaluate the moisturizing properties of a test product following a single application of each test product and after one week of daily use. Instrumental evaluations were conducted to compare the test material to untreated skin on the same test panelists at 15 minutes, 1, 2, 4, 6 post application and after one week of daily use.

#### 2.0 Sample Description:

On September 25, 2007 one test sample labeled Agua Scoop, 1057B1-16 was received from Pure Source, Inc. and assigned AMA Lab No. L-1358.

#### 3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test materials were assigned unique laboratory code numbers 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 Population Demographics:

| Number of subjects en | rolled         | 5      |
|-----------------------|----------------|--------|
| Number of subjects co | mpleting study | 5      |
| Age Range             |                | 6 - 56 |
|                       | Male           |        |
|                       | Female         | 5      |
| Race                  | Caucasian      | 5      |
|                       | Hispanic       | 0      |

## 4.1 Standards For Inclusion In a Study:

- 1. Individuals in general good health and free of any acute or chronic health problems, including neurological, dermatological, ophthalmologic or systemic disorder that may interfere with the results, at the discretion of the Study Director.
- 2. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with instrumental readings.
- 3. Individuals who have completed a preliminary medical history and screening document mandated by AMA Laboratories, Inc.
- 4. Individuals who have read, understood and signed an informed consent document required by CFR Title 21, Part 50, Subpart B regulations.
- 5. Individuals able to cooperate with the Investigator and research staff, willing to have test material applied according to the protocol, and complete the course of study.
- 6. Individuals with no known abnormal responses to topically applied products.

## 4.2 Standards For Exclusion From a Study:

- 1. Individuals who are under the care of a physician.
- 2. Individuals who are currently taking any medication that may mask or interfere with the test results at the discretion of the Study Director.
- 3. Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes or any disease that would increase risk associated with study participation.
- 4. Females who are pregnant, lactating, have been pregnant, or given birth within the six month period immediately preceding study commencement. Females who intend to become pregnant over the study period.

- 5. Subjects exhibiting current sunburn, rashes, scratches, burn marks, etc., which might interfere with the evaluation of test results.
- Individuals diagnosed with chronic skin allergies or with history of hypersensitivity to cosmetics in general and moisturizers in particular.

## 4.3 Informed Consent and Medical History:

Prior to initiating the study, a signed informed consent was obtained, in accordance with CFR Title 21, Part 50, Subpart B, from each panelist, describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. 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.

#### 4.4 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 also 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 Methodology:

Five healthy panelists between the ages of 26 and 56 were inducted into this study. In order to pre-condition the test sites and keep all topical treatments constant for all test subjects, panelists were required to abstain from using lotions, creams, or any other cosmetic moisturizers on the inner forearms for a period of three days prior to commencement.

The inner forearm region, midway between the wrist and elbow, was designated as the test area. Two, 4 cm by 4 cm (16 cm<sup>2</sup>), test sites were delineated using a gentian violet surgical skin marker and standard template. The test article was assigned according to a randomized complete block design wherein one site served as the untreated control while the remaining site received treatment with the test material. Test material was applied to the surface of each panelist's forearm by a trained technician at a concentration of 2.0 mg/cm<sup>2</sup>.

Biophysical measurements were conducted on the skin surface at time 0 (pre-treatment baseline), 15 minutes, 1, 2, 4 and 6 hours following a single application of the test material and after 1 week of daily use (prior to being applied on Day 7). Subjects returned to the test facility and filled out the self assessment questionnaire after 7 days of treatment.

## Moisturization via Electroconductivity-Novameter

A Novameter (NOVA DPM, Nova Technology Corp., Gloucester, Mass.) was used to obtain measurements of skin surface impedance to determine electroconductivity. This meter provides a relative measure of the retained water content in the skin as a measure of the skin's dielectric value. Skin impedance was recorded automatically when equilibrium was achieved. Increases in electroconductivity values are generally regarded as higher moisture retention.

#### References:

1) Leveque, J.L., Derigal, J.: Impedance Methods for Studying Skin Moisturization, J.Soc. Cosmet. Chem., 34: 419-428, 1983.

#### 6.0 Statistical Source Data:

The source data consist of Novameter readings taken prior to application, time 0 (pre-treatment baseline), 15 minutes, 1, 2, 4 and 6 hours following a single application of the test material and at 1 week after daily use. Data used in statistical analysis, where applicable, reflect changes observed on the treatment site compared to the untreated control site.

- 7.0 Results: Please see attached Table.
- 8.0 Observations:

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

9.0 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.

#### 10.0 **Discussion and Conclusions:**

Within the limits imposed by the conduct and population size of the study described herein, the following conclusions may be drawn: Test material (AMA Lab No.: L-1358; Client No.: Agua Scoop, 1057B1-16) yielded immediate increases in moisturization an average of 442.91% at 15 minutes post application. Statistically significant increases in moisture retention continued to be observed throughout the six hour test period following a single application. The same product also yielded statistically significant increases of 116.85% after 1 week of daily use and prior to any applications on the evaluation day.

The test material was reported by the majority of test panelists to be effective in improving skins overall health. 100% of the subjects felt the treatment caused their skin to look and feel significantly firmer and more plump after one week.

Tátsene. M.D

Study Director

David R. Winne, B.S. **Technical Director** 

11/12/07

**Technician** 

**Date** 

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# Table 1 MOISTURIZATION STUDY NOVAMETER READINGS

AMA Lab No.: L-1358 Client No.:

Aqua Scoop, 1057B1-16

|         | Untreated |        |        |        |       |        |        |
|---------|-----------|--------|--------|--------|-------|--------|--------|
|         | Baseline  | 15 Min | 1 Hr   | 2 Hr   | 4 Hr  | 6 Hr   | 1 Week |
|         |           |        |        |        |       |        |        |
| 72 2318 | 106       | 104    | 105    | 107    | 109   | 108    | 109    |
| 60 0082 | 112       | 111    | 109    | 108    | 109   | 109    | 110    |
| 48 5321 | 107       | 106    | 108    | 107    | 107   | 109    | 107    |
| 46 5776 | 109       | 109    | 108    | 107    | 109   | 107    | 110    |
| 62 2615 | 107       | 108    | 107    | 107    | 108   | 106    | 107    |
|         |           |        |        |        |       |        |        |
| Mean    | 108.2     | 107.6  | 107.4  | 107.2  | 108.4 | 107.8  | 108.6  |
| % Diff. |           | -0.55% | -0.74% | -0.92% | 0.18% | -0.37% | 0.37%  |
| t       |           | 1.18   | 1.21   | 1.12   | 0.21  | 0.39   | 0.49   |
| р       |           | 0.30   | 0.29   | 0.33   | 0.85  | 0.72   | 0.65   |

| L-1358  |          |         |        |        |        |        |         |
|---------|----------|---------|--------|--------|--------|--------|---------|
|         | Baseline | 15 Min  | 1 Hr   | 2 Hr   | 4 Hr   | 6 Hr   | 1 Week  |
|         |          |         |        |        |        |        |         |
| 72 2318 | 107      | 540     | 285    | 147    | 127    | 126    | 171     |
| 60 0082 | 111      | 752     | 189    | 169    | 136    | 136    | 273     |
| 48 5321 | 108      | 542     | 151    | 134    | 129    | 123    | 241     |
| 46 5776 | 110      | 556     | 188    | 145    | 137    | 133    | 225     |
| 62 2615 | 107      | 558     | 213    | 152    | 139    | 125    | 269     |
|         |          |         |        |        |        |        |         |
| Mean    | 108.6    | 589.6   | 205.2  | 149.4  | 133.6  | 128.6  | 235.8   |
| % Diff. |          | 442.91% | 88.95% | 37.57% | 23.02% | 18.42% | 116.85% |
| t       |          | 11.98*  | 4.26*  | 7.66*  | 11.53* | 11.18* | 7.00*   |
| р       |          | 0.00*   | 0.01*  | 0.00*  | 0.00*  | 0.00*  | 0.00*   |

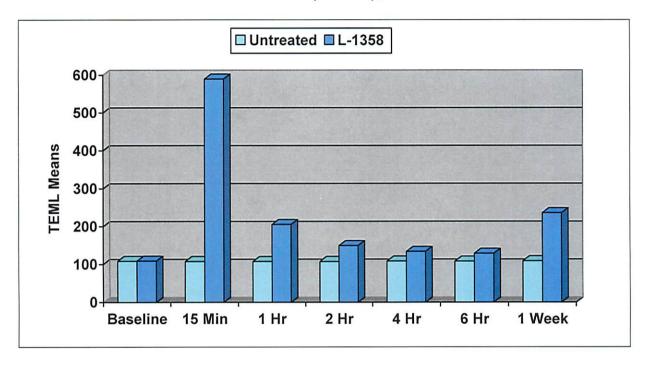
6

<sup>\*</sup>Statistically Significant

# Chart 1 MOISTURIZATION STUDY NOVAMETER READINGS

AMA Lab No.: L-1358 Client No.:

Aqua Scoop, 1057B1-16



# Table 2 MOISTURIZATION STUDY QUESTIONNAIRE SUMMARY

AMA Lab No.: L-1358 Client No.: Aqua Scoop, 1057B1-16

The following statement may or may not describe the product you just used. For each statement, please indicate whether you "agree strongly," "agree somewhat," "disagree somewhat," or "disagree strongly" with that statement as it relates to the product: Thank you.

|   | Yes | No | Somewhat |
|---|-----|----|----------|
| Skin looked significantly firmer after using product        | 80% | 0% | 20%      |
| 2. Skin felt significantly firmer after using product.      | 80% | 0% | 20%      |
| 3. Skin looked significantly more plump after using product | 80% | 0% | 20%      |
| 4. Skin felt significantly more plump after using product.  | 80% | 0% | 20%      |
| 5. Significantly improves skin's overall appearance.        | 80% | 0% | 20%      |
| 6. Significantly improves skin's overall health             | 80% | 0% | 20%      |



Date: 2/25/08

To: Todd Wilpon, Pure Source

305 477 8111

# of pages: 1 (incl.this one)

From: David R. Winne

Technical Director,

AMA Laboratories, Inc.

Tel: Cell: 914 382-9003

Fax: (845)-634-5565

Fax: 305 477 4002

### Dear Todd,

Ph.:

In response to your request, below please find some preliminary results we have seen on the study in progress on your Aqua Scoop, 1057B1-16.

- Immediate statistically significant increases in moisturization of greater than 440% at 15 minutes post application and maximum increases of greater than 500% after one week's use. Continued trends in increasing moisture observed after four weeks use.
- Decreases in the visual appearance of fine lines of up to 60% after four weeks and with decreased puffiness and pore size also observed.
- 100% of the test subjects felt the treatment caused their skin to look and feel significantly firmer and more plump after one week. Visual lifting and firming were also noted at four weeks.
- Test material has also been clinically tested and Dermatologist tested for safety and can be considered non-irritating and non-sensitizing.

Lab scale photography has also been conducted. Due to the size of the files, the initial sets of stripped images will be transferred to disc and will be sent to your attention.

We are continuing with evaluations to 8 weeks and will provide the final reports at study completion. Please feel free to call me if you have any questions or if I can supply any additional information.

Best regards,

David R. Winne Technical Director

AMA Laboratories, Inc.

#### FROM:

### Visual Wrinkle Scores

AMA Lab No.:

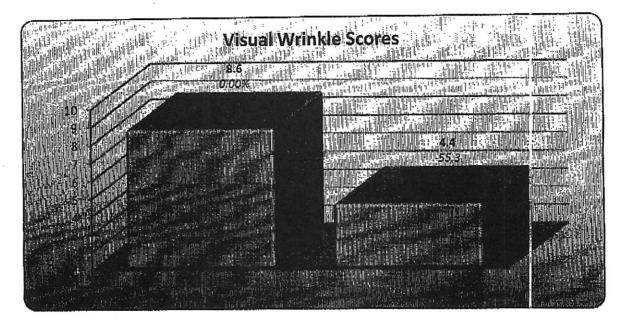
L-1358

Client No.:

Aqua Scoop, 1057B1-16

| #6 2253 10              | 4 -66. 36 |
|-------------------------|-----------|
| 146 4172 8<br>52 7818 8 | 6 -28.6%  |
| 547,157                 | 5 -42.9%  |
| \$0,6728 9              |           |
| & plifference:          | 0.005*    |
| n P                     | 5.715*    |

<sup>\*</sup> Statistically Significant



Quantification of the wrinkle condition was performed employing a ten point monadic scale, with one (1) representing the fewest, least prominent fine lines and wrinkles and ten (10) showing the maximum number of deep fine lines and wrinkles.

Visual Wrinkle Scoring method describes pattern representing 100% improvement in the condition as 1, therefore the following formula was used to calculate the reduction in wrinkle score:

where:

x = Baseline mean score

y = Week 4 mean score

z = 1 - minimum score on point monadic scale (100% reduction)