



Transepidermal Water Loss Assay

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Tradename: AC AmaraSense

Code: 12011

CAS #: 7732-18-5 & 84775-66-6 & 84082-82-6 & 84012-14-6 & 1686112-36-6 (or)
68333-16-4 (or) 9015-54-7

Test Request Form #: 8734

Lot #: N211119A

Sponsor: Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092

Study Director: Maureen Danaher

Principle Investigator: Grant Tyler

Test Performed:

Transepidermal Water Loss (TEWL) Assay

Introduction

An *in-vivo* study was conducted over a period of four weeks to evaluate the ability of **AC AmaraSense** to enhance barrier function through reduction in Transepidermal Water Loss (TEWL). Results indicate that this material is capable of efficiently reducing TEWL which allows moisture retention.

The Transepidermal Water Loss Assay was conducted to assess the moisture retention capabilities of **AC AmaraSense**.

Materials

A. Equipment: DermaLab Skin Combo (Transepidermal Water Loss Probe)

Methods

Transepidermal water loss is measured by the DermaLab Combo based on Nilsson's Vapor Pressure Gradient method. This method involves an open chamber with minimal impact on the skin, and therefore, a very low bias. Two temperature and humidity sensor sets are mounted in a chamber at different heights above the surface of the skin. The evaporation rate of the skin follows Fick's Law of Diffusion:

$$\text{Rate} = P \times [c_1 - c_2] / T$$

Where P = permeability coefficient of membrane, (c1-c2) = concentration gradient, and T = thickness of membrane).

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20 volunteers M/F between the ages of 23 and 45 and who were known to be free of any skin pathologies participated in this study. A DermaLab Combo was used to measure TEWL on the subject's volar forearms.

The instrument consists of a probe that is based upon the vapor gradient with an open chamber. This open chamber design maintains the free natural evaporation from the skin without interfering with the environment over the measurement area. This ensures unbiased and accurate readings. Operation of the water loss module is fully menu drive, allowing for pre-setting and standard deviation or measurement time. Baseline TEWL readings were taken on day one of the study.

Following initial measurements, all subjects were asked to apply 2 milligrams of each test material on their volar forearms. Measurements were taken weekly over the course of four weeks. The test material consisted of 2.0% **AC AmaraSense** in a base lotion.

Results

AC AmaraSense showed very effective moisture retention capabilities at a 2.0% concentration. Please note, each value is an average of three consecutive readings per test site.

Percent change in TEWL is calculated by the following formula:

$$\text{Percent (\%) Change} = \frac{\text{Average TEWL Value}_{T=24 \text{ hours.etc}} - \text{Average Baseline Value}_{T=0}}{\text{Average Baseline Value}_{T=0}} \times 100$$

Table 1. Average Transepidermal Water Loss of Individual Test Sites

| Averages | T = 0 | T = 1 Week | T = 2 Hours | T = 8 Hours | T = 24 Hours |
|--|-------|------------|-------------|-------------|--------------|
| Experimental (2.0% AC AmaraSense + Base Lotion) | 6.99 | 5.65 | 6.25 | 6.52 | 6.23 |
| Base Lotion | 7.61 | 7.05 | 7.32 | 7.48 | 7.25 |
| Untreated | 7.84 | 7.36 | 7.68 | 7.79 | 7.92 |

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Table 2. Comparative Transepidermal Water Loss Results Between Individual Test Sites

| Percent (%) Change | T = 0 vs 1 Week | T = 0 vs 2 Weeks | T = 0 vs 3 Weeks | T = 0 vs 4 Weeks |
|--|-----------------|------------------|------------------|------------------|
| Experimental (2.0% AC AmaraSense + Base Lotion) | -19.11 | -10.59 | -6.71 | -10.91 |
| Base Lotion | -7.26 | -3.82 | -1.62 | -4.64 |
| Untreated | -6.16 | -2.02 | -0.65 | 0.98 |

TransEpidermal Water Loss Average TEWL Readings

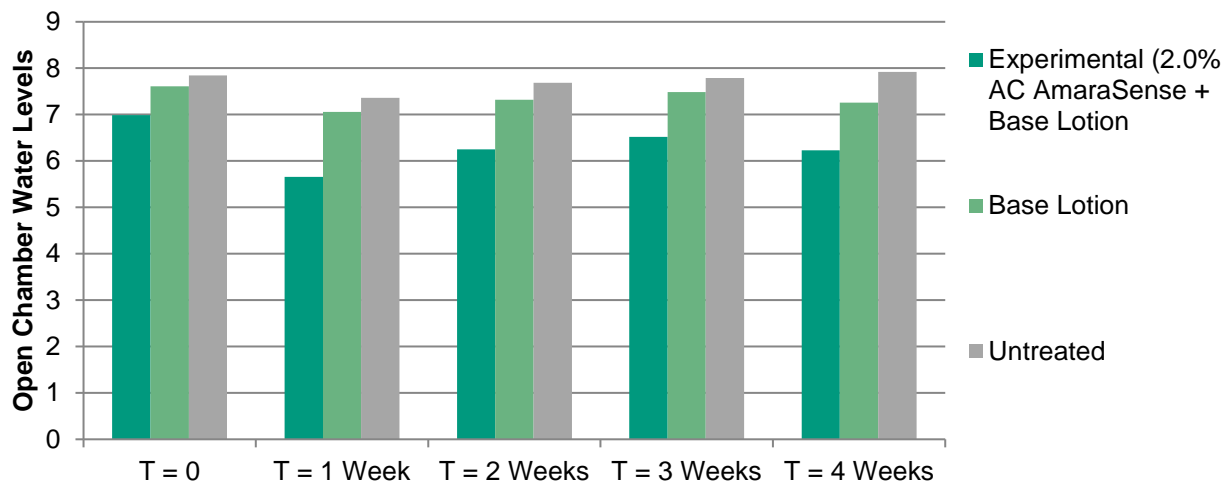


Figure 1: TEWL Measurements Taken at Individual Test Sites

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TransEpidermal Water Loss Percent (%) Change

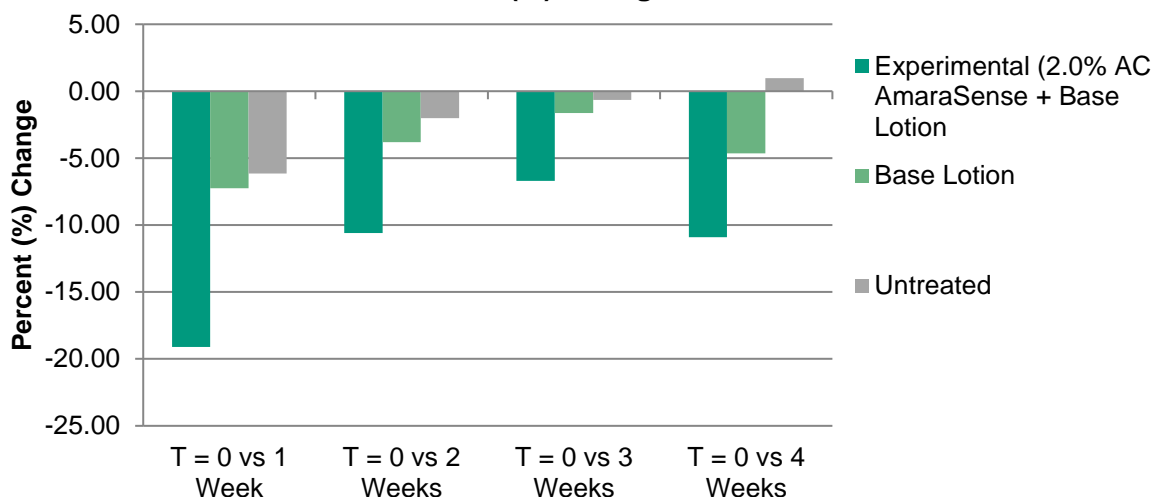


Figure 2: Comparison of Percent Reduction in Water Loss Over Time Between Two Test Sites

Discussion

As evidenced in a four week efficacy study of **AC AmaraSense** on the skin, it can be used to effectively reduce transepidermal water loss. TEWL levels were decreased by 19.11% after 1 week and by 10.91% after 4 weeks when compared to the baseline value. Results indicate that **AC AmaraSense** is capable of reducing TEWL, which allows for moisture retention.

AC AmaraSense was designed to provide moisture retention benefits, however with the present study we can confirm that this unique ingredient is not only capable of providing functional benefits but it is also capable of providing a decrease in transepidermal water loss therefore promoting moisture retention benefits when added to cosmetic applications.