

Tradename: AC PomeaShield

Code: 16935

CAS #: 7732-18-5 & 84961-57-9 & 1686112-36-6 (or) 68333-16-4

Test Request Form #: 10113

Lot #: N230313E

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

Study Director: Maureen Drumwright

Principle Investigator: Kayla Patterson

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 PomeaShield** to enhance barrier function through reduction in Transepidermal Water Loss (TEWL). Results indicate that this material is capable of efficiently reducing TEWL which allows for moisture retention.

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

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).

Twenty male and female volunteers between the ages of 23 and 45 who were known to be free of any skin pathologies and had Fitzpatrick skin types I to IV participated in this study (Table 1). 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 0.2 g of each test material on their volar forearms twice a day for a four-week period. Measurements were taken weekly over the course of four weeks. The test material consisted of 2.0% **AC PomeaShield** in a base lotion.

For added perspective, measurements of an untreated test site and a site treated with a base lotion (Cetaphil Moisturizing for All Skin Types) were recorded.

Table 1. The Fitzpatrick Classification of Skin Types Chart¹

Fitzpatrick Skin Type Descriptions*	
Skin Type	Description
I	Always burns, never tans
II	Burns easily, tans minimally
III	Burns moderately, tans to light brown
IV	Burns minimally, tans to moderate brown
V	Rarely burns, tans to dark
VI	Never burns, least sensitive to changes

*Adapted from The Surgeon General's Call to Action to Prevent Skin Cancer

Results

AC PomeaShield 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 2. Average Transepidermal Water Loss of Individual Test Sites

Averages (g/m ² /h)	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Experimental (2.0% AC PomeaShield + Base Lotion)	6.557	3.703	2.377	1.845	2.487
Base Lotion	6.315	8.063	5.963	7.238	6.432
Untreated Control	10.293	9.28	9.933	7.398	9.603

TransEpidermal Water Loss AC PomeaShield

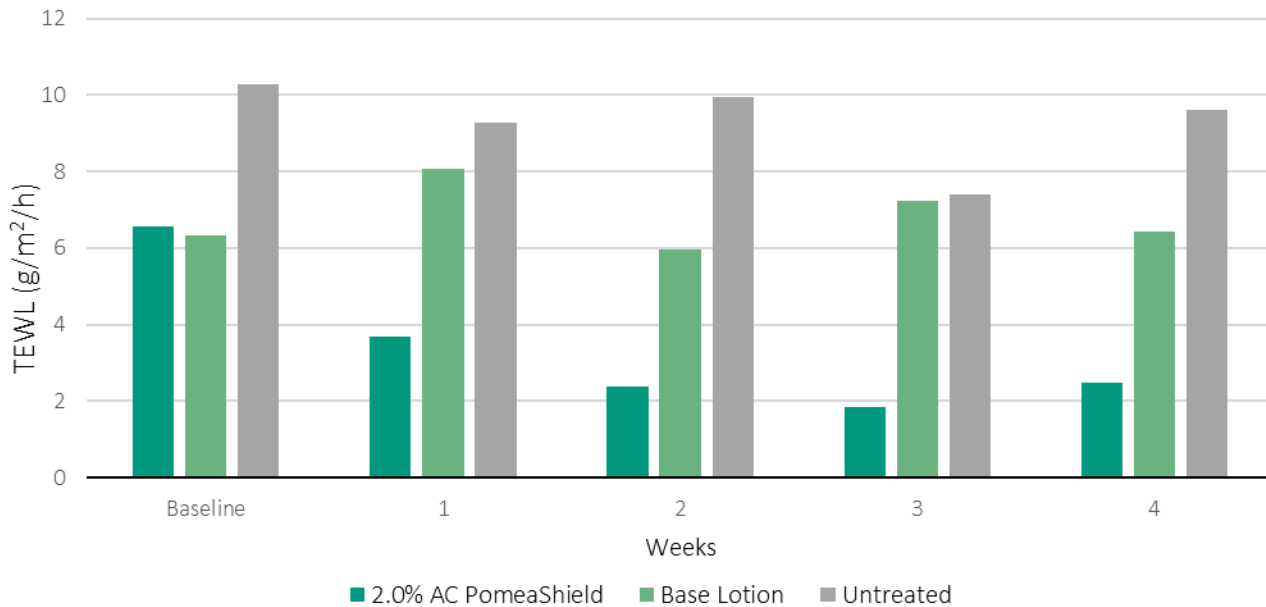


Figure 1. Average TEWL Measurements (g/m²/h) Taken at Individual Test Sites.

TransEpidermal Water Loss AC PomeaShield

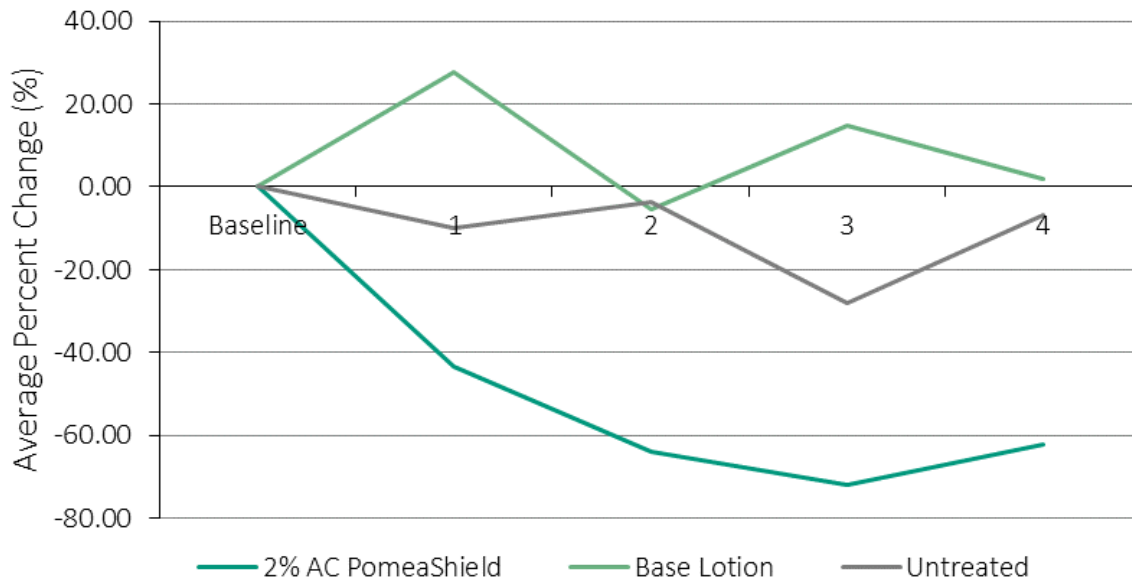


Figure 2. Percent Change in Transepidermal Water Loss of Each Time Point Compared to Baseline.

Table 3. T-test Analysis of the TEWL Percent Change (%) Between Baseline and T=4 Weeks of % AC PomeaShield (n=20, $\alpha=0.05$, df=23)

	T = 0	T = 4 weeks
Mean	6.55	2.48
Variance	68.40	6.91
t Stat	2.09	
P(T<=t) two-tail	0.047	
t Critical two-tail	2.06	

Table 4. T-test Analysis of the TEWL Percent Difference (%) Between 2.0% AC PomeaShield and Untreated Control at T = 4 weeks (n=20, $\alpha=0.05$, df=20)

	AC PomeaShield	Untreated Control
Mean	2.48	9.60
Variance	6.91	201.76
t Stat	-2.20	
P(T<=t) two-tail	0.039	
t Critical two-tail	2.085	

Discussion

As evidenced in a four-week efficacy study of **AC PomeaShield** on the skin, it can be used to effectively reduce transepidermal water loss with better results over time. When compared to the untreated control, **AC PomeaShield** had lower transepidermal water loss values by 118% ($p=0.039$) after four weeks (Table 4). After four weeks, **AC PomeaShield** reduced transepidermal water loss by 62% ($p=0.047$), while the base lotion increased values by 2% when compared to the baseline levels (Figure 1, 2; Table 3). Results indicate that **AC PomeaShield** in a lotion formulation is capable of reducing transepidermal water loss to a greater degree when compared to the base lotion and untreated sites alone.

With the present study, we can confirm that **AC PomeaShield** is capable of providing moisture retention benefits when added to personal care applications at recommended use levels. In conclusion, utilizing **AC PomeaShield** at recommended use levels enhances skin health, appearance, and feel by improving moisture retention and reducing dry, cracked, or peeling skin.

References

1. Sharma AN, Patel BC. Laser Fitzpatrick Skin Type Recommendations. [Updated 2022 Mar 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK557626/>