

Tradename: AC CytoPure PF

Code: 20757PF

CAS #: 999999-99-4

Test Request Form #: 1286

Lot #: NC130424-B

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

Study Director: *Daniel Shill*

Principal Investigator: *Kayla Goodson*

Test Performed:

Transepidermal Water Loss (TEWL) Study

Introduction

As the largest human organ, the skin's integrity is critical to properly function as a physical barrier and maintenance of a healthy appearance for aesthetics. Moisture retention is a fundamental component to the preservation of the skin's protective barrier function. Transepidermal water loss (TEWL) is the passive evaporation of water across the stratum corneum to the external environment because of the water vapor pressure gradient on both sides of the skin barrier. In healthy skin, TEWL is inversely proportional to skin hydration (i.e., decreased TEWL indicates properly hydrated skin). However, when the skin's protective barrier is compromised, TEWL levels are high and the skin feels dry, flaky, and rough. High TEWL levels, and reduced skin hydration, are correlated with skin aging and seen in many skin diseases. Consequently, moderating excessive TEWL improves the skin's protective barrier function and contributes to the appearance of healthier looking skin.

Accordingly, a transepidermal water loss study was conducted to evaluate the moisture retention properties of **AC CytoPure PF**.

Study Principle

TEWL measurements are made by placing a probe on the skin of preidentified test sites. By assessing changes in local humidity above ambient values the TEWL probe measures changes in water vapor density in a defined area over time. The controls and test materials are applied to the skin test sites twice a day and TEWL is measured weekly.

Materials

- A. Equipment:** DermaLab Skin Combo (Transepidermal Water Loss Probe)
- B. Products:** Base Lotion (Cetaphil® Moisturizing Cream for All Skin Types)
- C. Software:** Excel Analysis ToolPak (Microsoft)

Methods

10 volunteers between the ages of 23 and 45, who were known to be free of any skin pathologies with Fitzpatrick skin types I to III, participated in this study (Table 1).

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

Three randomly assigned test sites were identified on the volar forearm of participants and baseline TEWL measurements were recorded. Following baseline measurements, participants applied 0.2 g of each test material on their volar forearms twice a day for four weeks. TEWL measurements were recorded once a week for four weeks. The skin test site conditions and treatments are described below (Table 2). The Base Lotion utilized in this study was Cetaphil® Moisturizing Cream for All Skin Types.

Table 2. Descriptions of the Conditions and Treatments for each Skin Test Site

Skin Test Site	Condition	Treatment / Test Article Application Description
1	Untreated Control	None
2	Base Lotion	Base Lotion
3	AC CytoPure PF	2.0% AC CytoPure PF in Base Lotion

An average of three consecutive TEWL measurements per condition at each time point was recorded and expressed as g/m²/h. The percent change in TEWL values was calculated for each test site at every timepoint relative to Baseline values, using the following equation:

$$\text{Percent Change (\%)} = \frac{TEWL_{\text{Week}} - TEWL_{\text{Baseline}}}{TEWL_{\text{Baseline}}} \times 100$$

Results

The data obtained from this study met criteria for a valid study as the Untreated Control and Base Lotion performed as anticipated. Application of 2.0% **AC CytoPure PF** twice a day for four weeks demonstrated effective moisture retention properties by reducing TEWL throughout the study duration.

Transepidermal Water Loss AC CytoPure PF

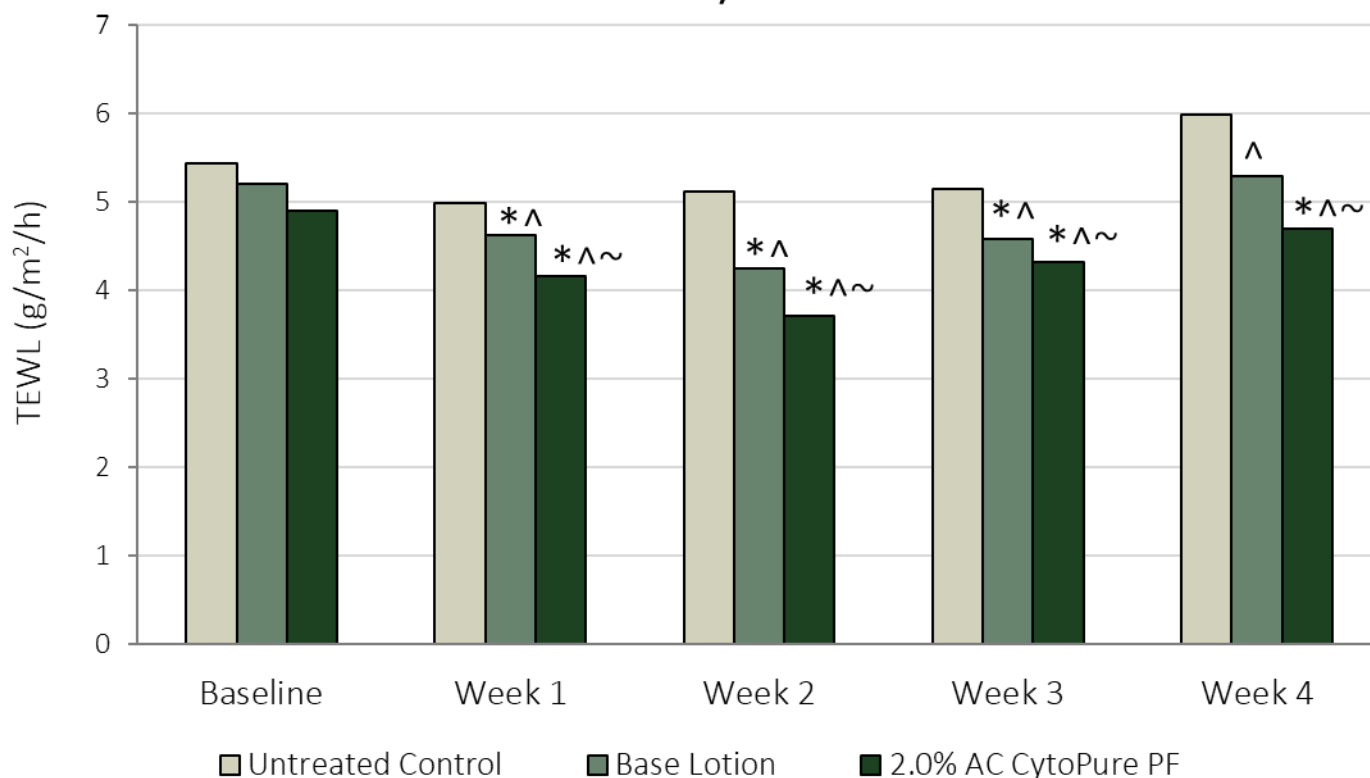


Figure 1. TEWL Measurements Overtime. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Untreated Control within the same timepoint. ~ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint

Table 3. T-test Analysis of TEWL Values After Four Weeks of Application. * indicates significance ($p \leq 0.05$) compared to Baseline values.

	Untreated Control	Base Lotion	2.0% AC CytoPure PF
P-value	0.512	0.089	0.021*

Table 4. T-test Analysis of TEWL Values After Four Weeks of Application. ^ indicates significance ($p \leq 0.05$) compared to Untreated Control within the same timepoint. ~ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

	Untreated Control vs Base Lotion	Untreated Control vs 2.0% AC CytoPure PF	Base Lotion vs 2.0% AC CytoPure PF
P-value	0.042^	0.022^	0.038~

Change in Transepidermal Water Loss AC CytoPure PF

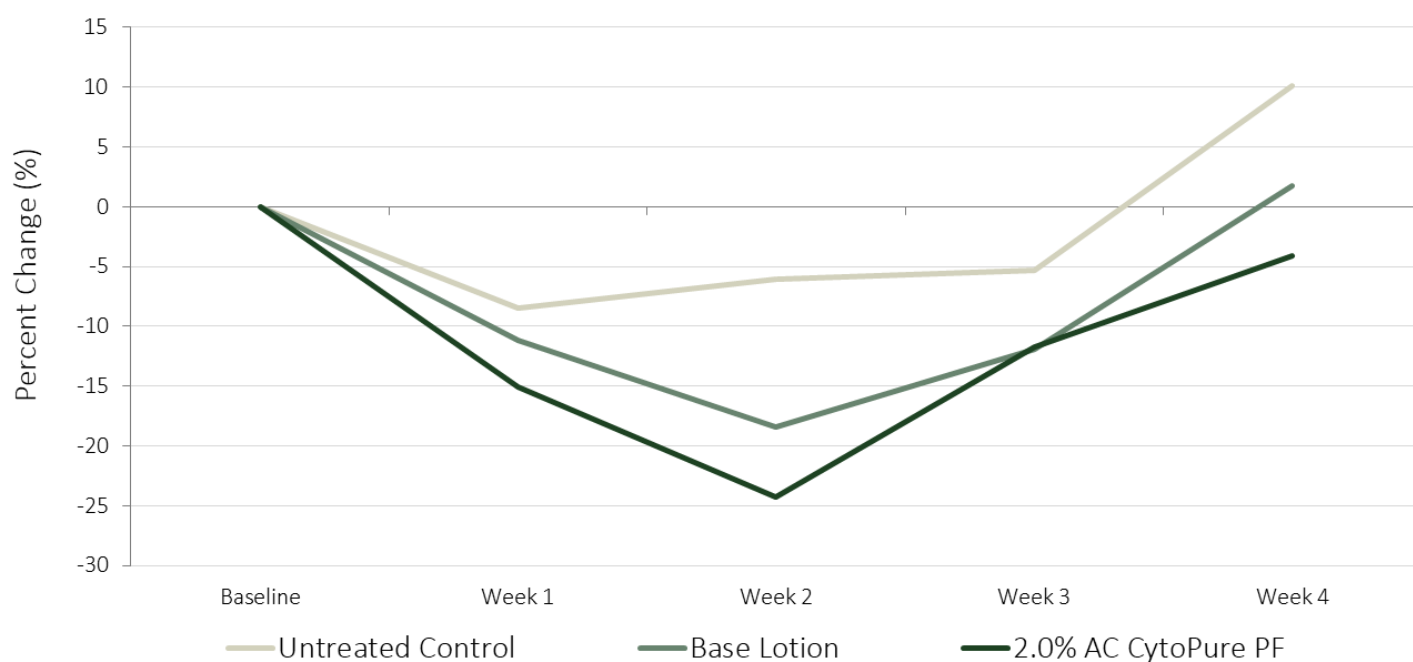


Figure 2. Percent Change in Transepidermal Water Loss Relative to Baseline Values

Discussion

The ability of **AC CytoPure PF** to retain skin moisture was assessed via TEWL throughout four weeks of twice daily application. As shown in Figure 1 and 2, TEWL did not significantly change throughout the study with the Untreated Control test site, indicating consistent skin moisturization throughout the four weeks (Table 3). The Base Lotion slightly reduced TEWL one week, two weeks, and three weeks after application, indicating the Base Lotion has a marginal moisturization effect (Figures 1, 2; Table 3). Conversely, applying 2.0% **AC CytoPure PF** twice a day for four weeks significantly reduced TEWL by 4% (Figures 1, 2; Table 3). These results demonstrate **AC CytoPure PF** has effective moisture retention properties.

Similar results are shown when examining the collective effect of each condition. There is a slight difference in TEWL between the Untreated Control and Base Lotion after four weeks (Figure 1; Table 4). However, applying 2.0% **AC CytoPure PF** significantly reduced TEWL compared to the Untreated Control and Base Lotion (Figure 1; Table 4). These results demonstrate **AC CytoPure PF** elicits moisture retention in the skin with repeated applications.

Taken together, these results indicate **AC CytoPure PF** reduces TEWL when added to personal care applications at recommended use levels. Collectively, **AC CytoPure PF** demonstrates moisture retention properties which improves the skin's protective barrier function and contributes to the appearance of healthier looking 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/>