

Tradename: Phytofuse Renew®

Code: 16586

CAS #: 90106-73-3

Test Request Form #: 3972

Lot #: NC1802103-C

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

Study Director: *Erica Segura*

Principal Investigator: *Maureen Danaher*

Test Performed:

Moisturization Study

Introduction

The skin's structural and functional integrity is predominantly dependent on sufficient hydration levels given several enzymes maintaining homeostasis within the stratum corneum are hydrolytic and do not occur efficiently if water is below an acceptable threshold. Adequately hydrated skin is flexible, resistant to shearing forces, an effective protective barrier, and appears more youthful with a reduction in fine lines and wrinkles. Conversely, insufficiently hydrated skin is present in many skin diseases and exhibits a compromised protective barrier, feels dry, flaky, and rough, and is correlated with skin aging. Consequently, proper hydration maintains the skin's structural and functional integrity and contributes to the appearance of healthier looking skin.

Accordingly, a moisturization study was conducted to evaluate the skin hydrating properties of **Phytofuse Renew®**.

Study Principle

Hydration measurements are made by placing a probe on the skin of preidentified test sites. The hydration probe evaluates conductance properties by alternating voltages in the upper layers of skin and provides a measurement of local hydration. The controls and test materials are applied to the skin test sites twice a day and hydration is measured weekly.

Materials

- A. Equipment:** DermaLab Skin Combo (Hydration 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 moisture 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. Moisture 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	0.5% Phytofuse Renew ®	0.5% Phytofuse Renew ® in Base Lotion

An average of three consecutive moisture measurements per condition at each time point was recorded and expressed as micro-Siemens (µS). Data are displayed as averages from all volunteers and analyzed using t-tests with statistical significance accepted at $p \leq 0.05$. The percent change in moisture was calculated for each test site at every timepoint relative to Baseline values, using the following equation:

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

Results

The data obtained met criteria for a valid study as the Untreated Control and Base Lotion performed as anticipated. Application of 0.5% **Phytofuse Renew**® twice a day for four weeks demonstrated effective skin hydrating properties by enhancing moisturization throughout the study duration.

Skin Hydration Phytofuse Renew®

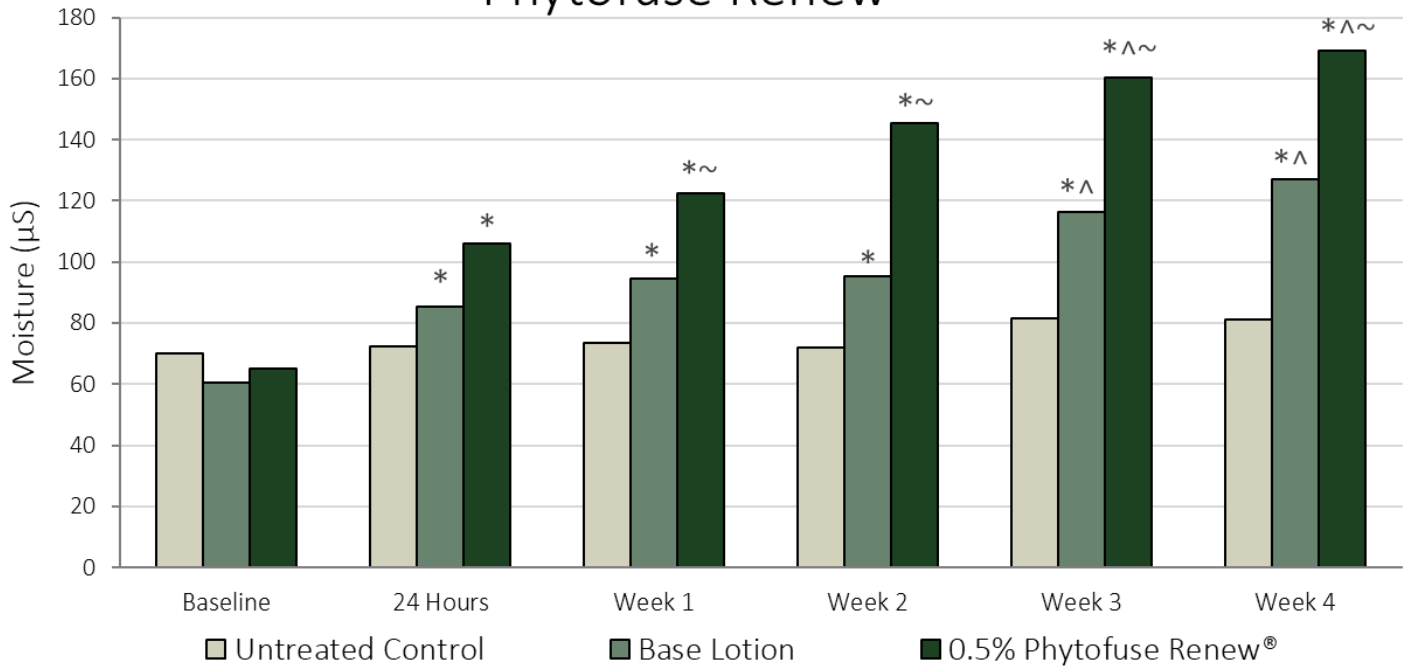


Figure 1. Skin Hydration Overtime. * indicates significance ($p \leq 0.05$) compared to Baseline values. ^ indicates significance ($p \leq 0.05$) compared to Untreated Control within the same timepoint. ~ indicates significance ($p \leq 0.05$) compared to Base Lotion within the same timepoint.

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

	Untreated Control	Base Lotion	2.0% Phytofuse Renew®
4 Weeks After Application	0.516	0.041*	0.026*

Table 4. T-test Analysis of Moisture Levels 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% Phytofuse Renew®	Base Lotion vs 2.0% Phytofuse Renew®
4 Weeks After Application	0.048^	0.034^	0.028~

Change in Skin Hydration Phytofuse Renew®

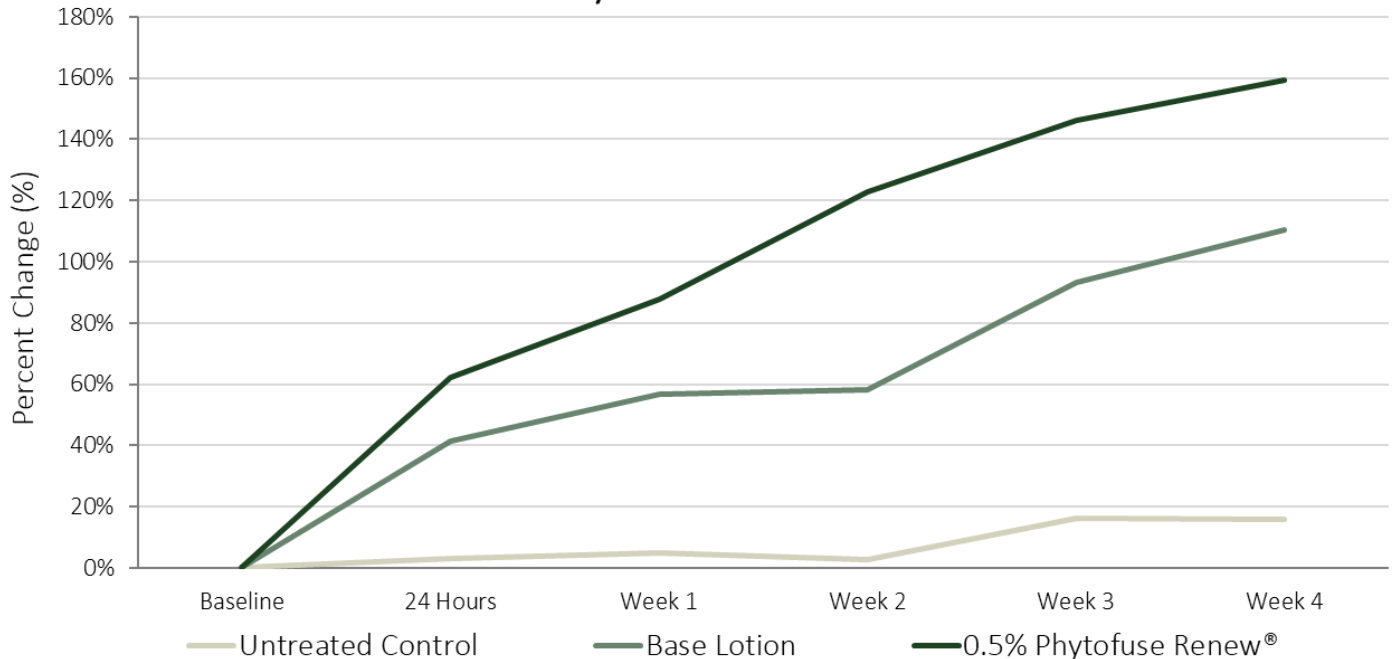


Figure 2. Percent Change in Skin Hydration Relative to Baseline Values

Discussion

The ability of **Phytofuse Renew®** to enhance skin moisturization was assessed via hydration throughout four weeks of twice daily application. As shown in Figure 1 and 2, skin moisture did not significantly change throughout the study with the Untreated Control test site, indicating consistent skin hydration over four weeks of application (Table 3). The Base Lotion slightly improved moisturization throughout the study after application, indicating the Base Lotion has a marginal moisturization effect (Figures 1, 2; Table 3). However, applying 0.5% **Phytofuse Renew®** twice a day for four weeks significantly augmented skin moisturization by 159% (Figures 1, 2; Table 3). These results demonstrate **Phytofuse Renew®** has effective skin hydration properties.

Similar results are shown when examining the collective effect of each condition. There is a slight difference in skin hydration between the Untreated Control and Base Lotion after four weeks (Figure 1; Table 4). However, applying 0.5% **Phytofuse Renew®** significantly increased hydration compared to the Untreated Control and Base Lotion (Figure 1; Table 4). These results demonstrate **Phytofuse Renew®** elicits skin moisturization with repeated applications.

Taken together, these results indicate **Phytofuse Renew®** increases skin moisturization when added to personal care applications at recommended use levels. Collectively, **Phytofuse Renew®** demonstrates skin hydration 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/>