

ACTIVE CONCEPTS LLC

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Tradename: AcquaSeal® Coconut

**Code:** 20742

CAS #: 8001-31-8

Test Request Form #: 1036

Lot #: N/A

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

Study Director: Erica Batounis

Principal Investigator: Meghan Darley

#### **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 AcquaSeal® Coconut.

#### 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)



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#### 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 IV, participated in this study (Table 1).

**Table 1.** The Fitzpatrick Classification of Skin Types Chart<sup>1</sup>

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. Additional moisture measurements were taken up to two weeks after application had ceased. 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	2.0% AcquaSeal® Coconut	2.0% AcquaSeal® Coconut in Base Lotion	

An average of three consecutive moisture measurements per condition at each time point was recorded and expressed as micro-Siemens ( $\mu$ S) for each volunteer. 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:

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

#### <u>Results</u>

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% **AcquaSeal® Coconut** twice a day for four weeks demonstrated effective skin hydrating properties by enhancing moisturization throughout the study duration.



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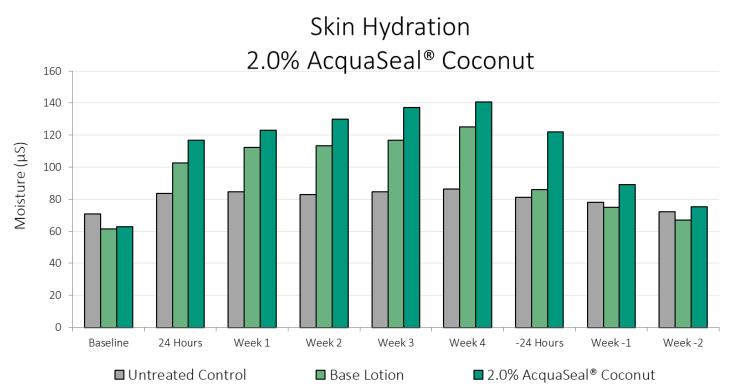


Figure 1. Skin Hydration Overtime

**Table 3.** T-test Analysis of Moisture Levels from Baseline to After Four Weeks of Application and 24 Hours and One Week of Regression with No Application

	Untreated Control	Base Lotion	2.0% AcquaSeal® Coconut
4 Weeks After Application	0.089	< 0.001	< 0.001
24 Hours of Regression	0.261	0.261 < 0.001	
1 Week of Regression	0.458	0.024	0.002

**Table 4.** T-test Analysis of Moisture Levels After Four Weeks of Application and 24 Hours and One Week of Regression with No Application

	Untreated Control vs Base Lotion	Untreated Control vs 2.0%  AcquaSeal® Coconut	Base Lotion vs 2.0% AcquaSeal®  Coconut
4 Weeks After Application	< 0.001	< 0.001	0.021
24 Hours of Regression	0.427	< 0.001	< 0.001
1 Week of Regression	0.625	0.055	0.046



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# Change in Skin Hydration 2.0% AcquaSeal® Coconut

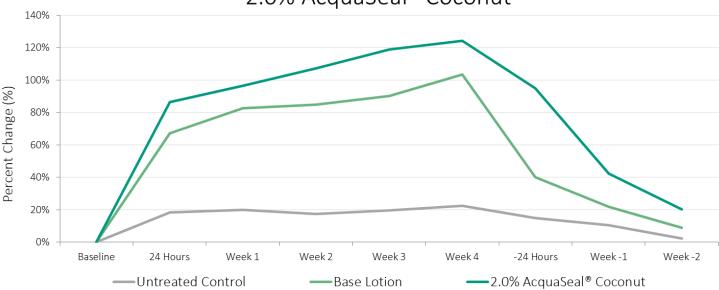


Figure 2. Percent Change in Skin Hydration Relative to Baseline Values

#### **Discussion**

The ability of AcquaSeal® Coconut to enhance skin moisturization was assessed via hydration throughout four weeks of twice daily application and 2 weeks without 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 throughout the four weeks (Table 3). The Base Lotion slightly increased skin hydration 4 weeks after application, indicating the Base Lotion has a marginal skin hydrating effect (Figures 1, 2; Table 3). Conversely, applying 2.0% AcquaSeal® Coconut twice a day for four weeks significantly augmented skin moisturization by 124% (Figures 1, 2; Table 3). Additionally, after daily application of 2.0% AcquaSeal® Coconut ceased for 24 hours and 1 week, skin moisturization remained significantly elevated by 95% and 42% compared to baseline levels, respectively (Figures 1, 2; Table 3). These results demonstrate AcquaSeal® Coconut 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 2.0% **AcquaSeal® Coconut** significantly increased hydration compared to the Untreated Control and Base Lotion (Figure 1; Table 4). These results demonstrate **AcquaSeal® Coconut** elicits skin moisturization with repeated applications.

Taken together, these results indicate **AcquaSeal® Coconut** increases skin moisturization when added to personal care applications at recommended use levels. Collectively, **AcquaSeal® Coconut** 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/