

**Tradename:** AC ExoCalm

**Code:** 60192

**CAS #:** 7732-18-5 & 84775-66-6 & 123465-35-0 (or) 8002-43-5

**Test Request Form #:** 11947

**Lot #:** 9400822

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

**Study Director:** *Daniel Shill*

**Principal Investigator:** *Kayla Patterson*

**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 immediate and short-term skin hydrating properties of **AC ExoCalm**. A sample of **Competitive Exosome C** was tested to demonstrate the superior nature of Bioauthentic Exosomes as a delivery system.

**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 site once and hydration is measured at four time increments within a 24-hour period.

**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

20 volunteers between the ages of 23 and 54, 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

Four 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 treatment to their volar forearm once during the 24-hour test period. A dry down phase was not incorporated into the study design, prior to baseline measurements, to resemble a real-world consumer application experience. Moisture measurements were recorded at four-time increments after the application of test materials. 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% <b>Competitive Exosome C</b>	2.0% <b>Competitive Exosome C</b> in Base Lotion
4	2.0% <b>AC ExoCalm</b>	2.0% <b>AC ExoCalm</b> in Base Lotion

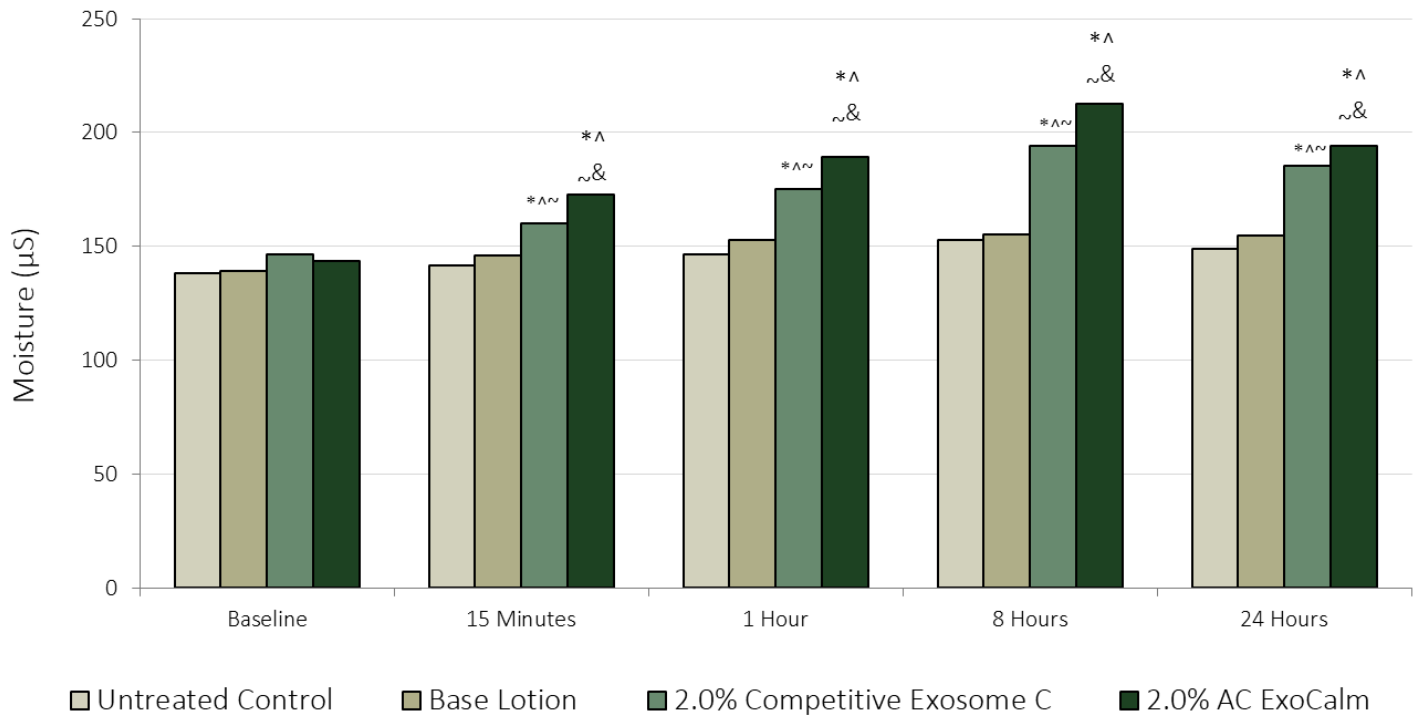
An average of three consecutive moisture measurements per condition at each time point was recorded and expressed as micro-Siemens ( $\mu\text{S}$ ) for each volunteer. Data are displayed as averages from all volunteers and analyzed using t-tests with statistical significance accepted at  $p \leq 0.05$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

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

## Results

The data obtained met criteria for a valid study as the Untreated Control and Base Lotion performed as anticipated. Application of 2.0% **AC ExoCalm** once in a 24-hour period demonstrated effective immediate and short-term skin hydrating properties by enhancing moisturization throughout the study duration to a greater extent than 2.0% **Competitive Exosome C**.

## Skin Hydration AC ExoCalm



**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. & indicates significance ( $p \leq 0.05$ ) compared to **Competitive Exosome C** within the same timepoint.

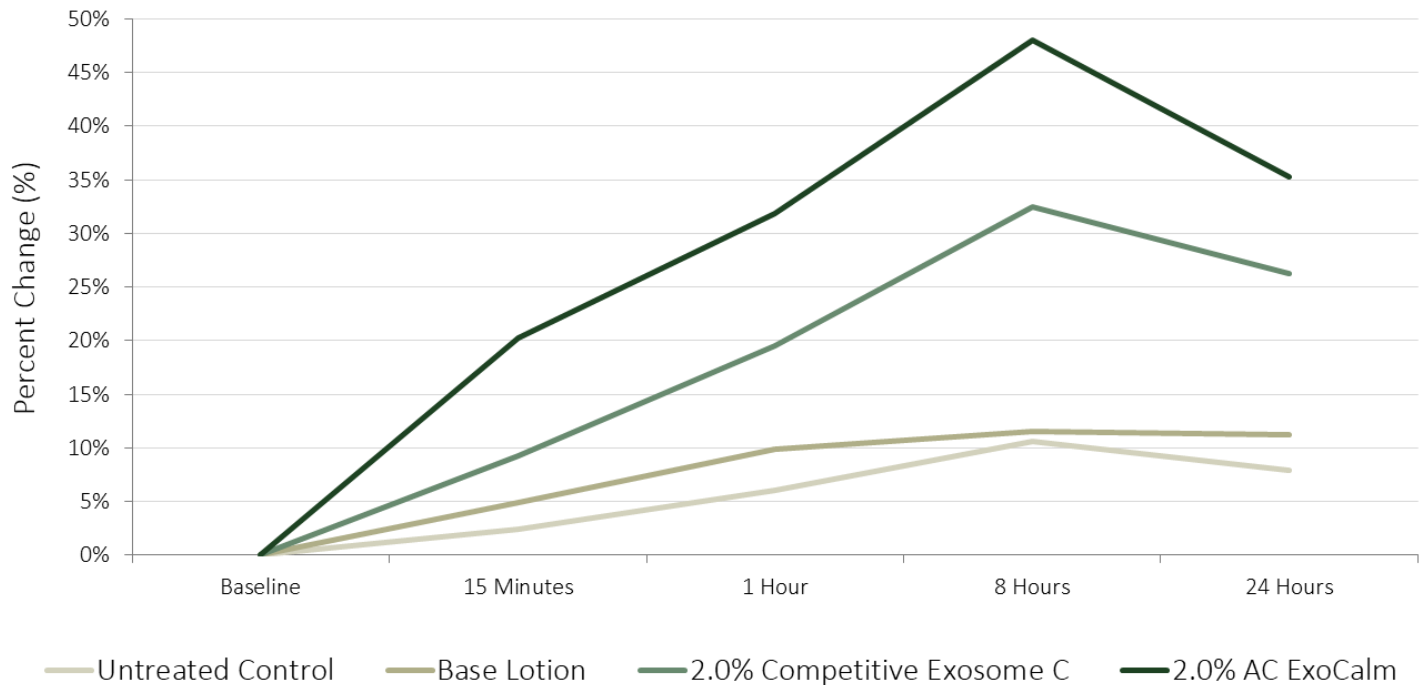
**Table 3.** P-values from t-test Analyses of Moisture Levels from Baseline to 8 Hours and 24 Hours After Application. \* indicates significance ( $p \leq 0.05$ ) compared to Baseline values.

	Untreated Control	Base Lotion	2.0% <b>Competitive Exosome C</b>	2.0% <b>AC ExoCalm</b>
<b>8 Hours After Application</b>	0.086	0.102	< 0.001*	< 0.001*
<b>24 Hours After Application</b>	0.061	0.096	< 0.001*	< 0.001*

**Table 4.** T-test Analysis of TEWL Values 8 Hours After Application. ^ indicates significance ( $p \leq 0.05$ ) compared to Untreated Control. ~ indicates significance ( $p \leq 0.05$ ) compared to Base Lotion. & indicates significance ( $p \leq 0.05$ ) compared to Competitive Exosome C within the same timepoint.

	Untreated Control	Base Lotion	2.0% Competitive Exosome C	2.0% AC ExoCalm
Untreated Control	----	0.794	< 0.001 <sup>^</sup>	< 0.001 <sup>^</sup>
Base Lotion	0.794	----	0.003 <sup>~</sup>	< 0.001 <sup>~</sup>
2.0% Competitive Exosome C	< 0.001 <sup>^</sup>	0.003 <sup>~</sup>	----	0.032 <sup>&amp;</sup>
2.0% AC ExoCalm	< 0.001 <sup>^</sup>	< 0.001 <sup>~</sup>	0.032 <sup>&amp;</sup>	----

## Change in Skin Hydration AC ExoCalm



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

## Discussion

The ability of **AC ExoCalm** to enhance skin moisturization was assessed via hydration throughout 24 hours with one initial 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 24 hours (Table 3). Similarly, skin moisture was not significantly altered throughout the study with Base Lotion application, indicating the Base Lotion does not exert significant hydration on the skin (Figures 1, 2; Table 3). Conversely, 2.0% **Competitive Exosome C** significantly augmented skin hydration compared to baseline, by 32% eight hours after application (Figures 1, 2; Table 3). However, applying 2.0% **AC ExoCalm** once in a 24-hour period significantly augmented skin moisturization by 48% eight hours after application, and remained elevated 24 hours after application (Figures 1, 2; Table 3). These results demonstrate **AC ExoCalm** provides superior effective immediate and short-term skin hydration properties compared to **Competitive Exosome C**.

Similar results are shown when examining the collective effect between each condition. There is no difference in skin hydration between the Untreated Control and Base Lotion eight hours after application (Figure 1; Table 4). However, applying 2.0% **AC ExoCalm** significantly increased hydration compared to the Untreated Control, Base Lotion, and 2.0% **Competitive Exosome C** (Figure 1; Table 4). These results demonstrate **AC ExoCalm** elicits acute skin moisturization with just one application.

Taken together, these results indicate **AC ExoCalm** increases skin moisturization immediately when added to personal care applications at recommended use levels. Importantly, the absence of a dry down phase prior to baseline measurements emphasizes these results and is more reflective of a real-world consumer application experience. Collectively, **AC ExoCalm** demonstrates immediate and short-term 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/>