

# **Moisturization Performance of a Novel, Foaming Instant Hand Sanitizer (IHS) Containing a Synergistic Skin Moisturizing Blend**

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## Abstract

Hand hygiene regimens play an integral role in the prevention of disease transmission; however the rigors of these regimens in a typical healthcare setting can result in poor skin condition and the disruption of skin barrier function. It is proposed the proper formulation of hand hygiene products can maintain and improve skin condition under these rigorous conditions<sup>1-3</sup>. Although many formulations contain ingredients known to provide skin hydration, the levels at which these ingredients are incorporated may not provide the intensive moisturization required to meet the needs of healthcare workers<sup>2</sup>. For this reason, a well documented and scientific approach to substantiation of moisturization claims is especially necessary in healthcare settings.

## Methods

**Acute Moisturization Study:** 30 adult female healthcare workers were recruited and consented for study participation. Subjects pre-washed their forearms with a bland, foaming handwash and allowed skin to equilibrate for 30±1 minute in a temperature (70°F±4°F) and humidity (45%RH±15%RH) controlled room prior to beginning study treatment. The corners of four 3cmX4cm rectangles were marked on the volar forearm of each subject with a permanent marker. A Courage+Khazaka MPA9 with Corneometer CM825 probe was used to take skin capacitance readings at 30±1 minute post pre-wash to determine the baseline value. Experimental treatments (PURELL® Skin Nourishing Foam, Ecolab Quick-Care Aerosol, 3M Avagard Foam, DEB Microsan Encore Foam, Steris Alcare OR Aerosol, Untreated Control) were randomly assigned to the demarcated areas on subjects' arms. Approximately 110 minutes post pre-wash, 2mg/cm<sup>2</sup> of test article was applied to the appropriate site and gently rubbed into the skin with a gloved finger in a clockwise motion for 15 seconds. 10±1 and 120±1 minutes after test article application, Corneometer readings were taken to assess skin hydration. Results were analyzed using an ANOVA with multiple comparisons at an alpha = 0.05.

**Clinical Trial:** Four intensive care units at Akron General Medical Center in Akron, Ohio participated in a four week clinical trial where 2 units were assigned to the PURELL Skin Nourishing Foam group and two units were assigned to the control group. Units designated as controls continued to use the hospital provided PURELL Instant Hand Sanitizer Foam. Test articles were blinded and placed in dispensers on the units for four weeks. Health Care Worker skin capacitance measurements were taken using a Courage+Khazaka MPA9 with Corneometer CM825 probe at baseline, 2 weeks and 4 weeks (February 11 – March 21, 2008). D-Squame® skin analysis disks were used to collect skin samples from all subjects at baseline, 2 weeks and 4 weeks and analyzed by CuDerm Corporation in Dallas,

Texas. Self-assessment questionnaires to measure perception of skin condition were administered to subjects at baseline, 2 weeks, and 4 weeks. Results were analyzed with parametric and non-parametric statistics as appropriate at an alpha = 0.05.

## Conclusions

Formulation of a moisturizing IHS is a significant technical challenge which is further complicated by the absence of standardized methods for substantiating moisturization claims. As skin condition is a major factor in hand hygiene compliance, robust analysis of product skin performance beyond simple assessment of individual ingredient moisturization data is critical to truly evaluating the skin benefit of an IHS.<sup>1-2</sup> The results of these studies suggest:

- PURELL® Skin Nourishing Foam's synergistic moisturizing blend improves skin condition in as little as 14 days to an extent noticeable to health care workers.
- The moisturization performance of PURELL Skin Nourishing Foam is superior, both immediately and over time, to other marketed IHS foams making moisturization related claims.
- The presence of moisturizers in an IHS formulation is not sufficient to improve skin condition and significantly increase skin hydration. Therefore, moisturization claims can be misleading.
- Proper ingredient selection and formulation are imperative to providing the substantial moisturization needed by healthcare workers.
- PURELL Skin Nourishing Foam meets the APIC recommendations for the skin performance of hand hygiene products.<sup>3</sup>
- Criteria for substantiating IHS moisturization claims should be established.

## Additional Information

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## References:

1. Kaiser NE, Newman JL. Formulation technology as a key component in improving hand hygiene practices. *Am J Infect Control* 2006;34:S82-97.
2. Kampf G, Löffler. Dermatological aspects of a successful introduction and continuation of alcohol-based hand rubs for hygienic hand disinfection. *J Hosp Infect* 2003;55:1-7.
3. Association for Professionals in Infection Control and Epidemiology, Inc. (2005). Healthy Skin: An ounce of prevention for your front line of defense. [Brochure]. Fardo, R.: Reviewer.

## Results

**Figure 1: Comparison of Various Foaming Instant Hand Sanitizers with Moisturizing Claims Using an Acute Moisturization Method**

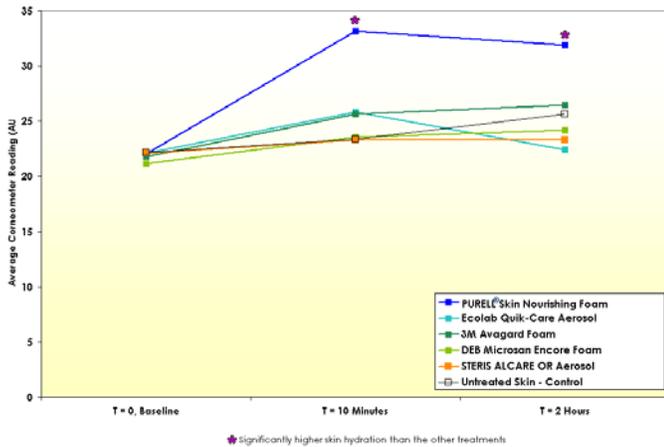


Figure 1: After one use, four of the five foaming instant hand sanitizers with moisturization related claims did not produce average skin hydration (AU) significantly different from an untreated control at 10 minutes or 2 hours ( $p < 0.05$ ). PURELL Skin Nourishing Foam produced superior average skin hydration (AU) when compared to all other treatments at 10 minutes and 2 hours ( $p < 0.05$ ). Therefore, the skin hydration produced by a one time use of PURELL Skin Nourishing Foam was superior to the other foaming instant hand sanitizers tested.

**Figure 2: Skin Hydration Improvement in an Intensive Care Setting**

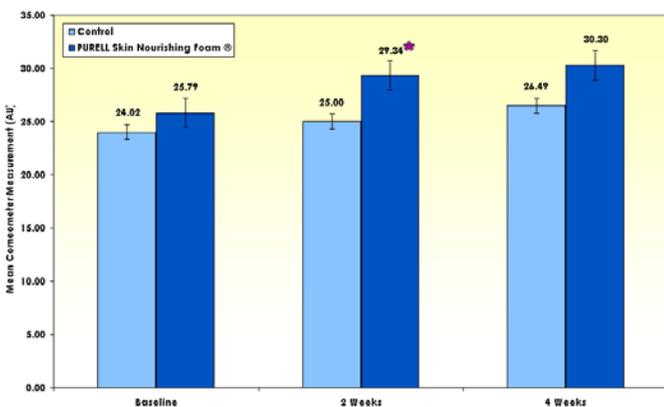


Figure 2: Baseline measurements demonstrate equivalent skin hydration between groups. After two weeks of use, the skin hydration of the treatment group significantly improved from baseline and had significantly higher skin hydration than the control group ( $p < 0.001$ ). After four weeks of use, the skin hydration of the treatment group significantly improved from baseline, was equivalent to the two week time point, and showed significantly higher skin hydration than the control group ( $p < 0.037$ ). These results demonstrate that PURELL Skin Nourishing Foam is able to improve skin moisturization in as little as 14 days and maintain the hydration for a duration of at least one month.

**Figure 3: Change in Average Desquamation Index During a Clinical Trial Using PURELL Skin Nourishing Foam in Four Hospital Intensive Care Units**

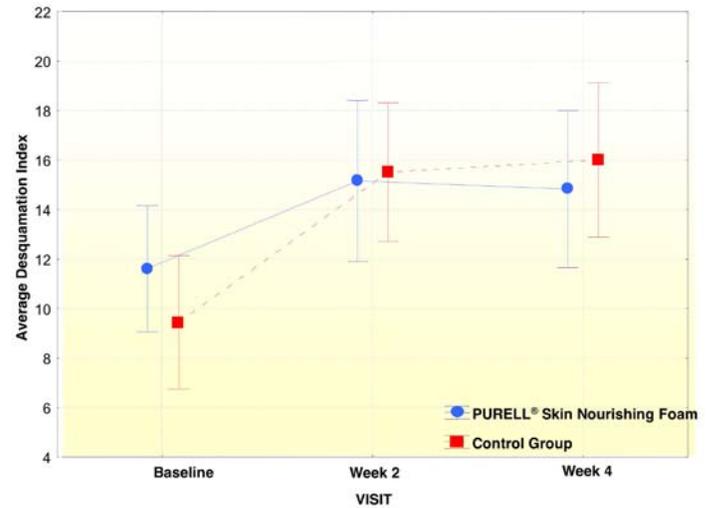


Figure 3: Desquamation index is a good overall measure of skin dryness and correlates with typical clinical grades. The change in Desquamation Index from baseline to 14 days for the PURELL Skin Nourishing Foam group was not significant ( $p < 0.0522$ ). In comparison, the change in Desquamation Index from baseline to 14 days for the Control Group indicated a significant change ( $p < 0.0000$ ). Similar differences were observed between baseline and 28 days for the PURELL Skin Nourishing Foam Group ( $p < 0.0804$ ) vs. the Control Group ( $p < 0.0001$ ). It is hypothesized that cold, dry, winter weather caused the control group to increase in dryness, whereas PURELL Skin Nourishing Foam was able to reduce the harsh effects of winter in the skin of healthcare workers.

**Figure 4: Self Assessment of Skin Condition During a Clinical Trial Using PURELL Skin Nourishing Foam in Four Hospital Intensive Care Units**

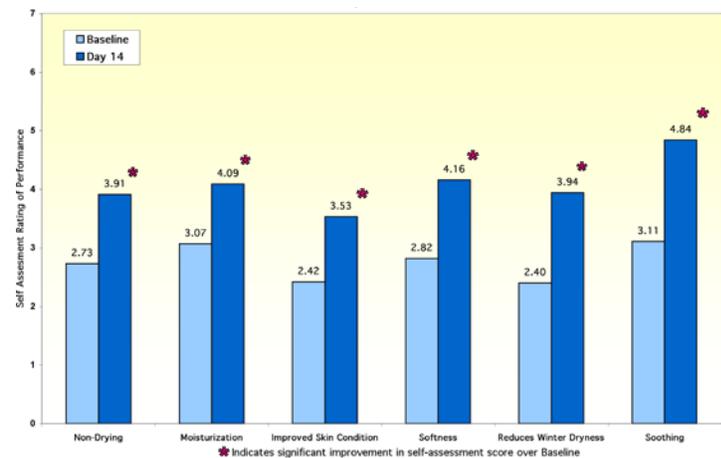


Figure 4: Health care workers completed self-assessments of skin performance using a 7 point scale where ratings ranged from 0 (poor) to 7 (excellent). After 14 days of PURELL Skin Nourishing Foam use, subjects rated skin condition and product performance based on the following criteria: non-drying, moisturization, improved skin condition, softness, reduction of winter dryness and soothing. A  $\chi^2$  analysis revealed significant improvement from baseline in all performance parameters after 14 days of use ( $p < 0.05$ ). Therefore, PURELL Skin Nourishing Foam produced perceptible improvements in the skin of healthcare workers in 14 days.

- Front cover footnotes:**
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