

# Comparison of Waterless Alcohol-Based Hand Antiseptics on Moisturization Efficacy in Subjects with Dry Skin

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## BACKGROUND/OBJECTIVES

Waterless hand antiseptics are designed to aid in the prevention of the transfer of health-care-associated pathogens. In the United States, such preparations usually contain 60%-95% ethanol or isopropanol. Frequent use of alcohol-based formulations for hand antisepsis can cause drying of the skin unless humectants, emollients, or other skin-conditioning agents are added to the formulations.

The main objective of the study was to evaluate the potential of three instant waterless hand antiseptics (with a commercially available skin lotion used as a control) to enhance skin moisturization in subjects with dry skin on their legs. A secondary objective was to compare the moisturizing properties on hand skin by one of the waterless hand antiseptics and the skin lotion.

## METHODS

California Skin Research Institute (CSRI) in San Diego, California, a division of DermTech International (DTI) conducted a study entitled "Effect Of Topical Products On Moisturization In Normal Subjects With Dry Skin" for Ecolab, Inc., in Mendota Heights, Minnesota.

The three waterless alcohol-based hand antiseptics that were tested were designated as: Test Article A, Test Article B, Test Article C. Test Article D was a commercially available Fragrance Free Amino Lotion.

Eighteen female subjects, who met the inclusion/exclusion criteria, entered a 10-day "wash out" period using a non-moisturizing soap (Neutrogena® Glycerin bar) on their lower legs, and were asked to refrain from using any moisturizing products on this area. In addition, the subjects were asked to stop using any moisturizing products on their hands approximately 48 hours before the day of the study. After the wash-out period, 17 subjects returned to CSRI. Ten subjects (35 to 63 years of age) were selected for the treatment phase of the study, based a NOVA (NOVA DPM 9003®, NOVA Technology Corporation, Portsmouth, NH) instrument reading of less than 110 on their lower legs. All 10 female subjects completed the one-day study.

The subjects equilibrated in a controlled environment (less than 50% relative humidity and 70°F±3°F) for thirty minutes before undergoing any testing measurements. At baseline, the subjects had test sites delineated on the outer aspect of the lower legs and the top of one hand. Then, baseline NOVA meter readings for skin surface moisture were performed in duplicate. The ten subjects had a CSRI Clinical Assistant apply the test articles to the appropriate sites on the lower legs and the top of one hand ten times within approximately one hour (except for the lotion product which was applied for five times during the approximate one hour application time period). The subjects remained in the controlled environment for the duration of the study. NOVA meter readings were taken at each test site approximately one-half hour and one hour after the last application of the test articles. There were no adverse events reported.

Statistical analysis for the hands was performed using two tailed paired t-tests utilizing the deltas from baseline to 30 minutes and baseline to one hour. Statistical analysis for the legs was performed using ANOVA followed by Tukey-Kramer Multiple Comparisons Test utilizing the deltas from baseline to 30 minutes and baseline to one hour. All calculations were done in Microsoft® Excel 2000. All statistics were performed using GraphPad Instat® (GraphPad Software, San Diego, CA). The graphs were created in Origin (OriginLab® Corporation, Massachusetts, USA).

## RESULTS: Changes in Moisturization Levels- Legs

**Untreated site:** 0.6% increase (p=0.28) at 30 minutes; aprx. 0.9% increase (p=0.0528) at 1 hour

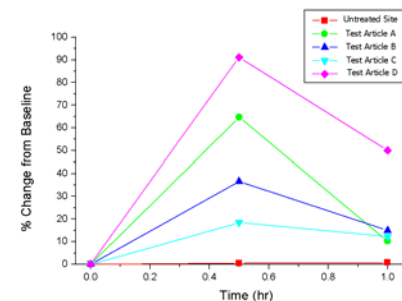
**Test Article A:** aprx. 65% increase (p=0.017) at 30 minutes; aprx. 10% increase (p=0.0071) at 1 hour. Comparison of the Untreated site versus the Test Article A treated site at the 30 minute measurement revealed statistically significant improvement in moisturization (p<0.01). No other comparisons were statistically significant.

**Test Article B:** aprx. 37% increase (p=0.0002) at 30 minutes; aprx 15% increase (p=0.0075) at 1 hour. No other comparisons were statistically significant.

**Test Article C:** aprx. 18% increase (p<0.0001) at the 30 minutes; aprx. 12% (p<0.0001) at 1 hour. No other comparisons were statistically significant.

**Test Article D:** aprx. 91% (p=0.0024) at 30 minutes; approx. 50% (p=0.0008) at 1 hour. At the 30 minute measurement, the Test Article D treated site showed statistically significant increases in moisturization over the Untreated site (p<0.001), Test Article B (p<0.05), and the Test Article C site (p<0.01). At the one hour measurement, the Test Article D site showed statistically significant increases in moisturization over the Untreated site, as well as the Test Article A, B, and C sites (all p<0.001), No other comparisons were significant.

TREATMENT	% Change between Baseline and 30 Min. Readings	%Change between Baseline and 1 Hour Readings
UNTREATED	0.64%	0.86%
Test Article A	64.73%	10.22%
Test Article B	36.51%	14.88%
Test Article C	18.40%	12.23%
Test Article D	91.09%	50.00%

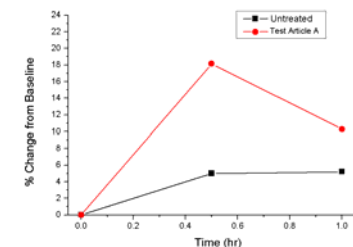


## RESULTS: Changes in Moisturization Levels- Hands

The Untreated site improved the moisturization of the skin on the top of the hands by 4.99% (p=0.0986) at the 30 minute measurement and by 5.19% (p=0.0412) at the one hour measurement.

Test Article A improved the moisturization of the skin on the top of the hands by approximately 18% (p=0.0207) at the 30 minute measurement and approximately 10% (p=0.0289) at the one hour measurement. Test Article A showed a statistically significant increase in moisturization over the Untreated site at the 30 minute measurement (p=0.316). The difference at the one hour measurement was not significant (p=0.2002).

TREATMENT	% Change between Baseline and 30 Min. Readings	%Change between Baseline and 1 Hour Readings
UNTREATED	4.99%	5.19%
Test Article A	18.15%	10.27%



## CONCLUSIONS

Instant hand antiseptics containing moisturizing ingredients help minimize the drying effects commonly seen from their use. There are quantifiable differences among these products in their ability to moisturize the skin at 30 minutes and one hour after application. Under the conditions of the study, Test Article A improved the moisturization of the skin on the top of the hands by approximately 18%. Test Article A improved the moisturization of the skin on the outer aspect of the lower legs by approximately 65% at the 30 minute measurement. Of the products tested, only the moisturizing lotion, Test Article D (the positive control) demonstrated a greater moisturizing capacity than Test Article A at the 30 minute time point.