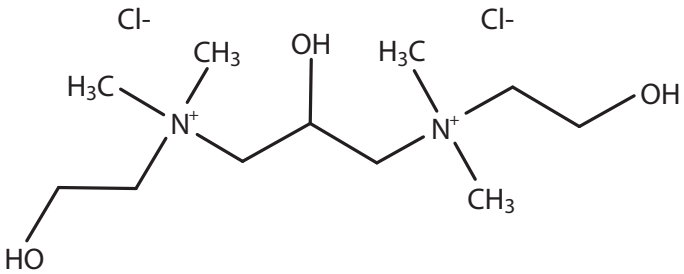
Clinical Evaluation of Cationic Humectant in Sulfate-Free Cleanser

Dennis Abbeduto, Colonial Chemical, Inc.

Abstract

The effect of a cationic humectant in a sulfate-free cleanser was evaluated in a placebo controlled, double-blind clinical study. Using both subjective and objective measurements, it was determined that the placebo cleanser significantly ($p < 0.005$) **decreased** moisturization of skin throughout the course of the study. In the meantime, the cationic humectant significantly ($p < 0.005$) **improved** the moisturization potential of the cleanser for at least 12 hours, without sacrificing important aesthetic parameters.



Hydroxypropyl bis-hydroxyethyldimonium chloride

Introduction

Dry skin can originate from a variety of factors, including climate, age, and lifestyle. Daily use cleansers can also contribute to dry skin conditions (1,2). Developing consumer-acceptable cleansers which not only mitigate the drying effect, but also contribute to skin hydration remains a challenge for many formulators.

Glycerin, for example, is a powerful humectant (3,4) and is useful for reducing dryness caused by soap (5) but has poor substantivity on skin in rinse-off cleansing applications (6). Increasing the glycerin to an effective level can cause undesirable aesthetics, including tackiness and greasiness (6,7). To avoid this, formulations have introduced polyols like glycols and sugar alcohols or additives like silicones to reduce the undesirable aesthetics. Alternately, lipophilic occlusive additives like vegetable oils and petrolatum have been used with some success, but at the cost of formulation clarity. Products formulated with lipophilic ingredients also tend to create undesirable films in showers and sinks.

Unfortunately, those solutions still fail to address the lack of substantivity, so the state of the art is being directed to cationic humectant molecules like polyether amine quats (8) choline chloride (9,10) and similar chemistry (11). Discussed here are the effects of a next-generation cationic humectant, hydroxypropyl bis-hydroxyethyldimonium chloride (CAS 110528-94-4), which also possesses a similar charge density and even greater water binding potential compared to choline chloride, with similarly favorable formulation aesthetics.

Materials and Methods

This study was independently conducted by Princeton Consumer Research Corp (Chelmsford, Essex, UK) according to a protocol approved by Colonial Chemical, Inc. (South Pittsburg, TN, USA). The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013). This was a double-blind placebo controlled study designed to assess the difference in skin moisture after washing with a typical cleanser (Water, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Hydroxysultaine, Cocamide MIPA, Sodium Chloride, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone) with and without the cationic humectant added. The cationic humectant was added to the base cleanser at 3.0% as supplied (70% solid material in water).

Twenty-six healthy female volunteers between 18 and 55 years of age with a baseline visual dryness score of 1.5 – 3.0 (0 – 4.0 scale) consented and were enrolled into the study. Exclusion criteria were: current participation in another clinical study; participation in the last four weeks on a study where the lower legs were the test area; insulin-dependent diabetic; obvious skin pathology, or conditions of the skin which prevent clear evaluations (psoriasis, eczema, atopic dermatitis, allergy, sunburn, excessive suntan, scars, cuts, abrasions, tattoos, uneven skin tones or significant erythema in the test area); current use of any topical drugs on the lower legs; allergies to soaps, detergents, latex, perfumes, preservatives and fragrances; any condition or factor, in the opinion of the Investigator or study staff, that could affect skin response or the interpretation of the test results; pregnancy or lactation, as determined by initial paperwork. Additionally, volunteers agreed to follow the washout protocol and to avoid designated products or activities during the study.

For the washout phase, volunteers were instructed to use only the simple bar soap provided to cleanse themselves for seven (7) days prior to the active testing phase of the study. After the seven-day washout period, volunteers returned to the study center to conduct the active testing phase of the study.

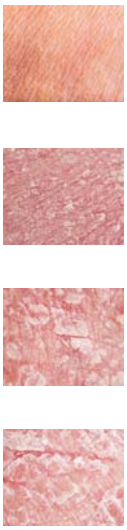
On the active test day, four test sites, approximately 5 cm x 5 cm, were marked on the outer aspect surface of the right and left lower legs of each volunteer. The markings avoided any small scars or skin lesions. Subjects then acclimated in a room maintained at 22°C ± 2°C and 45% ± 5% relative humidity for at least 30 minutes prior to instrument measurements and visual evaluations. A visual assessment of the test sites and baseline instrumental readings were done to determine continued eligibility.

Test sites were assigned randomly one of four treatments:

1. **Water**
2. **Untreated**
3. **Experimental Wash A** (Placebo control)
4. **Experimental Wash B** (with 3.0% cationic humectant, as supplied)

Visual evaluations for skin dryness were performed by a trained evaluator with the aid of a rolling adjustable magnifying lamp. The evaluation was performed at baseline to determine eligibility and at 4, 8 & 12 hours following the test wash. The following dryness scale was used:

Grade	*Dryness*
0	No dryness
0.5	Perceptible dryness, fine white lines
1.0	Fine dry lines, white powdery appearance and/or some uplifting flakes on less than 30% of the test site
1.5	Uniform flaking, covering 30-50% of the test site
2.0	Uniform, marked flaking covering more than 50% of the test site
2.5	Slight to moderate scaling
3.0	Moderate to severe scaling with uplifting scales
3.5	Severe scaling and/or slight fissuring
4.0	Severe scaling and fissuring



Subjects with a dryness scores of 1.5 - 3.0 and no more than a 1.0 point difference in dryness between the sites were accepted for the study.

Skin hydration measurements were made using a Corneometer® (Courage & Khazaka GmbH, Germany). The Corneometer uses capacitance measurements to represent skin hydration. The instrument reads in arbitrary units (AU), with higher numbers representing increased surface hydration. Three readings were taken of each site and averaged. Instrumental readings were taken at baseline prior to product application, approximately 4, 8 and 12 hours following the wash. Approximately was defined as +/- 10 minutes.

After baseline visual and instrumental readings, test sites were washed (as appropriate) per a standardized wash procedure. Except for the untreated site, remaining sites were wet with water, lathered with 0.25 mL of test product as appropriate, rinsed, and blotted dry.

Upon completion of the study, the blinding was decoded to allow the investigator to prepare conclusions for their report.

Results and Discussion

Figure 1: Visual Dryness Data Box Plots

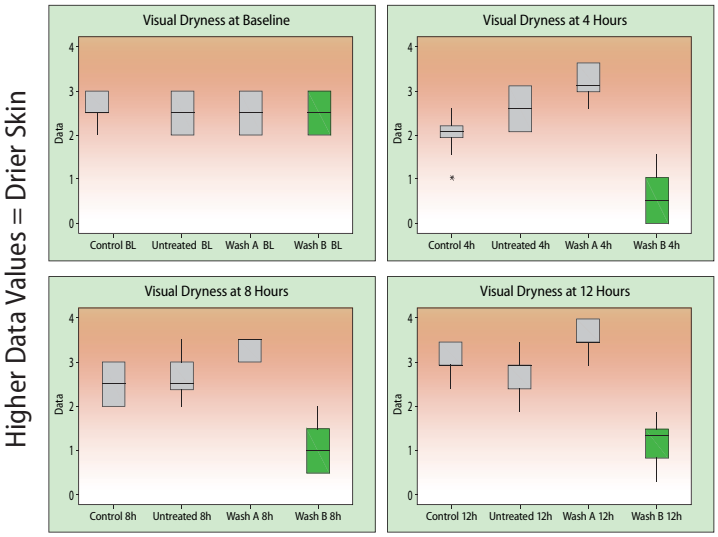
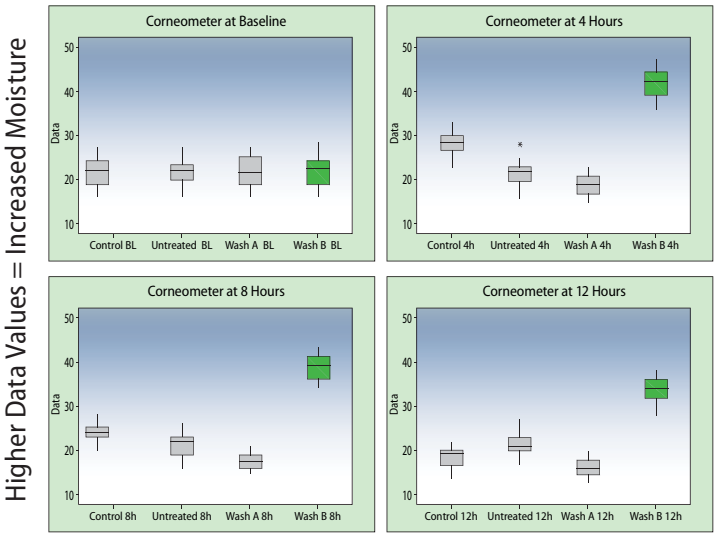
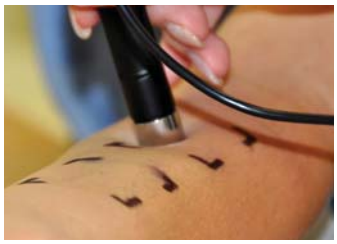


Figure 2: Corneometer Data Box Plots



All twenty-six (26) study participants completed washout and active testing phases of the study. Average visual dryness at baseline for all sites was 2.51 ± 0.41. Average Corneometer reading at baseline for all sites was 21.66 ± 3.05. There was no significant difference between test sites for baseline measurements.

At the 4-hour measurement interval, there was a 23.4% increase ($p < 0.005$) in visual dryness scores and a 12.7% reduction ($p < 0.005$) in Corneometer measurements for the placebo Wash A. At the same time interval, there was an **80.2% reduction** ($p < 0.005$) in visual dryness with a **91.9% increase** ($p < 0.005$) in Corneometer measurements for the active Wash B. The cleanser containing the cationic humectant significantly ($p < 0.005$) reduced visual dryness and increased moisturization (as measured by Corneometer) compared to other treatments, as well as the untreated site.



At the 8-hour measurement interval, there was a 33.6% increase ($p < 0.005$) in visual dryness scores and a 19.1% reduction ($p < 0.005$) in Corneometer measurements for the placebo Wash A. At the same time interval, there was an **61.1% reduction** ($p < 0.005$) in visual dryness with a **78.1% increase** ($p < 0.005$) in Corneometer measurements for the active Wash B. The cleanser containing the cationic humectant significantly ($p < 0.005$) reduced visual dryness and increased moisturization (as measured by Corneometer) compared to other treatments, as well as the untreated site.

At the 12-hour measurement interval, there was a 50.8% increase ($p < 0.005$) in visual dryness scores and a 25.8% ($p < 0.005$) reduction in Corneometer measurements for the placebo Wash A. At the same time interval, there was an 47.3% reduction ($p < 0.005$) in visual dryness with a 55.2% increase ($p < 0.005$) in Corneometer measurements for the active Wash B. The cleanser containing the cationic humectant significantly ($p < 0.005$) reduced visual dryness and increased moisturization (as measured by Corneometer compared to other treatments, as well as the untreated site.

Box plots for both visual dryness (Figure 1) and Corneometer (Figure 2) data demonstrate the effect size and consistent data distributions between treatments.

ANOVA analysis of all four treatments for the Corneometer data indicated that all the changes between treatments were statistically different at the 99% confidence level.

Conclusions

The inclusion of a cationic humectant greatly improved the moisturization of a typical sulfate-free cleanser. The wash containing the humectant significantly increased hydration, as measure by Corneometer, by as much as 92% over baseline and continued to improve hydration by 55% over baseline after **12 hours.** It also significantly reduced visual dryness by as much as 80% lower than baseline readings and continued to improve the appearance of dry skin by 47% after 12 hours. Without the additive, the cleanser significantly dried skin, both visually and by instrumental measurement throughout the study. **The cationic humectant not only mitigated the dryness caused by the cleanser, it substantially improved the moisturization potential of the same cleanser.** It also allowed for the formulation of a clear product with no perceivable difference in feel compared to the placebo formulation. In the future, additional testing could be done to prove the improvement is more resistant to rinse-off than nonionic humectants.

Cola®Moist 200

INCI Hydroxypropyl Bis-Hydroxyethyldimonium Chloride
CAS 110528-94-4 EC# 807-137-2

- Safe and non-irritating to skin or eyes
- Non-greasy, water-soluble, non-staining
- Stable at a broad range of temperatures and pH
- Compatible with a wide variety of formulations
- Stronger hydrating power than glycerin

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Acknowledgements

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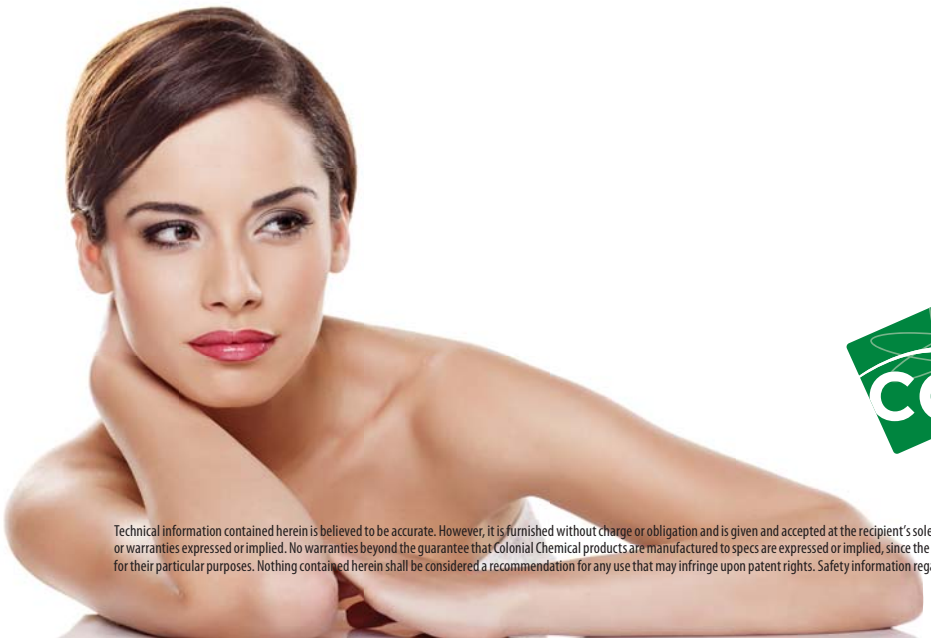
Test articles prepared by Molly McEnery, Colonial Chemical, Inc.



Colonial Chemical, Inc.
225 Colonial Drive · South Pittsburg, TN 37380
Phone: 423-837-8800 · Fax: 423-837-3888
www.colonialchem.com
Innovative Specialty Surfactants