

# **Efficacy, Skin Care and Performance Characteristics of a Well-Formulated Chlorhexidine Gluconate Hand Wash**

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## ABSTRACT

**Introduction:** Recent regulatory and consumer concerns are beginning to reduce the use of triclosan-based hand washes. Triclosan has been a preferred antimicrobial hand wash active in healthcare for years; typically preferred over other active ingredients which have been considered harsher on skin. The objectives of this study were to assess the efficacy, skin compatibility, and end user acceptability of a new hand wash containing chlorhexidine gluconate (CHG) relative to a marketed triclosan foam hand wash.

**Methods:** The control was a 0.3% triclosan foam hand wash currently used in the healthcare settings, and that meets FDA efficacy requirements. The test product was a novel FDA approved 2% CHG foam hand wash. Efficacy of the CHG hand wash was evaluated according to the FDA Health Care Personnel Hand Wash (HCPHW) (ASTM E1174). Skin compatibility was evaluated using a high-frequency use Forearm Controlled Application Test measuring skin barrier function and hydration. End user acceptability was evaluated after repeated-use by healthcare workers by aesthetics and acceptability questionnaires.

**Results:** The CHG foam hand wash met requirements of the FDA HCPHW. The CHG hand wash also exhibited long term skin hydration and barrier properties at parity or better than the triclosan hand wash. Additionally, the CHG hand wash performed significantly better for a number of performance attributes (e.g. skin feels soft, smooth, etc.) and was preferred overall to the triclosan hand wash.

**Conclusions:** This study demonstrates that a well-formulated CHG foam hand wash can obtain superior skin compatibility and be aesthetically preferred over a typical triclosan hand wash. Therefore, this CHG hand wash is a suitable alternative to triclosan formulations in a high-frequency use healthcare setting. As infection preventionists look to replace triclosan-based hand wash formulations with alternate antimicrobials, it will be important to ask manufacturers for data demonstrating the formulation's performance regarding efficacy, skin care, and aesthetics.

## INTRODUCTION

In 2015, the Food & Drug Administration reopened and proposed amendments<sup>1</sup> to the regulation on Safety and Effectiveness of Health Care Antiseptics, technically referred to as 21 CFR Part 310. This, in combination with general concerns within the consumer marketplace<sup>2</sup>, is driving a trend to phase out triclosan as an antimicrobial ingredient in many products. Although these new amendments currently focus on the consumer marketplace, triclosan has, and continues to be, the preferred<sup>3</sup> antimicrobial handwash active in healthcare. The antimicrobial active Chlorhexidine gluconate (CHG), used primarily in surgical scrub and surgical prep hand hygiene regimens (leave-on applications), is now transitioning to antibacterial handwashes. Though CHG is recognized for antimicrobial efficacy, it has developed a reputation for being harsh on skin. The objective of the studies presented here demonstrate that a novel 2% CHG foam handwash can be used not only as a suitable, but a preferred, alternative to the traditional

triclosan or chloroxylenol (PCMX) based handwashes. This suite of clinical studies evaluates efficacy, skin compatibility, and end user acceptability which represent the core features and characteristics of optimal hand hygiene products and regimens.

## METHODS

**Efficacy:** The FDA Health Care Personnel Hand Wash (ASTM E1174) and the Glove Juice Method were used to validate the efficacy of the novel 2% CHG foam handwash. The subject's hands were inoculated with 6 mL of a stock culture of *Serratia marcescens* (ATCC 14756) or *Bacillus subtilis* (ATCC 19659) to obtain a baseline of bacterial contamination. Inoculation of the hands was repeated, allowed to dry, and washed 10 times with the novel 2% CHG formula.

**Skin Compatibility:** To determine skin compatibility of the novel 2% CHG foam handwash, a high-frequency Forearm Controlled Application Test (FCAT) was performed on a Traditional Triclosan Based Foam Cleanser, Traditional PCMX Based Foam Cleanser, and the novel 2% CHG foam handwash. Baseline measurements were taken to capture the participants initial skin barrier function (Trans Epidermal Water Loss – BioX AquaFlux) and hydration levels (Courage+Khazaka MPA Corneometer). Their forearm surface was divided and assigned a single cleanser for product interaction. 48 washes were administered at each forearm site over the course of four days with objective skin measurements again recovered after Day 2 and Day 4 of the assessment.

**End-User Acceptability:** The cleanser aesthetics and skin feel performance were evaluated using a quantitative multi-use study using questionnaires among 30 Healthcare Workers. The assessment was based on the subjects' handwash experience after Wash 1 and Wash 4 with an assigned product (the Traditional Triclosan Based Foam Cleanser, Traditional PCMX Based Foam Cleanser, or novel 2% CHG foam handwash). This process was repeated two times so all three products were evaluated. Key measures used in the subjective study included overall acceptability, perceived mildness, and skin feel after product interaction.

## RESULTS

- The novel 2% CHG foam handwash met all criteria for the FDA HCPHW by achieving a bacterial population of 2 log<sub>10</sub> on each hand within 5 minutes after the first wash, and reduction of 3 log<sub>10</sub> on each hand within 5 minutes after the tenth wash (*Table 1*).
- At completion of the FCAT<sup>4</sup>, the change in TEWL measurements from 0 to 48 washes showed the novel 2% CHG foam handwash to have statistically milder effects on barrier disruption than the Traditional Triclosan Based Foam Cleanser (95.6% confidence) & Traditional PCMX Based Foam Cleanser (99.9% confidence) (*Figure 1*). The change in Corneometer measurements during the FCAT also showed favorable

results in long term skin hydration for the novel 2% CHG foam handwash. The novel 2% CHG foam handwash had better hydration recovery and fewer detrimental effects to the skin than the Traditional Triclosan Based Foam Cleanser (91.2% confidence) & Traditional PCMX Based Foam Cleanser (99.5% confidence) (Figure 2).

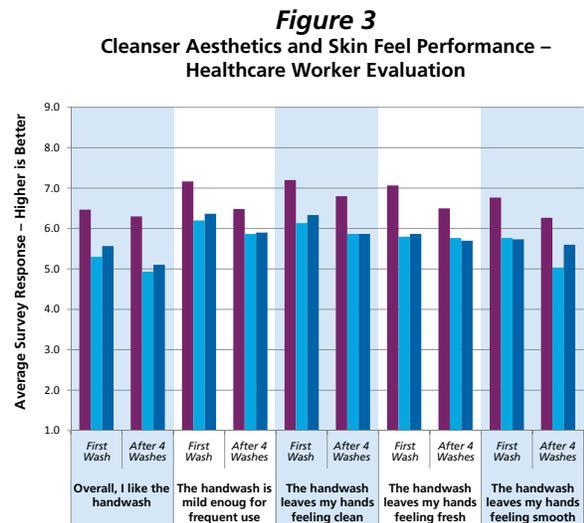
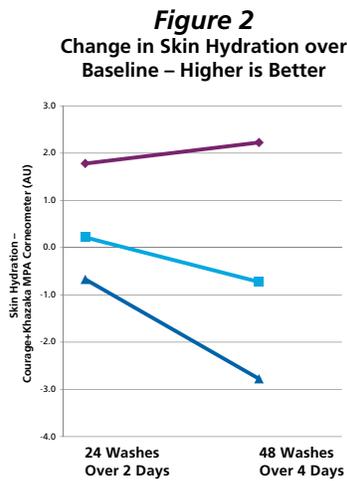
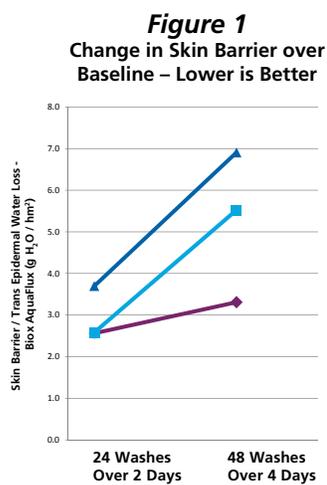
- The aesthetics and skin feel performance evaluation<sup>5</sup> showed the novel 2% CHG foam handwash as the user-preferred cleanser. The foam handwash surpassed the aesthetics of the Traditional Triclosan Based Foam Cleanser & Traditional PCMX Based Foam Cleanser during both Wash 1 and Wash 4 in key success attributes: overall acceptability, perceived mildness, and skin feel after product interaction (Figure 3).

**Table 1**

Wash 1	Wash 4	Wash 7	Wash 10
Log <sub>10</sub> Reduction	Log <sub>10</sub> Reduction	Log <sub>10</sub> Reduction	Log <sub>10</sub> Reduction
3.35	3.99	4.14	4.14

**Key for Figures 1-3**

- Novel 2% CHG Based Foam Handwash
- Traditional Triclosan Based Foam Handwash
- Traditional PCMX Based Foam Handwash



## CONCLUSIONS

- In contrast to recognized leave-on applications, a well-formulated novel 2% CHG foam handwash is milder to the skin than other traditional antimicrobial handwash options even under highly repeated use scenarios common within the healthcare environment.
- Beyond the first impression, a well-formulated novel 2% CHG foam handwash exceeds, even under repeated use, overall liking and other critical skin feel criteria compared to other traditional antimicrobial handwashes.
- A well-formulated novel 2% CHG foam handwash provides expected efficacy and is a suitable safe alternative to triclosan formulations in a healthcare setting.
- Selection of hand hygiene products and regimens which simultaneously deliver on the three critical components of efficacy, skin health, and healthcare worker acceptability and preference are crucial to meeting the long term needs and promoting high hand hygiene compliance.
- Healthcare facilities and Infection Preventionists looking to replace triclosan-based handwash formulations must solicit data from manufacturers demonstrating the formulation's comprehensive performance regarding efficacy, skin care, and aesthetics.

## REFERENCE

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