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 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 log₁₀ on each hand within 5 minutes after the first wash, and reduction of 3 log₁₀ on each hand within 5 minutes after the tenth wash (*Table 1*).
- At completion of the FCAT⁴, 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).

Table 1

<table>
<thead>
<tr>
<th>Wash</th>
<th>Wash 4</th>
<th>Wash 7</th>
<th>Wash 10</th>
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<tbody>
<tr>
<td>Log₁₀ Reduction</td>
<td>Log₁₀ Reduction</td>
<td>Log₁₀ Reduction</td>
<td>Log₁₀ Reduction</td>
</tr>
<tr>
<td>3.35</td>
<td>3.99</td>
<td>4.14</td>
<td>4.14</td>
</tr>
</tbody>
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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 tradition 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.

• The aesthetics and skin feel performance evaluation 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).

• 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
1. 21 CFR Part 310, Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record; Proposed Rule, Food and Drug Administration, Department of Health and Human Services, No. 84, May 1, 2015
3. Market share information derived through Global Healthcare Exchange, LLC dataset, 2015, GHX Headquarters, 1315 W. Century Dr., Suite 100, Louisville, Colorado 80027
4. GOJO Industries, Inc., Skin Care Learning Center, Clinical Study #2015-05-I10447
5. GOJO Industries, Inc., Skin Care Learning Center, Clinical Study #2015-05-I10448

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