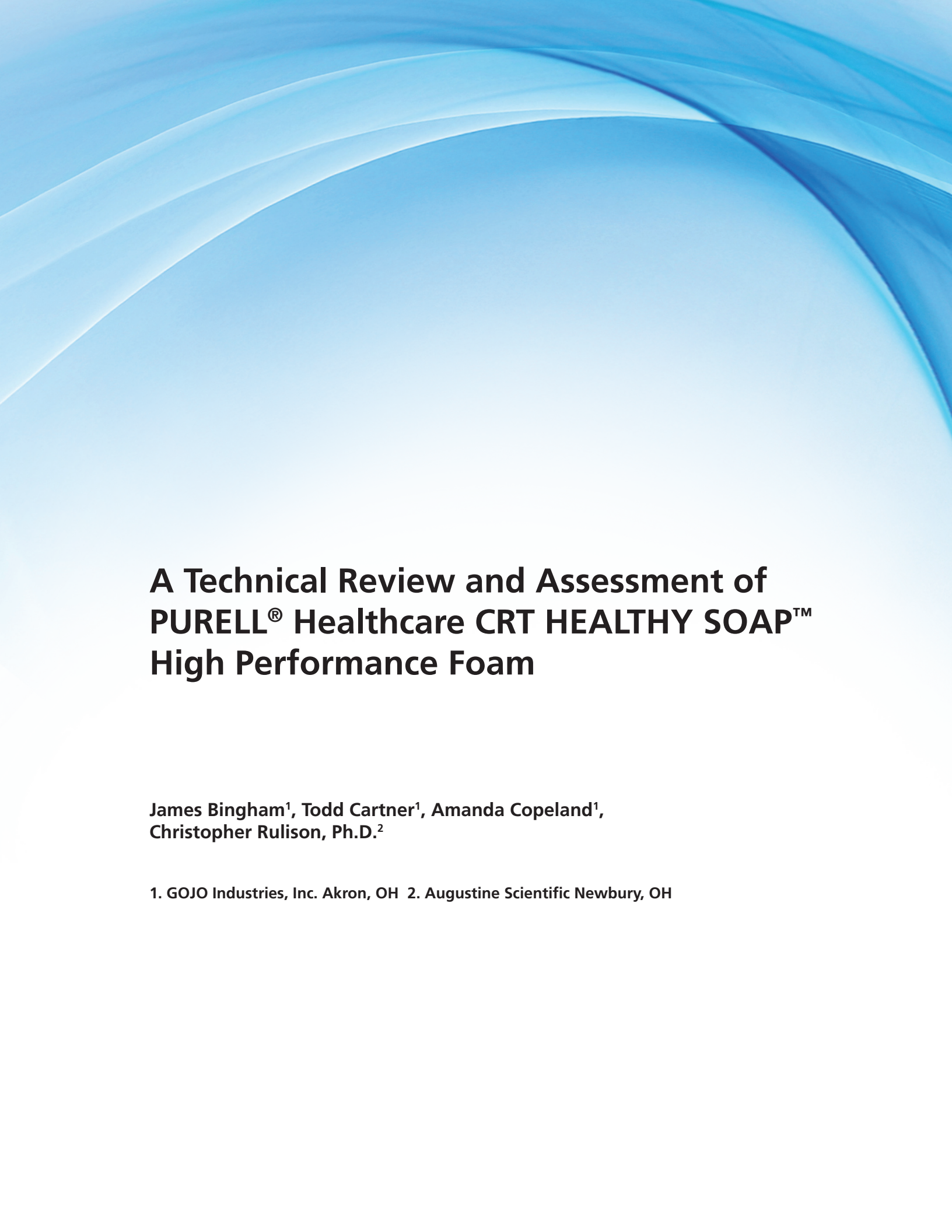




A Technical Review and Assessment of PURELL® Healthcare CRT HEALTHY SOAP™ High Performance Foam

**James Bingham¹, Todd Cartner¹, Amanda Copeland¹,
Christopher Rulison, Ph.D.²**

1. GOJO Industries, Inc. Akron, OH 2. Augustine Scientific Newbury, OH

Introduction:

The production and use of soap can be dated back thousands of years to the Babylonians, Egyptians, and Romans; however, it was not until the 1800's that the association of hand hygiene with infection prevention was established (1, 2). In healthcare settings, handwashing was used as the primary method for hand hygiene until 2002 when the Centers for Disease Control and Prevention updated their guidelines to recommend the use of alcohol-based hand rubs for hand hygiene except when hands are visibly soiled (1). Despite the guideline change, handwashing still plays a critical role in reducing the transmission of pathogens in healthcare settings. Hand soaps can be divided into two categories: antimicrobial and non-antimicrobial. Both categories contain surfactants for cleansing the skin (i.e. removal of soil and microorganisms). Antimicrobial soaps also contain an antimicrobial agent (e.g. chlorhexidine gluconate, chloroxylenol, benzalkonium chloride, or triclosan) to kill microorganisms. Antimicrobial soaps provide superior reduction in transient microorganisms due to the action of the antimicrobial agent.

CRT™ High Performance Soap Background:

There has been limited innovation in handwashing over the past 20 years, with the largest advances being the advent of foam formulations and improved skin compatibility, i.e., mild formulations. However, there haven't been major formulation advances in skin cleansing (i.e., removal of dirt, bodily fluids, microorganisms, etc.), the primary function of handwashing. With uncertainty around the future fate of antimicrobial soaps in the Healthcare market as the Food and Drug Administration's Topical Antimicrobial Drug Products for Over the Counter Human Use is pending finalization, having effective non-antimicrobial soaps which support compliance has become increasingly important. Thus, with the goal of more aesthetically pleasing, skin-compatible, non-antimicrobial soap formulas with better skin cleansing capabilities, a deeper understanding of the interaction between soap, soil, and skin is required. This document provides a review of PURELL® Healthcare CRT HEALTHY SOAP™ High Performance Foam [hereafter, CRT™ High Performance Soap], a new innovation within the category of non-antimicrobial soap.

GOJO has developed improvements in non-antimicrobial soap performance by optimizing the skin cleansing properties without sacrificing skin compatibility or aesthetics. One specific property on which GOJO has focused is interfacial tension. Interfacial tension is a measure of the interaction between two surfaces; in this case, skin and the soap formulation. Minimizing the interfacial tension with skin is a key component to enhancing the skin cleansing properties of soap. Lower interfacial tensions improve the fine wetting (spreading as depicted in Figure 1) and coverage of the soap allowing for interaction across the skin's topography, which results in an improved ability to displace soils from the surface (Figure 1). CRT™ High Performance Soap was therefore formulated with higher surface tension and lower surface polarity in order to be more in line with the surface properties of skin. The result is an interfacial tension that is approximately two times lower than a market-leading non-antimicrobial hand wash, and which leads to superior removal properties (Figure 2).

Bacterial Removal:

To assess the ability for CRT™ High Performance Soap to remove bacteria from hands several *in vivo* experiments were performed. First, CRT™ High Performance Soap was tested using the standard test method to evaluate topical antiseptics, Healthcare Personnel Handwash (ASTM E1174)(3). CRT™ High Performance Soap removed more than 99%, or greater than a 2 log reduction, of a marker organism, *Serratia marcescens*, from the hands of 24 study participants. To further evaluate the activity of CRT™ High Performance Soap, and because this product is not an antiseptic drug product, additional testing was performed using ASTM E2755, which allows for testing a more clinically relevant Gram-positive organism, *Staphylococcus aureus* (4). In this study CRT™ High Performance Soap was compared to another non-antimicrobial, market-leading, foam hand wash (PROVON® Green Certified Foam Hand Cleaner). Traditionally soaps have been tested with large application volumes and long wash times. For this study, two actuations from a dispenser – equaling 1.8mL of product – were applied to the hands of 12 study participants for 30 seconds and then rinsed off for 10 seconds, simulating more realistic conditions. The log reduction of *S. aureus* achieved by CRT™ High Performance Soap was improved by more than 0.34 log CFU as compared to PROVON Green

Certified Foam Hand Cleaner, which was a statistically significant difference ($p = 0.002$)(Figure 3A). This study demonstrates the superior bacterial removal of CRT™ High Performance Soap using a clinically relevant organism.

Finally, the ability to remove *S. aureus* from dry and irritated skin was tested. As many as 85% of healthcare workers have reported a history of skin problems with complaints often of dryness, roughness, erythema, scaling or fissures and these conditions can result in more frequent colonization of *Staphylococcus* and gram negative bacilli (5, 6, 7). To avoid applying a pathogen to compromised skin of human study participants, a novel *ex vivo* method was developed and utilized to test the ability to remove *S. aureus* from dry and irritated skin. Viable human skin donated from a cosmetic surgical procedure was irritated through exposure to an 8% sodium lauryl sulfate solution for 8 hours and then dried by placement in a desiccator at 4°C for 72 hours. Treatment of the skin resulted in a 2.47-fold increase in an inflammatory response and a 39.63% decrease in skin hydration, signaling both irritation and dryness, respectively, as compared to untreated controls. The treated skin was then cut into 42 pieces, contaminated with *S. aureus*, washed with either CRT™ High Performance Soap or PROVON Green Certified Foam Hand Cleaner for 30 seconds, and rinsed for 10 seconds. The log reduction of *S. aureus* achieved by CRT™ High Performance Soap was improved by more than 0.53 log CFU compared to PROVON Green Certified Foam Hand Cleaner. The difference was statistically significant ($p = 0.005$), demonstrating superior performance on dry and irritated skin (Figure 3B). In addition, 3.40 times fewer *S. aureus* organisms remained on the skin after use of CRT™ High Performance Soap. These three studies demonstrate the superiority of CRT™ High Performance Soap compared to a market-leading, non-antimicrobial soap in terms of bacterial removal.

Soil Removal:

Another novel *ex vivo* model was developed and used to quantify the soil removal properties of CRT™ High Performance Soap, as human handwashing studies are not sensitive enough to detect differences. Approximately 0.5 g of fetal bovine serum (i.e., blood serum) was applied to 400 mm² pieces of *ex vivo* skin donated from a surgical procedure and which were then exposed to either CRT™ High Performance Soap or PROVON Green Certified Foam Hand Cleaner for 10 seconds. The weight of the skin prior to and after exposure to the hand washes was recorded to determine the mass of soil removed. CRT™ High Performance Soap removed over 30% more blood serum from skin when compared to PROVON Green Certified Foam Hand Cleaner, demonstrating superior removal properties of the CRT™ High Performance Soap.

Skin Health:

Improved skin cleansing, whether it be dirt, bodily fluids, or microorganisms is often associated with harshness. CRT™ High Performance Soap has been formulated to maintain skin compatibility. CRT™ High Performance Soap was specifically formulated without any harsh preservatives to eliminate a common cause of severe skin irritation. Several studies were performed to evaluate the skin compatibility of CRT™ High Performance Soap. A forearm controlled application test (FCAT) in which 48 handwashes were completed over the course of 4 days, demonstrated CRT™ High Performance Soap is at parity with PROVON Clear & Mild Soap, a standard for mildness and skin compatibility. Additionally, a 14-day cumulative irritancy study (CIT), and human repeat insult patch test (HRIPT) have demonstrated parity with other mild soaps.

Rinsing, Water Usage, and Sustainability Impacts:

CRT™ High Performance Soap was hypothesized to have shorter rinsing time due to its ability to quickly spread and cover hands more efficiently. To test this hypothesis, 59 test volunteers representing the general population completed a handwashing study in which they were instructed to evaluate the aesthetic performance of two different soaps. While washing, participants were discretely observed and the time they spent rinsing their hands was recorded. Experiments were performed at three separate water flow rates (0.50 gal/min, 0.35 gal/min, and 0.25 gal/min) representing different levels of LEED standards (8). Participants used less water when washing with CRT™ High Performance Soap than when using PROVON® Green Certified Hand Cleaner at all flow rates indicating that it rinsed faster. Results from the three flow rates were combined and averaged, totaling a savings of 5.99 gallons of water per 1200mL soap refill in comparison to PROVON Green Certified Hand Cleaner. CRT™ High Performance Soap may therefore be a good solution to meet new LEED Standards in low-flow faucets for reduced water consumption.

CRT™ High Performance Soap contains 90% bio-based content (i.e., derived from plants and other renewable sources), meeting USDA Biopreferred criteria of 64% minimum for handwashes.

Formulation Aesthetics:

One of the key requirements of a soap is healthcare worker acceptance (1). Healthcare worker acceptance is commonly centered on the formulation aesthetics, skin feel and user experience. Aesthetic considerations include appearance (i.e., color or clarity), product form (foam or liquid), and the sensory experience during use which includes the fragrance, scent or odor of the product, and how it lathers and rinses. If healthcare workers do not like the product, they are less likely to use it (9), so aesthetic and skin feel considerations are critical and should not be overlooked. To determine overall end user acceptance of CRT™ High Performance Soap, it was compared to PROVON Green Certified Hand Cleaner in a blinded study using 58 study participants representative of the general population. Participants were instructed to compare the lather and wash characteristics of the two foam soaps. The results demonstrated that 95% of participants preferred CRT™ High Performance Soap, further supporting the superior characteristics of CRT™ High Performance Soap.

Figures:

Figure 1: Interfacial tension is a measure of the compatibility between skin and hand soap and can be depicted by contact angle (angle of incidence between skin and hand soap). Figure 1 below shows that lower contact angles have better spreading and coverage.

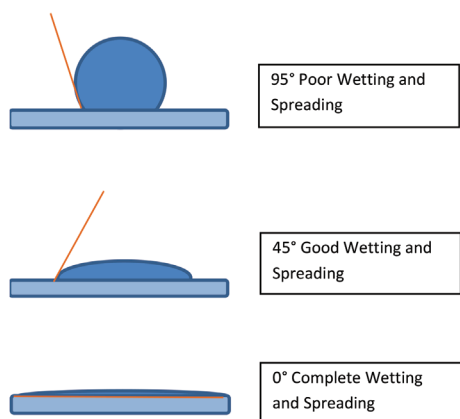


Figure 2: Interfacial tensions of three soaps.

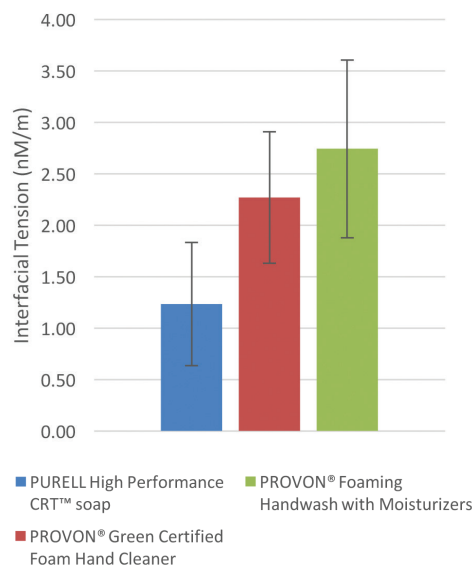
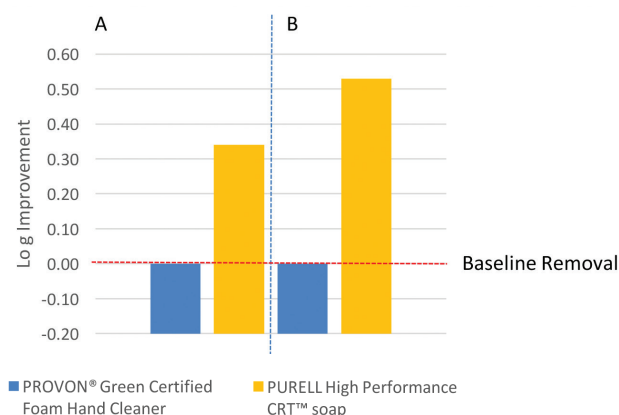


Figure 3: Improvement in bacterial removal of PURELL High Performance CRT™ soap using two different methods, A. ASTM E-2755 and B. novel ex vivo method



Conclusion:

CRT™ High Performance Soap has been formulated to deliver superior skin cleansing properties including removal of soil and bacteria, skin compatibility, improved sustainability and a better wash experience. The interfacial tension has been optimized to improve the spreading and coverage of hands resulting in interaction with skin's complex topography. Bacterial removal studies demonstrated that CRT™ High Performance Soap has significantly higher removal of *S. aureus* on both healthy skin and dry and irritated skin compared to a market-leading, non-antimicrobial soap. In addition, soil removal studies demonstrated a greater than 30% increase in blood serum removal. Due to its improved spreading and coverage, CRT™ High Performance Soap rinses faster resulting in a savings of 5.99 gallons of water per refill. Superior performance often includes tradeoffs in some other area such as skin compatibility and aesthetics, however, CRT™ High Performance Soap is as mild as several leading non-antimicrobial soaps and is preferred by users. Combined, this makes CRT™ High Performance Soap a superior non-antimicrobial handwash ideal for a high frequency hand hygiene environment such as healthcare.

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For additional information contact:
James Bingham, GOJO Industries, Inc.,
T: 330.255.6692, Email: BinghamJ@GOJO.com

Todd Cartner, GOJO Industries, Inc.,
T: 330.635.8818, Email: CartnerT@GOJO.com

Amanda Copeland, GOJO Industries, Inc.,
T: 330.802.5185 , Email: CopelanA@GOJO.com