Novel Non-Antimicrobial Soap Developed To Improve Skin Cleansing For Healthcare

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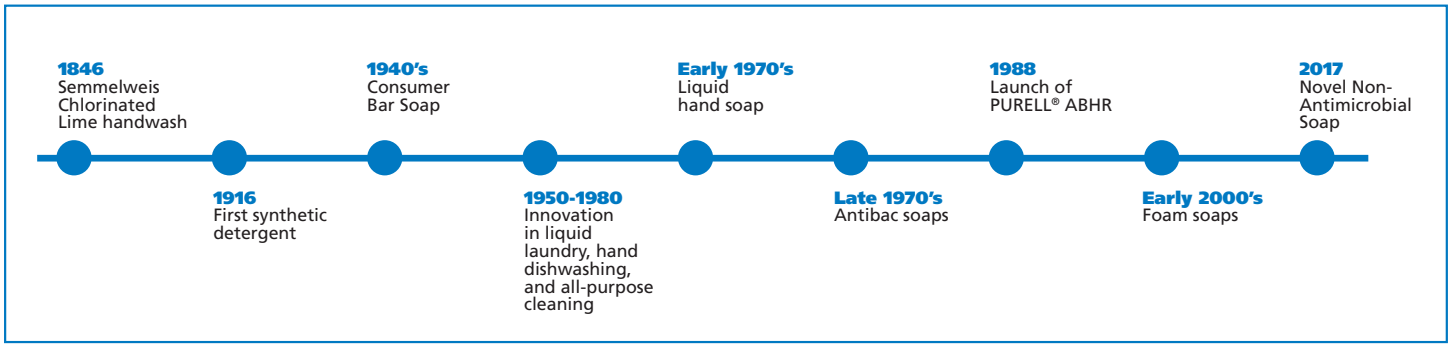
LEARNING OBJECTIVES

- Recognize the superior benefits that a non-antimicrobial soap may deliver when formulated for optimal interfacial tension
- Understand the limitations of soap innovation within the non-antimicrobial soap realm and the need for products with superior skin cleansing and compatibility
- Describe new methods, including interfacial tension and quantitative soil removal, of characterizing the attributes of a non-antimicrobial soap

FIGURE 1. BRIEF TIMELINE OF THE HISTORY OF SOAP



BACKGROUND

Hand hygiene is key to preventing the spread of infections. Innovation within the hand soap category has been limited to format (i.e. foam) and improved skin compatibility, and not on its ability to cleanse the skin better (i.e. removal of soils, bodily fluids, or microorganisms). Figure 1 displays a brief history of the evolution of soap as well as highlights of key areas of innovation. Because of uncertainty around future US regulations of antimicrobial soap in healthcare, a novel, patent-pending non-antimicrobial soap was developed with improved skin cleansing without compromising skin compatibility.

METHODS

A novel non-antimicrobial soap was compared to a standard, mild non-antimicrobial soap in a series of studies. Interfacial tension[1], a measure of the interaction between soap and skin, was measured on the skin to quantify wetting and spreadability. Interfacial tension is calculated from the formulation and skin surface energies using the van Oss equation. The compatibility of a soap formulation and skin surface is defined by the interfacial tension between the two. The higher the interfacial tension, the less compatible the two are. For a soap formulation, having a low interfacial tension to the surface is predictive of efficient spreading, good coverage of liquid on the surface, and better potential to displace dirt from the surface.

Contact angle[2] was another method used to describe how the formulations spread on the skin. Time resolved contact angle was obtained for each formulation by placing 5 drops onto the surface of synthetic skin. A highspeed data capture with video-triggered start was used and monitored each drop for 5.0 seconds.

Irritancy and sensitization potential were assessed by 14-day Cumulative Irritancy Testing (CIT) and Repeat Insult Patch Testing (RIPT)[3]. Removal of soil and bodily fluids (blood serum) was assessed through an ex vivo model of soil application and soap exposure. Human skin was attached to a plate connected to a tensiometer. The balance was tared prior to an application of the Fetal Bovine Serum soil. The skin was dipped into the soap solution three times: once as a "quick dip", a second as a "dwell dip", and a third as a dip with "agitation" to simulate the wash process. The balance was read following each dip to determine the amount of soil removed from the skin.

In microbial efficacy testing, Test Soaps were applied dry - a worst case scenario for skin compatibility. Determining that the Novel Non-Antimicrobial Soap can be applied dry over multiple uses without adverse skin impact was critical. To determine skin compatibility, a Forearm Controlled Application Test (FCAT)[4] was performed with the Novel Non-Antimicrobial Soap and Control Soap B. Eight female subjects, Fitzpatrick Skin Scale Type II to IV, were recruited and eight (n = 8) participated. On day one, the subject's forearm were divided into 8 test sites (3x4 cm areas), 4 per arm then baseline measurements were taken to capture the subjects' initial skin barrier function at each site (Trans Epidermal Water Loss (TEWL) – BioX AquaFlux) (single measurement) and hydration levels (Courage+Khazaka CM825 Corneometer) (average of 3 measurements). The 8-test sites were assigned treatments using a Latin Square Block Design of the two test products (each applied to wet and dry skin), the negative control (8% SLS, only applied to wet) or positive control (untreated skin, dry – no treatment) for a total of 8 different treatments. A 50 µL aliquoted

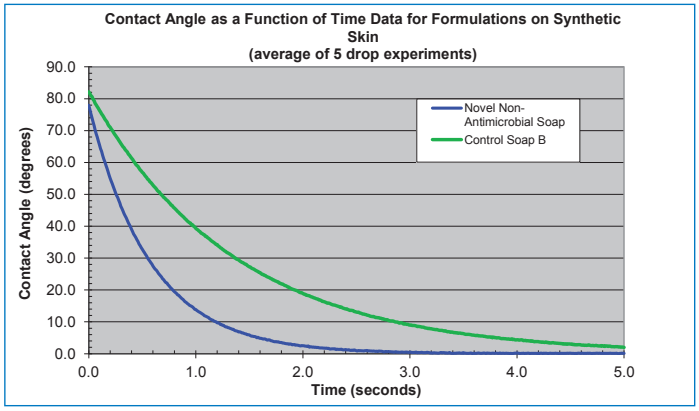
application of the test products and the negative control were applied to skin, followed by a 10-second rub or wash, and 10-second rinse. A total of 48 washes were administered over the course of four days (12 washes per day). Final skin measurements were taken on a fifth day following the product applications. The mean difference (baseline to final) in TEWL and hydration levels were calculated per treatment and statistical analysis was conducted with ANOVA General Linear Model $\alpha = 0.05$.

RESULTS

The interfacial tension, as displayed in Table 1, of the Novel Non-Antimicrobial Soap was 1.91 times lower than Control Soap B ($p < 0.01$), indicating that the Novel Non-Antimicrobial Soap has more efficient spreading and coverage of the product on the hands. It also is predictive of a better potential of the soap to remove soils from the skin.

Dynamic contact angle testing showed the Novel Non-Antimicrobial Soap spreads much quicker than Control Soap B over the course of 5.0 seconds, as displayed in Figure 2.

FIGURE 2: DYNAMIC CONTACT ANGLE DEPICTION

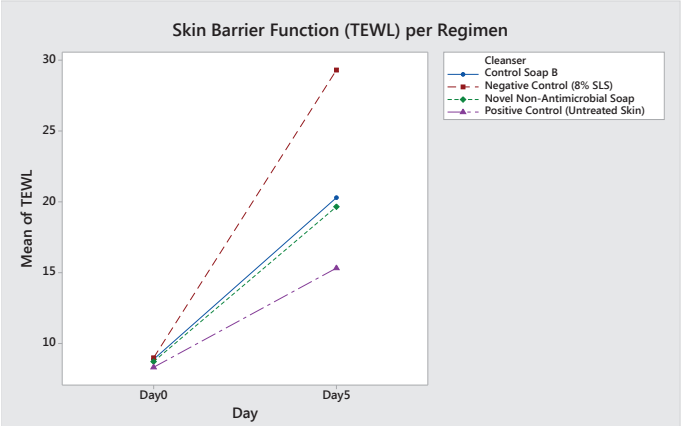


The Novel Non-Antimicrobial Soap CIT and RIPT testing showed no indication of eliciting dermal irritation or contact sensitization and were classified within Berger & Bowman as "Probably Mild in Use."

Thirty-two percent more blood serum was removed from skin with the Novel Non-Antimicrobial Soap compared to Control Soap B, confirming that the results of interfacial tension indeed predicted the superior soil removal of the Novel Non-Antimicrobial Soap.

The increased cleaning and rinsing benefit of the Novel Non-Antimicrobial Soap enabled by the unique interfacial tension could raise concern for skin mildness – a critical characteristic of cleansers used in high use environments such as Healthcare. Also, as previously stated, further concern could also stem from the application of the Novel Non-Antimicrobial Soap directly to dry skin – not a predominant application method but far from unheard of, particularly with foam soaps. The results of the FCAT (see Figure 3) comparing the Novel Non-Antimicrobial Soap against a typical foam Control Soap B plus standard controls of Positive Control (Untreated Skin) and the Negative Control (8% SLS) indicate that Skin Barrier Function (Trans Epidermal Water Loss (TEWL), a common and critical component of skin health) performance of the Novel Non-Antimicrobial Soap (see Table 3) was at parity to the Untreated Skin ($p = 0.669$) and the Control Soap B ($p = 1.000$) and statistically different from the Negative Control ($P = 0.000$).

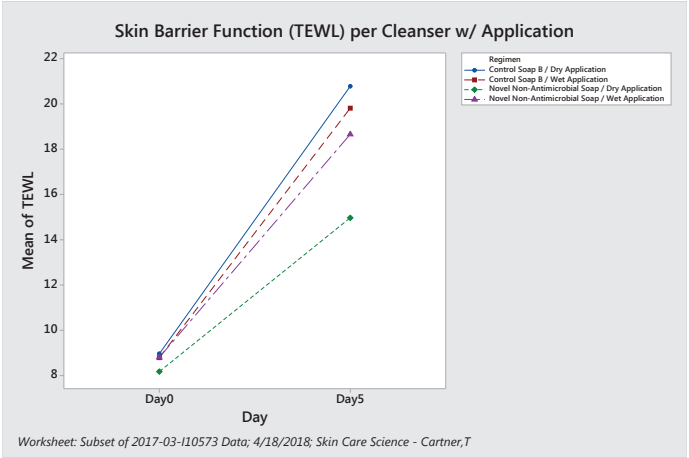
FIGURE 3. CHANGE IN SKIN CONDITION OVER TIME BY REGIMEN



Worksheet: 2017-03-I10573 Data; 4/18/2018; Skin Care Science - Cartner,T

During this study, both wet and dry application methods, where appropriate, were administered and the mean Skin Barrier results were combined for Figure 3 and Table 3. To address the specific concerns over the wet and dry application method, further analysis compared the Novel Non-Antimicrobial Soap against the Control Soap B (see Figure 4). This analysis demonstrates that the Novel Non-Antimicrobial Soap and the Control Soap B, whether applied wet or dry, yielded no statistical differences ($p > 0.10$) in Skin Barrier Function (see Table 4). These results dispel concerns that though superior at cleaning and rinsing, the Novel Non-Antimicrobial Soap does not compromise the skin, even at repetitive daily applications tested here, and would be appropriate for use in a Healthcare setting.

FIGURE 4. CHANGE IN SKIN CONDITION OVER TIME BY APPLICATION METHOD



Worksheet: Subset of 2017-03-I10573 Data; 4/18/2018; Skin Care Science - Cartner,T

CONCLUSIONS

These studies demonstrate the ability of the Novel Non-Antimicrobial Soap, a properly formulated soap, with lower interfacial tension to deliver improved spreading, coverage, and skin cleansing properties (removal of soil, bodily fluids, or microorganisms) over Control Soap B, a standard, mild nonantimicrobial soap, while maintaining skin mildness. Therefore, the Novel Non-Antimicrobial Soap is a superior choice and is ideal for a high frequency hand hygiene environment such as Healthcare.

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1. van Oss, C. (1994). Interfacial Forces in Aqueous Media. New York (NY): Marcel Dekker.
2. Good R and Stromberg R. (1979). Surface and Colloid Science. Boston (MA): Springer.
3. Wilhelm K, Freitag G, Wolff H. Surfactant-induced skin irritation and skin repair: Evaluation of a cumulative human irritation model by noninvasive techniques. J. Am. Aca. Of Derm., 1995;31(6):981-7.
4. Ertel K, Keswick B, Bryant P, A forearm controlled application technique for estimating the relative mildness of personal cleansing products. J. Soc. Cosmet. Chem., 1995; 46, 67-76.

TABLE 1. AVERAGE INTERFACIAL TENSION RESULTS

	NOVEL NON-ANTIMICROBIAL SOAP	CONTROL SOAP B
Average Interfacial Tension	1.07	2.04

TABLE 2: FETAL BOVINE SERUM REMOVAL RESULTS

FETAL BOVINE SERUM (BLOOD SERUM)			
	Control Soap B	Novel Non-Antimicrobial Soap	Percent Increase in Removal
Quick Dip	15.1	20.2	33.77%
Dwell Dip	35.8	40.5	13.13%
Agitation Dip	97.1	99.0	1.96%

TABLE 3. STATISTICAL COMPARISONS FOR SKIN BARRIER (TEWL) PER REGIMEN

Tukey Pairwise Comparisons: Response = Change In Skin Barrier (TEWL), Term = Regimen
Grouping Information Using the Tukey Method and 95% Confidence

REGIMEN	MEAN	GROUPING
Negative Control (8% SLS)	23.0912	A
Control Soap B	11.2960	B
Novel Non-Antimicrobial Soap	11.2912	B
Positive Control (Untreated Skin)	9.0322	B

DIFFERENCE OF REGIMEN LEVELS	ADJUSTED P-VALUE
Negative Control (8% SLS) - Control Soap B	0.000
Novel Non-Antimicrobial Soap - Control Soap B	1.000
Positive Control (Untreated Skin) - Control Soap B	0.719
Novel Non-Antimicrobial Soap - Negative Control (8% SLS)	0.000
Positive Control (Untreated Skin) - Negative Control (8% SLS)	0.000
Positive Control (Untreated Skin) - Novel Non-Antimicrobial Soap	0.669

Individual confidence level = 98.92%

TABLE 4. STATISTICAL COMPARISONS FOR SKIN BARRIER (TEWL) PER CLEANSER – APPLICATION

Tukey Pairwise Comparisons: Response = Change In Skin Barrier (TEWL), Term = Cleanser-Application Grouping Information Using the Tukey Method and 95% Confidence

CLEANSER	MEAN	GROUPING
Novel Non-Antimicrobial Soap / Dry Application	12.6265	A
Control Soap B / Wet Application	11.0225	A
Control Soap B / Dry Application	10.6565	A
Novel Non-Antimicrobial Soap / Wet Application	9.8575	A

DIFFERENCE OF CLEANSER LEVELS	ADJUSTED P-VALUE
Control Soap B / Wet Application - Control Soap B / Dry Application	0.995
Novel Non-Antimicrobial Soap / Dry Application - Control Soap B / Dry Application	0.755
Novel Non-Antimicrobial Soap / Wet Application - Control Soap B / Dry Application	0.955
Novel Non-Antimicrobial Soap / Dry Application - Control Soap B / Wet Application	0.800
Novel Non-Antimicrobial Soap / Wet Application - Control Soap B / Wet Application	0.811
Novel Non-Antimicrobial Soap / Wet Application - Novel Non-Antimicrobial Soap / Dry Application	0.432

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1. van Oss, C. (1994). Interfacial Forces in Aqueous Media. New York (NY): Marcel Dekker.
2. Good R and Stromberg R. (1979). Surface and Colloid Science. Boston (MA): Springer.
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