The Science of Soap

and a practical approach for selecting one that's right for your facility.

February 2024

Introduction

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Foreword

The use of soap for cleaning dates back thousands of years. However, it wasn't until the mid-1800s that the simple act of washing hands with soap was recognized as a way to prevent the spread of germs. Fast-forward two hundred years and manufacturers are still working to improve the soap products used in healthcare settings to enhance their performance and acceptability.

While alcohol-based hand rubs (ABHRs) have been broadly studied, handwashing and the impact of hand soaps don't have nearly the amount of relevant data or innovation in the market. As a result, when healthcare facilities are faced with evaluating soap options, they often seek technical information that typically does not exist. The element of choice in the guidelines and the uncertain regulatory future for many active ingredients used in soap can add further confusion.

The purpose of this eBook is to share some science related to the performance of soap and its impact on skin, and also to convey some practical considerations for infection preventionists and key decision-makers during product selection. Despite being used less frequently than ABHRs, handwashing remains an important infection prevention practice. As such, choosing a high-quality soap that is gentle on skin can optimize product acceptance and help ensure maximum usage (i.e., hand hygiene compliance).

We hope that this resource proves to be a valuable tool when you are considering making a hand hygiene product change. If you would like to share feedback or need further help, please do not hesitate to reach out to us at **healthcare@gojo.com.**

Stay well,

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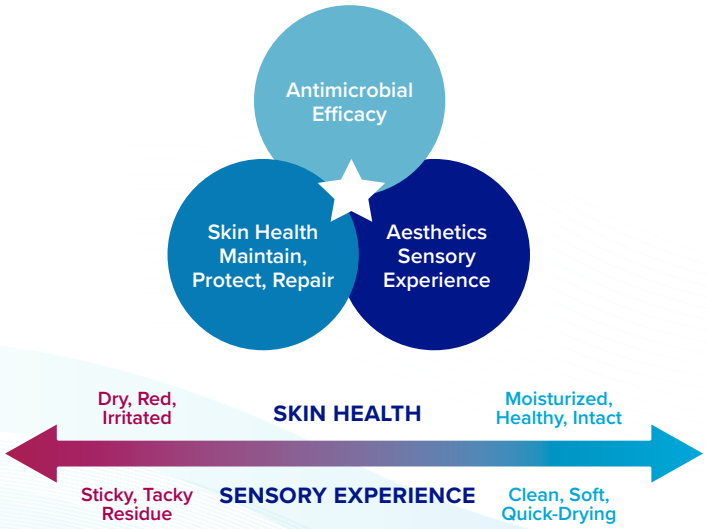
Soap Selection in Healthcare

Soap Efficacy and the Changing Regulatory Landscape

Hand hygiene is a cornerstone process in preventing the transmission of pathogens in healthcare facilities. Since publication of the 2002 Centers for Disease Control and Prevention (CDC) and the 2009 World Health Organization (WHO) hand hygiene guidelines, ABHR has been widely adopted as the preferred method for performing hand hygiene due to its many proven advantages such as superior efficacy, speed of procedure, better compliance, and skin health benefits.[1,2] However, soap and water play a critical role in hand hygiene, namely when hands are visibly soiled or contaminated with blood or other bodily fluids and when there are outbreaks of Clostridium difficile or norovirus.

That said, there are three important formula considerations when evaluating a hand soap: efficacy, skin health, and aesthetics (sensory experience).

Attributes of a Well-Formulated Soap



Efficacy

The starting point for soap selection is choosing between an antimicrobial or a non-antimicrobial soap, and unfortunately, data are lacking in this area to help guide decision making. This is because there are no outcome studies demonstrating a reduction in healthcare-associated infections (HAIs) when a particular soap is used. However, there are in vivo studies (i.e., on hands). Further, studies of pathogen reduction on hands in controlled laboratory settings have demonstrated that ABHR is the most efficacious, followed by antimicrobial soap, with non-antimicrobial soap as least efficacious.[1]

Unfortunately, executing an outcomes study to prove reduction of HAIs with a particular soap would be difficult due to challenges in study design, confounding variables, and cost.

As a result, there is a lack of evidence demonstrating real-world, clinical benefit of an antimicrobial soap versus a non-antimicrobial soap as a single variable. Given that, both the CDC and WHO hand hygiene guidelines allow for the use of either an antibacterial or a non-antibacterial hand soap, leaving it to the discretion of each facility or location.

Active Ingredients and the Changing Regulatory Landscape of Soap

In addition to the element of choice in prevailing hand hygiene guidance, it is helpful to have context on the changing regulatory landscape of active ingredients commonly used in soaps, the role the Food and Drug Administration (FDA) plays, and its impact on different alternatives available for use in healthcare facilities.

The FDA Division of Over-the-Counter (OTC) Drug Products regulates the use of topical antiseptic drug products used in healthcare, including ABHRs and antimicrobial soaps, under the 1994 Tentative Final Monograph. The Monograph establishes conditions under which certain OTC active ingredients are generally recognized as safe and effective (GRASE); specifies allowed ingredients, claims, doses, product form, indications for use, and warnings; and provides a set of labeling and testing requirements for manufacturers.[3]

In 2015, the FDA issued a proposed rule asking for more data around active ingredients used in healthcare hand hygiene products and established a new safety framework to ensure that the ingredients are both safe and effective.[4] The FDA later issued a final rule in 2017 in which certain active ingredients, such as triclosan, in OTC topical antiseptics used in healthcare settings were were not considered GRASE due to insufficient data.

Rulemaking was deferred on six active ingredients (benzalkonium chloride, benzethonium chloride, chloroxylenol, ethyl alcohol, isopropyl alcohol, and povidone-iodine) that are the most commonly used in OTC healthcare antiseptic products to provide manufacturers more time to complete the scientific studies necessary to fill the data gaps identified so that the agency can make a safety and effectiveness determination about these ingredients.[5]

While the FDA awaits the data on the commonly used ingredients, they recommend that healthcare personnel continue to use the currently available products, consistent with infection control guidelines. This final rule went into effect in December 2018. The status of the six deferred active ingredients will be addressed either after completion and analysis of ongoing studies to address the safety and effectiveness data gaps of these ingredients or at a later date, if these studies are not completed.

Importantly, the Final Rule that was published is focused on finalizing the monograph as it relates to active ingredients only. Further clarification and guidance will be needed from the FDA as it relates to efficacy requirements for finished products that are allowed to be marketed to healthcare facilities once all the testing is complete on the deferred actives.

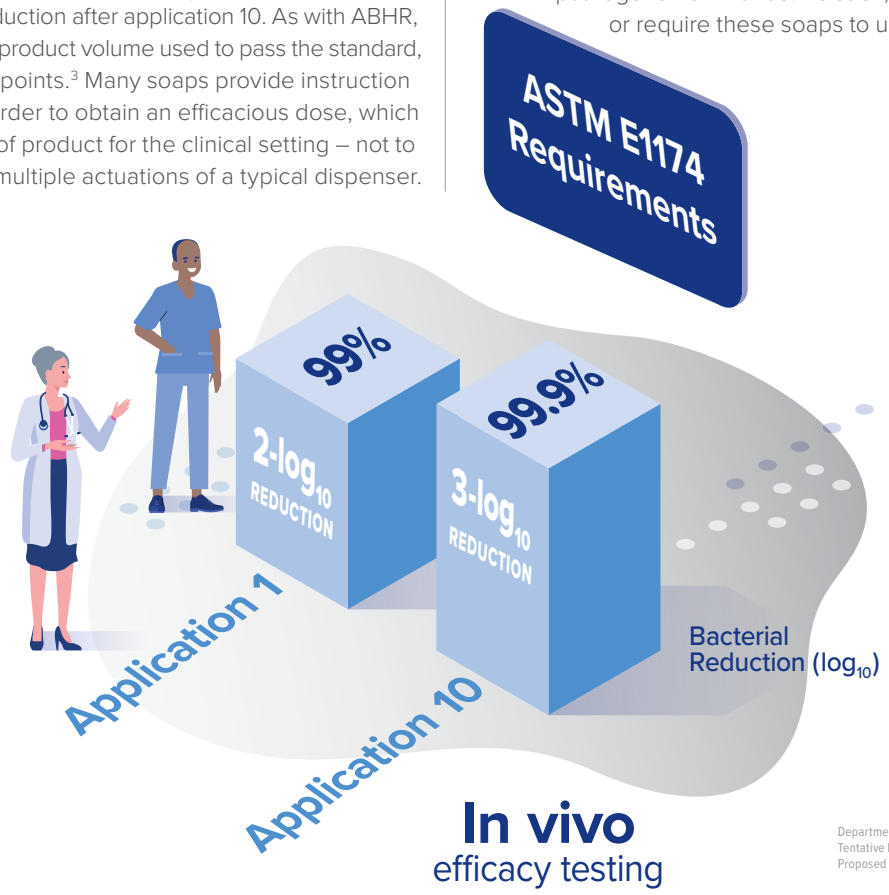
FDA

EFFICACY TESTING – Healthcare Personnel Handwash Test/ASTM E1174

For antimicrobial soaps, it is important to consider not only the efficacy of individual active ingredients but also how they interact and perform in more complex finished formulations. The Healthcare Personnel Handwash Test, or ASTM E1174, measures the reduction of a transient marker organism (Serratia marcescens) on the hands of adult subjects after a single product use and after 10 consecutive product uses.[6]

The FDA requires products to achieve a 2-$\log_{10}$ reduction after application 1 and a 3-$\log_{10}$ reduction after application 10. As with ABHR, the FDA does not dictate the product volume used to pass the standard, only bacterial reduction endpoints.[3] Many soaps provide instruction to use a volume of 5 mL in order to obtain an efficacious dose, which is an unreasonable amount of product for the clinical setting – not to mention that would require multiple actuations of a typical dispenser.

There are some soaps that have been tested at in-use volumes.[7] This is important because it provides reassurance that the volume delivered from one pump of a dispenser is providing the necessary germ-kill needed for the clinical environment. This is additional information to ask for and consider when choosing an antimicrobial soap. Non-antimicrobial soaps do not have efficacy data due to a lack of an antimicrobial active ingredient. Due to this, non-antimicrobial soaps rely on surfactants and friction alone to remove pathogens from hands. As such, the FDA does not expect or require these soaps to undergo efficacy testing.



In vivo efficacy testing

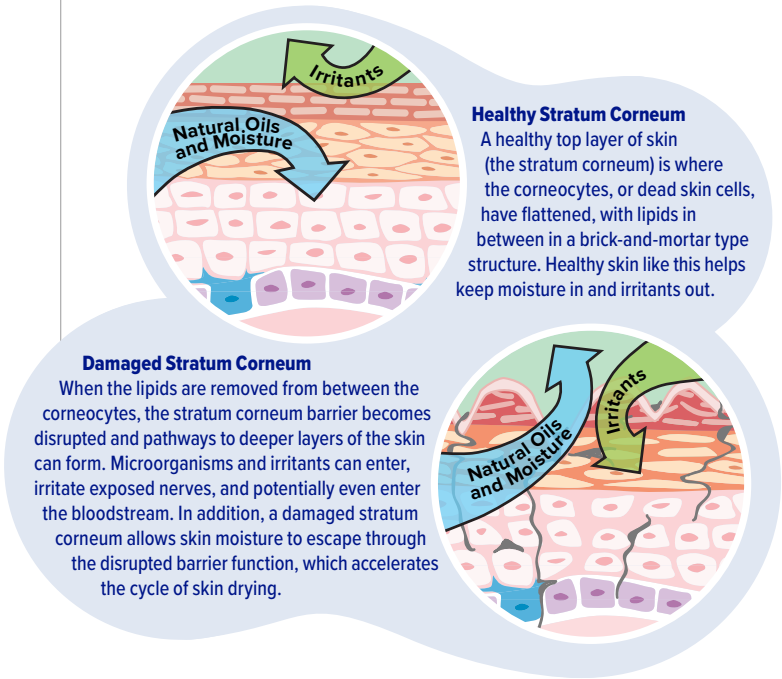
Department of Health and Human Services: Food and Drug Administration. Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule. Federal Register. 1994;59(116):31402-31452.

Soap's Mechanism of Action and Effects on Skin

The Structure and Function of Skin

When discussing the impact/effect of soap on skin, it is important to first review the role of skin and the natural barrier function it provides. Skin is the human body's largest organ. It is complex and performs many functions, among which is its ability to protect the body by shielding it from external threats like chemicals and pathogens and preventing the loss of vitally important electrolytes and water.[8]

The stratum corneum is the thin, but tough, outermost layer of the skin that comes into contact with hand hygiene products. Under a microscope, the stratum corneum looks like a brick wall. The "bricks," or corneocytes, are flattened dead skin cells held in place by a lipid bilayer that helps lock in moisture by acting as the "mortar." The stratum corneum is continually shedding. As the outermost cells age, they are sloughed off and replaced with new cells, a process of complete cell turnover that occurs typically every 28-30 days.[9]



Soap's Mechanism of Action

The general mechanism of action of soap is lifting and suspending oil, dirt, and other organic substances from hands so they can be rinsed off, much like cleaning a dirty dish. A cleansing soap contains surfactants (surface-active agents) which are comprised of both hydrophilic (water-loving) and hydrophobic (water-hating or oil-loving) parts that encourage soils to be lifted from skin or surfaces and attracted to the hydrophobic part. The hydrophobic parts cluster together and form a micelle, a spherical structure with the water-loving parts on the outside. This then allows the soils to become "water-soluble" and washed away during the rinsing process.

Common types of surfactants include sulfates, polyglucosides, betaines, hydroxysultaines, and amine oxides. Generally, a combination of surfactants is used to achieve the targeted foam, lather, cleansing, and rinsing properties of the soap formulation.

Plain or non-antimicrobial soaps remove organic substances and transient, non-resident microorganisms on the skin. Some resident microorganisms on the surface of skin get removed in the handwashing process but quickly regrow to a normal/natural level. Antimicrobial soaps also remove organic substances and microorganisms and contain the addition of an antibacterial active ingredient that interacts with and kills bacterial cells.

Only a few active ingredients remain approved for use in healthcare hand soaps, with varying spectrums of activity and efficacy against microorganisms. It is important to note that active ingredient and level alone are not an indicator of efficacy, as the interaction of all the ingredients in the formulation along with handwashing technique establish the ultimate efficacy of soap.

Effects on Skin

All soap disrupts the brick-and-mortar structure of skin to a degree, but poorly formulated soaps will be very harsh and disruptive to the stratum corneum. Additionally, healthcare workers (HCW) are asked to perform hand hygiene dozens, if not more, times per hour. Over-use of soap sets up a vicious dry skin cycle that worsens with each wash as more lipids are removed deeper into the stratum corneum allowing more moisture to evaporate through the skin, drying it out even more. When the skin's lipids are removed, it can lead to an increase in epidermal nerve density, causing sensations of stinging, burning, itching, tingling, and tightness.[9]

These symptoms are recognized during ABHR use, but the condition is created by the use of soap. Often, as a result of the stinging and burning from ABHR use, HCW will resort to increased use of soap and water because it is perceived as soothing, even though it contributed to the cause of the damage in the first place. In addition to damage from soap itself, environmental stressors such as low relative humidity, hot water use, and poor quality of paper towels can compound the damage. This cyclical damage can be hard to interrupt since HCW do not typically have prolonged periods of respite from intensive hand hygiene regimens to allow their skin to heal.

Numerous studies suggest that damaged skin is associated with changes in the composition of microbial flora of the hands, such as colonization with potential pathogenic organisms.[10,11]

Irritant contact dermatitis is also common among nurses, with prevalence ranging from 25%-55%.[2] Occupational dermatitis is likely to affect the quality of life of HCW and, in severe cases, their ability to work due to an inability to perform requisite hand hygiene.[12] In any given healthcare organization, there are HCW who must seek help from occupational health departments to find alternative hand hygiene products. Preventing occupational skin damage in the first place through selection of high-quality products to support elevated levels of hand hygiene compliance and ensuring correct use of products when indicated is essential to an infection prevention strategy.

The Cycle of Skin Damage

Measuring Skin Health

Soap should optimally maintain skin condition, or at the very least not adversely affect it. The industry standard for measuring skin tolerance is a 14-day human cumulative irritancy assay with delayed challenge. This study assesses the irritation potential of the test product through daily, consecutive applications of product in "patches" to the forearm of human subjects for 14 days. A control product is also included in the study.

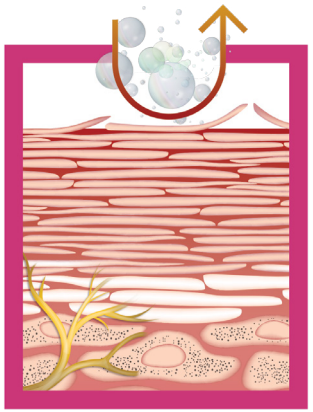
Dermal reactions, including erythema (redness), edema (swelling), and other signs of irritation, are rated by expert visual assessments using a mean cumulative irritation score on a scale of 0-4. In this scale, lower numbers indicate a lower potential for skin irritation and allergic contact dermatitis. Forearm controlled application tests are also used to determine irritation or skin improvement effects of products under "real world" conditions over an extended period of time.

The most important tests, however, are field or clinical tests that determine irritation or skin improvement effects of products with realistic conditions and behaviors in healthcare settings with HCW.

IMPACT OF SOAP vs. ABHR

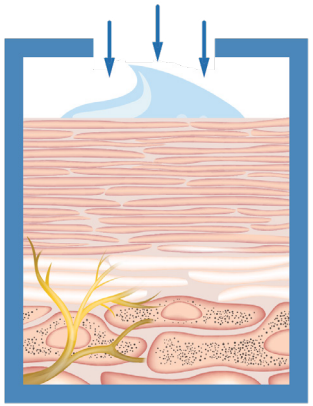
Using a properly formulated soap and ABHR is essential for promoting the health of your skin.

Poorly Formulated Soaps



Soaps that are not formulated well **can reduce the skin's oils and lipids**, eventually creating pathways to deeper layers of the skin, **allowing damage to become more severe**.

ABHR



Alcohol-based hand rubs **do not physically remove skin lipids.** They contain conditioners and emollients which can **benefit the skin**.

Aesthetics of Soaps

Defining Aesthetics and Why They Matter

Product aesthetics, or skin feel, are focused on the visual and sensory experience during use and the washer's overall acceptance of the product. Aesthetic considerations range from the format of the soap (foam or liquid/gel) to how the product looks (color, foam quality) to how it is perceived both during use (lathering, odor/fragrance, rinsability) and after use (skin feel – soft, dry, irritated).

Although not a commonly published component, soap aesthetics factor greatly into HCW acceptance and should not be overlooked.[13] If HCW do not like the product, or believe it is causing harm to their skin, they may not use it. Extensive internal testing of soaps with HCW reveal the most impactful aesthetic attributes on overall preference and HCW acceptance are fragrance/odor, latherability, rinsability, and skin feel after use.

Given that some soaps have been proven to rinse more cleanly than others, including both modern and traditional (saponified) soaps, this aesthetic factor also becomes a data-based decision point for assessing a potential product's link to skin health. Soaps that rinse more cleanly than others leave less soap residue on the skin, which can further decrease irritation potential.

Balancing efficacy, skin health, and skin feel can be difficult to accomplish as it requires investment, exploration, and test methods sensitive enough to pick up on subtle differences that would represent repeated use over time. When formulated properly, soap can provide the right balance of the three and help ensure overall acceptance by HCW, supporting hand hygiene compliance.

During a product trial period, skin undergoes an adjustment phase during which the skin's natural defenses must adapt to the new product and this has been described as "skin accommodation" by occupational dermatologists.[14]

This transitional phase occurs with any hand hygiene product change, regardless of product type or formulation quality. A minimum two- to three-week trial is necessary to account for the stratum corneum renewal or "turnover" that occurs in that timeframe. If trialing more than one product in succession, a washout period of one week between products is advised during which time the previous product is reimplemented. The WHO provides two protocols for evaluation of tolerability and acceptability of ABHR, which can be adapted for soap evaluations.[15]

Factors to Consider When Selecting a Soap

Soap Selection Framework for Healthcare Facilities

Factor	Considerations
Antimicrobial vs. Non-Antimicrobial Soap	Your choice – clinical guidance allows for either. Often driven by strong points of view by subject experts in a given organization. • Controlled laboratory studies of germ reduction on hands demonstrate superior efficacy with antimicrobial soaps. • Due to a lack of studies demonstrating clinical effectiveness of antimicrobial soaps in real-world settings the choice between an antimicrobial and a non-antimicrobial soap remains a healthcare facility's decision. Using a combination approach (mix of antimicrobial and non-antimicrobial soap) adds complexity for environmental services but might allow for higher levels of efficacy in higher acuity areas (e.g., neonatal ICU), which is a common approach by many healthcare facilities.
Skin Health/ Mildness	Soap should optimally maintain skin condition, or not adversely affect it, when used as indicated. • Solicit skin health testing data from product manufacturer. • 14-day cumulative irritancy tests are used to determine exaggerated irritant potential with repeated exposure. • Forearm controlled application tests (FCAT) are used to determine irritation or skin improvement under "real world" conditions over an extended period of time. FCAT can include skin hydration, trans-epidermal water loss, skin erythema, redness and dryness, and other measures to evaluate product performance. • Field tests are used to determine irritation or skin improvement with realistic conditions, behaviors, and timeframe.

Factor	Considerations
Efficacy (Antimicrobial Soaps only)	Product should meet FDA efficacy requirements (Healthcare Personnel Handwash Test, ASTM E1174). Solicit technical data from product manufacturer for in vivo/on hands efficacy data. • Ensure manufacturer shares the dose needed to achieve stated efficacy. Non-antimicrobial soap will not have efficacy data because it does not contain an active ingredient.
Aesthetics (Sensory Experience)	Do you have dye or fragrance policies that would dictate your selection? • Color and fragrance have no effect on soap performance. • If carefully selected and of high quality, fragrance can be used in levels appropriate for the healthcare environment to minimize unpleasant base odors of soap ingredients. Both liquids and foams can work as soaps. Markets have been migrating toward foam because it has better lather and rinsability. Liquid soaps can also often drip onto counters or in sinks, causing waste or sink staining. • A very rich foam, while pleasant to use, can be the result of high levels of surfactant resulting in more lipid removal and difficulty rinsing. Rinse - Soaps should be easily and quickly removed from hands with water rinsing and leave behind little to no perceptible residue.

Soap Selection Framework for Healthcare Facilities (cont.)

Factor	Considerations
Dispensing Solutions	Touch-free vs. Manual Touch-free dispensers are programmed to deliver a set amount of product per actuation and can potentially reduce cross-contamination by multiple users. Touch-free dispensers have also been shown to increase hand hygiene compliance.[16] • Manual (push to actuate) dispensers allow the user to adjust the amount of product delivered by not fully depressing the push bar on the dispenser, potentially resulting in an insufficient dose of product. Soaps and sanitizers used in healthcare settings should come in sanitary sealed containers. Both the CDC and WHO recognize refilling bottles or "topping off" with product is not an acceptable practice for healthcare and have issued guidelines against the practice.[1,2] • There is no way to effectively "clean" a bulk or refillable system, even with a disinfectant like bleach, and once it is contaminated, research has proven that the issue is chronic. Further, research demonstrates the potential for hands to have up to 25 times more germs after washing with a contaminated soap.[17,18] Ask product manufacturer about overall product recyclability (refill container, pump, collar, batteries, etc.). Dispensers should be easy to maintain and designed to withstand the high volume demands of healthcare settings.

Factor	Considerations
HCW Acceptance	It's important for appropriate person(s) in the facility to first screen products and introduce options based on science before trialing with HCW. Infection Prevention guidelines strongly recommend including HCW in the product selection process to maximize acceptance.[1,2] • The WHO provides two product trial protocols originally designed for ABHR evaluation that can be adapted for soap.[15]
Product Compatibility and Known Interactions	Solicit information from product manufacturer on product compatibility. Inquire about known interactions between sanitizer, lotion, and gloves.

Conclusion

A proper hand hygiene regimen as a part of an infection prevention strategy should include:

1) Well-formulated hand washes and ABHRs designed for high-use environments and proven to be both effective and mild to the skin

2) ABHRs as the primary means if hands are not visibly soiled or per policy

3) Use of an approved and compatible skin moisturizer made available to HCW.[1,2]

Although ABHR should remain the primary method for performing hand hygiene, soap continues be an important piece of the hand hygiene regimen. Careful consideration should be given when selecting soap due to its potential for adverse skin effects if not properly formulated. Because of an uncertain future for several active ingredients used in soap and the desire by many facilities to avoid frequent product changes, working with your product manufacturer to evaluate available options is important.

Further, key decision-makers should evaluate soap based on a decision framework that includes efficacy, skin health, and aesthetics or sensory experience, and once it's properly vetted, solicit HCW feedback via a meaningful trial methodology.

Hand hygiene remains a critical cornerstone in all infection prevention programs and supports every healthcare facility's goal of keeping patients, visitors, and staff safe and germ-free. It is also true that the hand hygiene products chosen by a healthcare facility can significantly impact acceptance, compliance to protocols, and ultimately healthcare-associated infections.

The science of soap, its impact on skin, and other relevant considerations provided in this eBook are designed to help key decision-makers focus on the most important factors during the hand hygiene product evaluation process. The best soaps are those that are highly effective and optimize skin health and product acceptance to support good hand hygiene compliance.

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