



Soap: The science behind it, the changing regulatory landscape ahead, and tools and tips for selecting a soap that's right for your facility.

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Introduction

Hand hygiene is the primary measure to prevent transmission of pathogens in healthcare facilities¹ and alcohol-based hand rub (ABHR) is designated as the preferred method for performing hand hygiene by the 2002 Centers for Disease Control and Prevention (CDC) and the 2009 World Health Organization (WHO) hand hygiene guidelines. However, soap and water also plays 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.² Because ABHR has been the primary focus for hand

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Background

Prior to publication of the 2002 CDC hand hygiene guidelines, soap was the predominant hand hygiene product. Today, alcohol-based hand rub (ABHR) represents about two-thirds of all hand hygiene product sales in healthcare.³ While ABHR is the primary pillar of hand hygiene due to its many proven advantages such as superior efficacy, speed of procedure, better compliance, and skin health benefits,⁴ soap remains an important aspect of the hand hygiene regimen that is not always given as much consideration as it deserves.

The Science of Soap

Soap's Mechanism of Action

When selecting the type of soap for a healthcare facility, it's important to first understand how soap works. The general mechanism of action is lifting and suspending oil, dirt, and other organic substances from hands so they can be rinsed down the drain, much like cleaning a dirty dish. Alkali metal salts of fatty acids, such as sodium laurate and potassium cocoate, are traditionally used as soaps. Soaps are classified as surfactants (surface active agents) as they possess both polar (ionic/hydrophilic) and non-polar (long hydrocarbon/hydrophobic) groups. When soap is added to water, tiny clusters called micelles are formed due to aggregation of hydrophobic segments. The ionic segments of surfactants orient outward of the core aggregates/micelles. Hydrophobic segments of micelles have strong affinity towards oil-type dirt and germs, and the hydrophilic segments of micelles attract toward the water-soluble materials. As a result, soaps are capable of cleaning skin and other substrates by removing both water soluble and water-insoluble dirt from the substrates and suspending them in aqueous solutions.

In recent decades, detergents have also been used as soaps. Detergents have similar functional groups as soaps but their hydrophilic groups can be of various types including anionic, non-ionic, cationic, or amphoteric, instead of carboxylic salts. Examples

of detergents include sodium laureth sulfates, alkyl polyglucosides, cocamidopropylbetaine and fatty alkyl amine oxides.

With plain or non-antimicrobial soaps, organic substances and some microorganisms on the skin are removed, but the commensal resident organisms that are reduced quickly regrow to a normal level. The target organisms for removal are transient, non-resident organisms that may cause illness. Antimicrobial soaps also contain an antibacterial

active ingredient that interacts with and kills bacterial cells. Some actives (e.g. chlorhexidine gluconate or CHG) may deposit on the skin's surface in low levels, which keeps the number of microorganisms to a reduced level by static activity for an extended period of time. There are several active ingredients that are used in antimicrobial soap formulations in healthcare, and their spectrum of activity and efficacy against microorganisms varies and can be greatly affected by the other non-active ingredients in the formula. (Table 1).

Table 1. Active Ingredients Commonly Used in Soaps and Sanitizers Today and Their Spectrum of Activity

Product Type	Active Ingredient	Gram + activity	Gram – activity	Viral activity Enveloped/ Non-enveloped	Fungal activity	Currently Monograph Ingredient
Sanitizer	Ethyl alcohol	+++	+++	+++/>++	+++	Yes
Soap	Triclosan	+++	+	+/?	±	Yes
	Chloroxynol (PCMX)	+++	+	+/>±	+	Yes
	Quaternary ammonium compounds (quat)	++	+	+/?	±	Yes
	Chlorhexidine gluconate (CHG)	+++	++	++/>+	+	No; requires NDA

Good = +++, moderate = ++, poor = +, variable = ±, none = –, unknown=?

Adapted with permission from Pittet, Allegranzi & Sax, 2007.⁴⁷⁹ WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge Clean Care Is Safer Care. Geneva: World Health Organization; 2009.

Lack of Consensus around Antimicrobial versus Non-antimicrobial Soap

Both CDC and WHO hand hygiene guidelines allow the use of either an antimicrobial or a non-antimicrobial soap, and due to a lack of evidence demonstrating clinical benefit (i.e. resulting reduction of infection rates), do not recommend one over the other. Clinical data are lacking due to complexity of designing such a study, eliminating confounding variables, cost, and reasons of practicality. However, studies of germ reduction on the hands support that ABHR is most efficacious, followed by antimicrobial soap, followed by non-antimicrobial soap as least efficacious.¹ That said, healthcare facilities are permitted the choice between antimicrobial and non-antimicrobial soap, or may use a combination of the two.

Handwashing Technique

While there's a lack of consensus on type of soap, there's more consensus around handwashing technique. The CDC recommends wetting hands first with water, applying a manufacturer-recommended volume of product to hands, and rubbing vigorously for at least 15 seconds, covering all surfaces of the hands and fingers, followed by rinsing and drying thoroughly with a disposable towel. The WHO recommends a similar method, though they provide more specifics when it comes to vigorously rubbing all surfaces of hands and fingers, separating the process into very specific steps such as palm to palm, fingers interlaced, rotational rubbing of thumb and so forth. Despite published recommendations, healthcare workers (HCW) have been observed not rubbing for an adequate amount of time. In ten observational studies, the duration of handwashing ranged on

average from as little as 6.6 seconds to as much as 30 seconds.⁵ In addition, HCW often failed to cover all surfaces of their hands and fingers highlighting the fact that there is a need for education around proper technique.

Soap's Effects on Skin

Even though ABHR is positioned as the most efficacious and mildest hand hygiene approach, ABHR are not intended or effective at removing visible soil from hands. Soap is still a critical component of a hospital hand hygiene program and should be used when hands

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are visibly soiled or contaminated with blood or other bodily fluids, before eating, and after using the restroom. Many healthcare facilities also mandate soap and water use when caring for patients with *C. difficile*. In all other clinical situations, an ABHR should be used for routine decontamination of hands.

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with current hand hygiene products today, especially when not properly formulated. It is well known that washing with soap, specifically surfactants, can damage the skin's barrier. The stratum corneum (SC) is the very top layer of skin and it can be described using a "brick and mortar" model. Under a microscope, the skin barrier, when healthy, looks like a brick wall. The "bricks," are called corneo-

cytes, which are really dead skin cells. They are held in place by a lipid bilayer and moisture which is the "mortar." The lipid bilayer is composed of two layers of fatty acids. Its role is to help "lock in" moisture.

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As discussed earlier, antimicrobial soaps remove dirt, oil, and organic substances from the skin; however, they also have the addition of an active ingredient to help kill germs. Traditionally, antimicrobial soaps have been less mild to skin than non-antimicrobial soaps; however the latest generation of antimicrobial soaps can provide antimicrobial efficacy as well as

improved skin mildness. Choosing a well-formulated soap with low potential for irritation can help mitigate skin health issues and will be discussed later in this paper. But first, it's important to understand that choices around antimicrobial soaps may be limited in the future due to regulatory changes underway.

The Regulatory Landscape

The Food and Drug Administration (FDA) Division of Over-The-Counter Drug Products (OTC) regulates the use of antiseptic drug products used in health-care. There are two regulatory pathways for these products; one is a New Drug Application (NDA) and one is the Monograph process. OTC Drug Monographs are a practical alternative to the FDA reviewing individual drugs on the market, as is the process with prescription drugs.

The Monograph Process

The monograph is a “recipe book” that specifies allowed ingredients, doses, and formulations and provides a set of labeling and testing requirements for manufacturers. There are three phases of the public rulemaking process that establishes a Monograph.⁷

Phase 1: an FDA-appointed advisory review panel comprised of scientifically qualified experts evaluate data about the ingredients and classify them into three different categories:

- *Category I:* Generally recognized as safe and effective (GRASE)
- *Category II:* Not GRASE – these active ingredients cannot be marketed and sold
- *Category III:* Not enough data to make a final decision on safety and effectiveness, but sufficient data for the sale of products containing these active ingredients until the monograph is finalized.

Phase 2: the FDA evaluates information, including panel findings, public comments, and additional data that had become available and was eligible for inclusion. After this evaluation process, the agency publishes its tentative conclusions as proposed rules in the *Federal Register*. These are referred to as tentative final monographs (TFM). Once a TFM is published, manufacturers can develop and market products that comply with TFM requirements.

Phase 3: the FDA considers the comments and responses to the published TFM and new data received. Then, FDA publishes a final rule (called a final monograph) that establishes standards for both the active ingredients and the labeling in each OTC drug category. Upon publication of a final monograph, only active ingredients that are GRASE are included. Category I-III designations are no longer used and the final monograph is followed. This document is first published in the *Federal Register*, and later in the *Code of Federal Regulations*.

Regulatory Changes in Healthcare

The Monograph under which healthcare is currently operating has been in phase 2 (TFM) since 1994. The Healthcare OTC Monograph is not to be confused with the Consumer Monographs, which may have an impact of perceptions of products used in healthcare. The Consumer Monograph has been separated into leave-on (sanitizer) and rinse-off (soap) products, but the Healthcare Monograph remains combined. Consumer Monographs, while they have no legal bearing on healthcare facilities, can impact public perceptions around products which could result in confusion or questions arising from healthcare staff. The FDA released a Proposed Rule, or an addendum to the Healthcare 1994 TFM on April 30, 2015. Within the Proposed Rule, the FDA called for more data on the safety and efficacy of active ingredients used in hand hygiene products and established a new, protocol-driven safety framework to ensure that hand hygiene ingredients used by HCW are both safe and effective. This framework did not exist in the previous OTC monograph; therefore, all antiseptic ingredients' statuses were moved to a Category III/SE (designation for safety and effectiveness) by default. The FDA was clear that there was no indication of a potential problem with efficacy or safety; rather because many changes and advances have occurred since the FDA began review of health care antiseptics in the 1970s such as frequency of product use, new technology that can detect low levels of antiseptics in the body, and scientific knowledge about the impact of widespread antiseptic use, the FDA has requested more data on active ingredients.⁸

Based on their review of the safety and efficacy studies, the FDA will make a final decision about which active ingredients will continue to be permitted

for use in hand hygiene products. Certain active ingredient such as ethyl alcohol, are well-positioned to be included in the Final Monograph. Other actives such as Triclosan have uncertain regulatory stability and may no longer be available once the Monograph finalizes. Upcoming changes may have a significant impact on a healthcare facility’s decision about which soap to choose. The final OTC Monograph for healthcare is scheduled to be published in January 2018. Category I-III designations will be eliminated,

and active ingredients will either be permitted or not. Though they do not directly affect healthcare, the Tentative Final Monograph for consumer leave-on (sanitizer) products is scheduled to publish on June 30, 2016, and the Final Monograph for consumer rinse-off (soap) products is scheduled to publish on September 15, 2016 (**Table 2**). The outcome of either of these Monographs may affect how actives used in healthcare are perceived.

Table 2. Consumer versus Healthcare Antiseptic Monograph Timeline

	Consumer Antiseptic Handwash Monograph	Healthcare Antiseptic Products Monograph
Scope: products	Antimicrobial soaps	Antimicrobial soaps and hand sanitizers
Scope: markets	Consumer settings, excludes healthcare	Healthcare settings only
TFM publication date	December 16, 2013	April 30, 2015
Final Monograph publication date	September 15, 2016	January 15, 2018

Alternative Regulatory Pathway – New Drug Application

There are hand hygiene products used in healthcare today that are not affected by upcoming Monograph changes because they have already been proven to be safe and effective. Products that contain active ingredients not included in the Monograph or combinations of active ingredients follow a different regulatory pathway. The New Drug Application (NDA) pathway is the vehicle through which drug sponsors (the person or entity who assumes responsibility for the marketing of a new drug) formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The FDA reviews the application to determine whether the drug is safe and effective when used as proposed, whether the drug’s labeling is appropriate, and whether the drug was manufactured in a way that maintains quality of the drug. If the NDA is approved, then the drug may be marketed and sold in the U.S.⁹

As an example, chlorhexidine gluconate (CHG) is an active ingredient used in a variety of applications in healthcare today, including patient bathing, pre-operative skin preparation, impregnated dressings and a variety of other antiseptic uses to prevent colonization and infection by bacteria. CHG is not an active

ingredient covered by the Monograph and therefore requires a NDA. The use of CHG hand soaps may increase in the future given its trusted efficacy, broad spectrum of activity, proof of safety and efficacy and as a result its regulatory stability as an NDA product.

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Choosing a Soap for Your Healthcare Facility

With all of the considerations around soap, selecting the right product can be confusing. Additionally, there can be reluctance to changing hand hygiene products in healthcare facilities due to the many considerations that go along with it, such as potential for a period of adjustment among HCW, the logistics involved with switching dispensers, and disruptions to the clinical workflow. When considering a product change or when utilizing a soap active ingredient with an uncertain future, it’s important to carefully select the right product and right

dispensing solution for your facility.

As previously discussed, soap has not been given as much consideration as ABHR when healthcare facilities have chosen hand hygiene products. Poorly formulated soap can have profound negative effects on HCW skin condition and can contribute to a cycle of skin damage that is reinforced by avoidance of ABHR and continued over-use of soap. Therefore, selecting well-formulated products is an important foundational aspect of a hand hygiene and an infection prevention and control program.

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How to select the Right Soap for your Facility

Factors to consider when selecting soap for your healthcare facility are summarized in **Table 3**. Deciding whether to use an antimicrobial or a non-antimicrobial soap is often the first decision. Many healthcare facilities take a risk-reduction approach by utilizing an antimicrobial soap for added protection, while some choose a hybrid approach by deploying antimicrobial soap to high acuity areas such as intensive care units, hematology-oncology areas, and surgical areas. Others use non-antimicrobial soaps throughout the facility. While the evidence around whether antimicrobial soaps result in better clinical outcomes remains elusive, it is estimated that as much as two-thirds of the soaps sold into healthcare today is antimicrobial, and triclosan represents over half of antimicrobial soaps.³ Therefore, there is a possibility that many healthcare facilities will be forced to make a switch in the coming years if certain actives are no longer permitted in soap.

Four Key Factors to Consider When Selecting a Soap

Developing a truly mild, yet effective soap that can be used multiple times during a HCW's shift is a significant technical challenge, so it's important to carefully assess products under consideration. It can be very helpful to evaluate soaps within the context

of four important factors: efficacy, skin health, aesthetics (skin feel) and regulatory stability. It is important to note that more sensitive skin often undergoes a period of adjustment during which the skin's natural defenses better tolerate any product change that is made. As a result, trialing products for a minimum of two-three weeks is essential since the stratum corneum renewal time or "turnover" typically occurs in that timeframe.¹⁰ If there are skin adjustment issues that occur during the beginning of a trial period, they should also subside within that two-three week window. It is also advisable that if trialing more than one product back-to-back, a washout period of around one week is scheduled during which time the previous product is re-implemented. The WHO provides two protocols for evaluation of tolerability and acceptability of ABHR which can be adapted for soap evaluations.¹¹

Efficacy. For antimicrobial soaps, it is not only important to consider different active ingredients, but also evaluate the efficacy of finished formulations. The Healthcare Personnel Handwash Test is the only FDA-accepted test for healthcare hand wash products and it measures the reduction of a transient market organism (*Serratia marcescens*) on the hands of adult subjects after a single product use and after 10 consecutive product uses. The FDA requires antimicrobial handwash and hand rub agents achieve a 2-log₁₀ reduction at Application 1 and a 3-log₁₀ reduction at Application 10.¹² Product manufacturers should supply customers with this data for products being sold into healthcare.

Skin health. How a product affects the skin health of those using the products is especially important in environments such as healthcare where repeated use scenarios are common. While the OTC Monograph does not specify irritancy testing requirements, ensuring skin tolerance of products is critical to maximizing HCW acceptance and hand hygiene compliance.¹ Industry standard is a 14-day human cumulative irritancy assay with delayed challenge. This type of study is designed to assess the irritation potential of test product and involves daily, consecutive application of product in "patches" to the forearm of human subjects for 14 days. A control material or product is also included in the study. Dermal reactions, including erythema, edema, and other features indicative of irritation, are scored by expert visual assessments using a standard scale. A mean

cumulative irritation score on a scale of 0-4 is reported with lower numbers indicating 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 more “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 clinical settings.

Aesthetics/Skin Feel. Product aesthetics and skin feel are focused towards end-user acceptance. Aesthetic considerations can begin with how the product looks (color), the 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. The bottom line is that if HCW do not like a product, they are less likely to use it,¹³ so aesthetic and skin feel considerations are critical and should not be minimized. Balancing efficacy, skin health, and skin feel can be difficult to accomplish,

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Balancing efficacy, skin health, and skin feel can be difficult to accomplish, but with proper formulation, of both ABHRs and soaps, it is possible to achieve this balance.

Regulatory Stability. Lastly, regulatory stability may become a more important consideration as the regulatory landscape changes in the coming years. Because changing products can be a challenging undertaking in healthcare and is often avoided whenever possible, choosing an active with greater regulatory stability can minimize or eliminate the possibility of a future product switch. NDA soap products have already gone through the process of ensuring safety and efficacy and will not be impacted by Monograph changes. **Table 3** summarizes other important factors to consider when selecting a soap for your healthcare facility.

Table 3. Factors to Consider when Selecting a Soap for a Healthcare Facility

Factor	Considerations
Antimicrobial vs. Non-Antimicrobial Soap	<ul style="list-style-type: none"> Determine level of “risk tolerance” <ul style="list-style-type: none"> For greatest risk reduction, choose an antimicrobial soap Consider a single soap product approach or a hybrid approach (e.g. antimicrobial in high acuity areas only) <ul style="list-style-type: none"> A hybrid approach can add complexity for Environmental Services (EVS)
Efficacy (Antimicrobial Soaps)	<ul style="list-style-type: none"> Product should meet FDA efficacy requirements defined in OTC Monograph <ul style="list-style-type: none"> Solicit product manufacturer for technical bulletin
Skin Health/Mildness	<ul style="list-style-type: none"> Maintains skin condition with repeated use Solicit skin health testing data from product manufacturer <ul style="list-style-type: none"> <u>14 day irritancy test</u> is used to determine exaggerated irritant potential that may be cumulative with repeated exposure of a material <u>Forearm controlled application test</u> is used to determine irritation or skin improvement effects of products under more “real world” conditions over an extended period time. As part of this test, skin hydration, TEWL, skin erythema, redness and dryness and other measures may be conducted to evaluate product performance. <u>Field or home-use tests</u> are used to determine irritation or skin improvement effects of products with realistic conditions & behaviors

Table 3. Factors to Consider when Selecting a Soap for a Healthcare Facility (conti.)

Factor	Considerations
Aesthetics (Skin Feel)	<ul style="list-style-type: none"> • Color or dye-free <ul style="list-style-type: none"> o Color can be used to connote or visually depict features and benefits of the product (ex. aloe-containing products are often green and perceived as soothing) o Some facilities prefer dye-free products whenever possible • Format (foam vs. liquid) - this is purely a preference • Lather – product should have an acceptable lather • Rinse - product should rinse easily and leave behind a “clean feeling” • Scent/odor/fragrance <ul style="list-style-type: none"> o Fragrance can be a positive aspect of the sensory experience, and in one study had a positive effect on hand hygiene compliance¹⁴ o Some facilities have a fragrance-free policy o Fragrance is often used to minimize the base odor of raw ingredients and active ingredients which can often have an unpleasant odor o Fragrance can either be synthetic or natural (e.g. essential oils) o If carefully selected, fragrance can be used in levels appropriate for the healthcare environment
Dispensing Solutions	<ul style="list-style-type: none"> • Touch-free <ul style="list-style-type: none"> o In one study, touch-free dispensers were used significantly more than manual dispensers and were associated with an increased hand hygiene compliance rate¹⁵ o Believed to reduce cross-contamination by multiple users¹⁶ • Manual <ul style="list-style-type: none"> o Allows for adjustment of amount of product dispensed, which may impact efficacy¹⁶ • Sealed container- products used in healthcare should come in sealed containers. Refilling bottles or “topping off” product is not acceptable practice in healthcare facilities.¹ • Environmental considerations – inquire with product manufacturer as to whether empty refills containers are recyclable • Compatibility with Electronic Compliance Monitoring (ECM) technology – determine if dispensers are ECM-ready should upgrading to this technology be of future interest
Other Value Added Programs	<ul style="list-style-type: none"> • Education – inquire if the vendor offers education around their product in the form of in-services, peer-reviewed publications, or other materials

Table 3. Factors to Consider when Selecting a Soap for a Healthcare Facility (conti.)

Factor	Considerations
Regulatory Stability	<ul style="list-style-type: none"> • There is uncertainty around the availability of some antimicrobial soap active ingredient when the OTC finalizes in the future • New Drug Application (NDA) – products that have undergone the NDA process will not be affected by changes to the Monograph
HCW acceptance	<ul style="list-style-type: none"> • Both the CDC and the WHO recommend soliciting input from HCW when selecting hand hygiene products to maximize acceptance. Ideally, HCW should be given the opportunity to trial products at minimum for two weeks. The WHO provides two product trial protocols for consideration.¹¹
Product Compatibility and Known Interactions	<ul style="list-style-type: none"> • Solicit information from product manufacturer on product compatibility. Inquire about known interactions between products used to clean hands, skin care products, and type of gloves used.¹
Cost	<ul style="list-style-type: none"> • While cost is an important consideration for most healthcare facilities, it should not be the overriding factor when selecting a product.¹ If a product is not of acceptable quality, well-formulated, and liked by HCW, then it may not be used.

Conclusion

Because of the changing regulatory landscape, it is important for key decision makers to be armed with as much knowledge around soap as possible. Some soap active ingredients that are known and used today have uncertain futures and may not be available long-term. Although ABHR should remain the primary method for performing hand hygiene, soap continues to 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. Evaluating soap and ABHR in terms of efficacy, skin health, aesthetics/skin feel, and regulatory stability can be helpful. As always, allowing HCWs the opportunity to trial products and provide input is a critical aspect of product acceptance. While selecting the right soap may not be easy, being well-informed about the options and key selection factors can help make the process easier.

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Biography



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Megan DiGiorgio has worked in infection prevention for over 10 years. She received her bachelors of science and masters of science in nursing from Case Western Reserve University in Cleveland Ohio. Prior to her career in infection prevention she was a pediatric nurse. She has presented posters and oral abstracts at several national conferences and has published several peer-reviewed articles. Megan began working at GOJO in 2013 as a Clinical Specialist for Healthcare.