GOJO

HAND HYGIENE TIMES

Your resource for the latest news in effective infection control program development and best practices.

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The Regulatory Changes Ahead for Hand Soap in Healthcare

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Soap and water hand washing plays a critical role in infection prevention, namely when hands are visibly soiled or contaminated and when there are outbreaks of *C. difficile* or Norovirus. Because alcohol-based hand rub (ABHR) has been the primary focus for hand hygiene and due to the limited data around soap, it has been given less attention during product selection in the past. This may change in the near future because Federal regulations for over-the-counter antiseptic active ingredients typically used in hand soap are undergoing revisions and the landscape of available actives is likely to change soon. These forthcoming regulatory changes may force many healthcare facilities to rethink their soap choices.

The Food and Drug Administration (FDA) Division of Over-The-Counter Drug Products (OTC) regulates the use of antiseptic drug products, like hand sanitizers and antimicrobial soaps, used in healthcare. There are two regulatory pathways for these products; one is a New Drug Application (NDA) and the other is the Monograph process. NDA products are individually reviewed by the FDA for safety and efficacy, and if approved, can be marketed and sold. Active ingredients like chlorhexidine gluconate (CHG) that are not covered in the Monograph must undergo the NDA process. There are other ingredients commonly used in hand hygiene products that do not require individual review and these ingredients are included in the Monograph. The Monograph is a "recipe book" that specifies allowed ingredients, doses, and formulations and provides a set of labeling and testing requirements for manufacturers.

On April 30th, 2015, the FDA released a Proposed Rule, or an addendum to the Healthcare 1994 Tentative Final Monograph asking 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 hand hygiene ingredients used by healthcare workers are both safe and effective.[1] Based on their review of the safety and efficacy studies submitted, the FDA will make a final decision about which active ingredients will continue to be permitted for use in hand hygiene products. Certain active ingredients, such as ethyl alcohol, are well-positioned to be included in the Final Monograph. Other soap actives such as Triclosan, have an uncertain regulatory future and may no longer be available once the Monograph publishes in January 2018.

What does this mean for healthcare facilities?
Choices may be limited in the future. The FDA was clear that healthcare facilities should continue using these products. The Proposed Rule is a call for more data on these active ingredients, not a declaration that they are problematic. Hand hygiene is the foundation of an infection prevention program, and using antiseptic active ingredients when performing hand hygiene to reduce the spread of microorganisms is responsible use. Some active ingredients such as Triclosan have been used so widely in consumer applications such as hand soaps, body washes, toothpaste, footwear, adhesives and fabrics, as both an antimicrobial and a material preservative that concerns around environmental impact have been raised. It is unclear whether other active ingredients for soap will be impacted. NDA products will be not be affected by the Monograph changes and are a stable regulatory option. While no one can predict the decisions the FDA will make in 2018, it is likely that there will be some impact on healthcare facilities. Key decision makers in healthcare facilities need to understand the changes that are underway so they can respond quickly and appropriately to concerns that may be raised and make sound and informed decisions around product choice if changes must be made.

For more information on the science of soap and Federal regulations download **Soap: The science behind it, the changing regulatory landscape ahead, and tools and tips for selecting a soap that's right for your facility Whitepaper (Authored by GOJO Industries, Inc.)**

THAT'S a FACT!

Plain or non-antimicrobial soaps remove organic substances and some microorganisms on the skin, but the resident organisms that are reduced quickly regrow to a normal level. Antimicrobials soaps, in addition to removing organic substances, also contain an antibacterial active ingredient that interacts with and kills bacterial cells.[4]

Product Feature

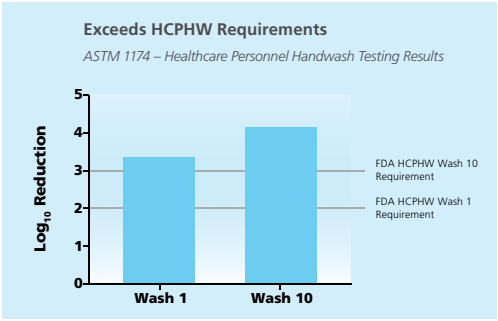
Introducing New PROVON® Antimicrobial Handwash with 2% CHG

TRUSTED EFFICACY. **UNEXPECTED** MILDNESS

PROVON Antimicrobial Handwash with 2% CHG is one of our most effective and gentle formulations yet and will help keep healthcare workers' hands both clean and healthy. In fact, it exceeds FDA Healthcare Personnel Handwash requirements,[2] which is why this formula can be used anywhere in the hospital. And, it's just as mild as our top-selling non-antimicrobial soap.[3] After all, what good is a soap if it's too harsh to use?

Choose the PROVON line of products from GOJO, a leading brand in anti-bacterial skin care solutions and make PROVON products an integral part of your regimen for reducing the spread of infections, maintaining good hygiene and promoting good skin health.

As a leader in skin health and hand hygiene GOJO understands that effective formulations are important in sustaining your hand hygiene and skin care regimen. As part of a total solution GOJO offers the PROVON line of hand soaps with a full range of antimicrobial and non-antimicrobial solutions that help reduce the spread of germs that can cause infection while being gentle to the skin.



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LEAVES HANDS FEELING CLEAN & SOFT

RINSES QUICKLY WITH NO STICKY, TACKY RESIDUE

COMPATIBLE WITH LATEX GLOVES

Description	Order Number	Case Pack	Uses Dispenser
PROVON Wall-Mount & Table-top Dispensing			
PROVON Antimicrobial Foam Handwash with 2% CHG			
LTX™ - 1200 mL Refill	1922-02	2	–
ADX™ - 1250 mL Refill	8842-03	3	–
Pump Bottle - 535 mL	5742-06	6	–

1. FDA issues proposed rule to address data gaps for certain active ingredient in health care antiseptics [press release]. Silver Spring, MD. Food and Drug Administration; April 30, 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm445002.htm. Accessed June 30, 2016.
2. Exceeds FDA Healthcare Personnel Handwash requirements
3. GOJO SCLC Study #2015-12-I10484 Antibacterial (CHG-TCS-PCMX-BAK) 4D-48X FCAT II
4. World Health Organization. WHO guidelines on hand hygiene in health care. First global patient safety challenge: clean care is safer care. http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Published 2009. Accessed March 1, 2015.

A Look Ahead

next month's issue