

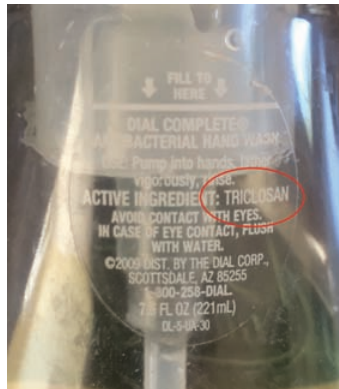


Handwashing Products Used by the Home Care Patient and Their Caregiver

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The Food and Drug Administration (FDA) compares the risks and the benefits of drugs under specified conditions on their use to determine whether a product is generally recognized as safe and effective (GRAS/GRAE). Recently, the FDA evaluated over-the-counter (OTC) antiseptics to ensure that the safety and effectiveness evaluations and determinations for antiseptic active ingredients are consistent, up-to-date, and appropriately reflect current scientific knowledge and increasing use patterns. Since their last evaluation many things have changed, including: new technology that can detect low levels of antiseptics in the body, FDA safety standards, the frequency of use of some products, and scientific knowledge about the impact of their widespread use. Based on this review, the FDA issued a rule declaring 19 active ingredients found in over 700 OTC consumer antiseptic wash products are not GRAS/GRAE and are misbranded. Antiseptic wash products are those that contain certain active ingredients and are intended for use with water and rinsed off after use, such as antibacterial soaps, and hand and body washes. It is important to note that this final FDA rule *does not* apply to:

- Healthcare antiseptics (refer to FDA, 2016b);
- Consumer antiseptic rubs (refer to FDA, 2016c);
- Antiseptics identified as “first aid antiseptics”; or



- Antiseptics used by the food industry (FDA, 2016a).

Triclosan (liquid soap) and triclocarban (bar soap) are the most widely used OTC consumer antiseptic wash active ingredients on the market; thus, the FDA’s analysis focused on these two products. Based on the total available data regarding the safety profile of triclosan, there was insufficient information to find that triclosan was GRAS for use in consumer antiseptic wash products. Moreover, the FDA determined studies to support the efficacy for triclosan were not designed as adequate and well-controlled clinical outcome studies, and as such were not sufficient to determine the GRAE status of triclosan as a topical antiseptic. The studies submitted to the FDA did not address the effectiveness of consumer antiseptic wash products in the prevention or reduction of infections, and lacked adequate controls, which made it difficult to determine the contribution of anti-

septic hand wash on the reduction of methicillin-resistant *Staphylococcus aureus* infections. The FDA did acknowledge there may be populations with increased vulnerability to bacterial infection, such as older adults and persons with suppressed immune systems; however, the data were lacking to support the benefit of consumer antiseptic wash products over that of nonantibacterial soap and water in these populations. Antibacterial manufacturers did not provide the necessary data to demonstrate the effectiveness for triclosan and the other 18 active ingredients and as such, the FDA deemed them not GRAS/GRAE for use in consumer antiseptic wash products.

Healthcare antiseptics, as defined by the FDA, are drug products intended for use by healthcare professionals in a hospital setting or other healthcare situations outside the hospital; and include healthcare personnel hand washes, healthcare personnel hand rubs, surgical hand scrubs, surgical hand rubs, and patient preoperative skin preparations (FDA, 2016b). If the FDA required that triclosan and the other active ingredients be removed from consumer product use, then why can they still be used by home care and hospice staff? The FDA evaluates OTC antiseptic drug products separately from healthcare antiseptics as each setting presents a different level of risk for infection and each has different effectiveness data requirements to

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support a GRAS/GRAE determination. In a healthcare setting, there are a myriad of infection risks, and the risks for serious adverse outcomes from a health-care-associated infection are much higher than in the general U.S. consumer population.

In time, the FDA may make the same determination for healthcare antiseptics. Until then, home care and hospice staff should:

- Routinely use an alcohol-based hand hygiene product, unless there is a need for staff to wash their hands with soap and water if they become dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids (Centers for Disease Control and Prevention [CDC], 2002), or prior to leaving the home or inpatient hospice facility room of a patient infected or colonized with *Clostridium difficile* (McGoldrick, 2015). The staff's hands may be washed with either a nonantibacterial soap and water, or water and an antibacterial soap or other detergent containing an antiseptic agent (e.g., alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol [PCMX], quaternary ammonium compounds, and even triclosan [although many manufacturers have discontinued its use]), unless there is an indication for the hands to be decontaminated. Examples

of when the hands must be decontaminated include prior to direct patient contact, after contact with a patient's intact skin, etc. (CDC, 2002).

- Review the active ingredients in the soap provided to the staff for their use in the home, and compare it to the list of 19 active ingredients that the FDA found not to be GRAS/GRAE for use as a consumer antiseptic wash (<https://federalregister.gov/a/2016-21337>). If the soap contains an active ingredient from the FDA's list, consider replacing the soap with a different product when stock is replenished.
- Reinforce patient and caregiver teaching on the importance of performing hand hygiene using either an alcohol-based hand sanitizer that contains at least 60% alcohol, or to wash their hands with soap and water.
- Instruct the patient to review the manufacturer's label on the soap used for hand hygiene in the home for an active ingredient, such as triclosan, that is no longer deemed to be GRAS/GRAE, and to replace the soap (if needed) when convenient.
- Instruct the patient and caregiver to be aware that soap manufacturers have until September 6, 2017 to comply with the FDA rule. Until that time, soap that

contains an active ingredient that is not recommended for consumer use may still be available for purchase.

For the home care and hospice patients and their caregivers, what is most important is not whether the soap used for hand hygiene is antibacterial or plain soap, but that they wash their hands using the correct technique when hand hygiene is indicated. ▲

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The author declares no conflicts of interest.

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