

FDA News Release

FDA issues final rule on safety and effectiveness of antibacterial soaps

Rule removes triclosan and triclocarban from over-the-counter antibacterial hand and body washes

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Release

[Español \(/NewsEvents/Newsroom/ComunicadosdePrensa/ucm519089.htm\)](#)

The U.S. Food and Drug Administration today issued a final rule establishing that over-the-counter (OTC) consumer antiseptic wash products containing certain active ingredients can no longer be marketed. Companies will no longer be able to market antibacterial washes with these ingredients because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections. Some manufacturers have already started removing these ingredients from their products.

[This final rule \(https://www.federalregister.gov/articles/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for\)](https://www.federalregister.gov/articles/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for) applies to consumer antiseptic wash products containing one or more of 19 specific active ingredients, including the most commonly used ingredients – triclosan and triclocarban. These products are intended for use with water, and are rinsed off after use. This rule does not affect **[consumer hand “sanitizers” or wipes \(/NewsEvents/Newsroom/PressAnnouncements/ucm509097.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm509097.htm)**, or antibacterial products used in **[health care settings \(/NewsEvents/Newsroom/PressAnnouncements/ucm445002.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm445002.htm)**.

“Consumers may think antibacterial washes are more effective at preventing the spread of germs, but we have no scientific evidence that they are any better than plain soap and water,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research (CDER). “In fact, some data suggests that antibacterial ingredients may do more harm than good over the long-term.”

The agency issued a **[proposed rule in 2013 \(/NewsEvents/Newsroom/PressAnnouncements/ucm378542.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm378542.htm)** after some data suggested that long-term exposure to certain active ingredients used in antibacterial products — for example, triclosan (liquid soaps) and triclocarban (bar soaps) — could pose health risks, such as bacterial resistance or hormonal effects. Under the proposed rule, manufacturers were required to provide the agency with additional data on the safety and effectiveness of certain ingredients used in over-the-counter consumer antibacterial washes if they

wanted to continue marketing antibacterial products containing those ingredients. This included data from clinical studies demonstrating that these products were superior to non-antibacterial washes in preventing human illness or reducing infection.

Antibacterial hand and body wash manufacturers did not provide the necessary data to establish safety and effectiveness for the 19 active ingredients addressed in this final rulemaking. For these ingredients, either no additional data were submitted or the data and information that were submitted were not sufficient for the agency to find that these ingredients are Generally Recognized as Safe and Effective (GRAS/GRAE). In response to comments submitted by industry, the FDA has deferred rulemaking for one year on three additional ingredients used in consumer wash products – **[benzalkonium chloride \(http://www.regulations.gov/document?D=FDA-1975-N-0012-0639\)](http://www.regulations.gov/document?D=FDA-1975-N-0012-0639)**, **[benzethonium chloride \(http://www.regulations.gov/document?D=FDA-1975-N-0012-0640\)](http://www.regulations.gov/document?D=FDA-1975-N-0012-0640)** and **[chloroxylenol \(PCMX\) \(http://www.regulations.gov/document?D=FDA-1975-N-0012-0638\)](http://www.regulations.gov/document?D=FDA-1975-N-0012-0638)** – to allow for the development and submission of new safety and effectiveness data for these ingredients. Consumer antibacterial washes containing these specific ingredients may be marketed during this time while data are being collected.

Washing with plain soap and running water remains one of the most important steps consumers can take to avoid getting sick and to prevent spreading germs to others. If soap and water are not available and a consumer uses hand sanitizer instead, the **[U.S. Centers for Disease Control and Prevention \(CDC\) recommends \(http://www.cdc.gov/handwashing/\)](http://www.cdc.gov/handwashing/)** that it be an alcohol-based hand sanitizer that contains at least 60 percent alcohol.

Since the FDA's proposed rulemaking in 2013, manufacturers already started phasing out the use of certain active ingredients in antibacterial washes, including triclosan and triclocarban. Manufacturers will have one year to comply with the rulemaking by removing products from the market or reformulating (removing antibacterial active ingredients) these products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by helping to ensure the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for helping to ensure the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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Consumers

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Related Information

- **Final Rule: Safety and Effectiveness of Consumer Antiseptics**
(<https://www.federalregister.gov/articles/2016/09/06/2016-21337/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for>)
- **Antibacterial Soap? You Can Skip It -- Use Plain Soap and Water**
([//ForConsumers/ConsumerUpdates/ucm378393.htm](http://www.fda.gov/oc/ohrt/ForConsumers/ConsumerUpdates/ucm378393.htm))
- **Topical Antiseptic Products** ([/Drugs/DrugSafety/InformationbyDrugClass/ucm444681.htm](http://www.fda.gov/oc/ohrt/Drugs/DrugSafety/InformationbyDrugClass/ucm444681.htm))
- **Handwashing: Clean Hands Save Lives (CDC)** (<http://www.cdc.gov/handwashing/>)

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