



Update on FDA Final Rule for Consumer Antiseptic Hand Wash Products

Background:

The U.S. Food and Drug Administration (FDA) has published its Final Rule for consumer antiseptic hand wash products. **This final rule applies to consumer antiseptic wash products** that are intended for use with water and are rinsed off after use, including hand washes and body washes. **It does not impact consumer hand sanitizer/rub/wipes used without water, healthcare antiseptics used with or without water, food handler antiseptics used with or without water, or first aid antiseptics.** Those rules are expected in the coming years.

The Rule states consumer antiseptic wash products are “intended for use with water by the general population in home or public settings on a frequent or daily basis”, including products used in institutional settings. The FDA further elaborates in postings that this rule applies to products used in homes, schools, daycares, or other public settings and which are typically sold in retail establishments. The FDA has yet to clarify if consumer use for home healthcare may be allowed under other rulemaking.

As the FDA was not provided sufficient safety and efficacy data, and certain data suggest there may be potential risks, Consumer Antiseptic Hand wash products with one or more of the following active ingredients must be removed from the market or reformulated to remove these ingredients by September 6, 2017:

- Triclosan
- Triclocarban
- Povidone-iodine 5 to 10%
- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodophors (Iodine-containing ingredients)
- Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
- Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
- Nonylphenoxypoly (ethyleneoxy) ethanoliiodine
- Poloxamer-iodine complex
- Undecoylium chloride iodine complex
- Methylbenzethonium chloride
- Phenol (greater than 1.5%)
- Phenol (less than 1.5%)
- Secondary amylicresols
- Sodium oxychlorosene
- Tribromsalan
- Triple dye

Consumer Hand wash products with the following active ingredients have a one year deferral to allow suppliers to provide additional safety and efficacy data: Benzethonium chloride, Benzalkonium chloride and PCMX (chloroxymenol). This deferral was granted in March 2016 and suppliers must submit a progress report to the FDA in February 2017. The FDA will determine at that time whether an additional deferral is appropriate or whether these ingredients must also be removed from the market.

Key Points:

- Veterinary Hospitals and other facilities are switching to basic hand soap, such as **ProVetLogic Foaming Eco Friendly** hand soap, for use in non-surgical and non-treatment areas of their facility.
- There will be an increased need for waterless hand sanitizers, such as **ProVetLogic Non-alcohol Hand Sanitizer**, for areas with limited access to water and paper towels.