

## 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, foodhandler antiseptics used with or without water, or first aid antiseptics. Those rules are expected in 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 Handwash 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

**NOTE: None of the products that Best Sanitizers, Inc., sells contain any of these banned ingredients.**

Consumer Handwash 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 (chloroxylenol). 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:

- The FDA has published its final rule for consumer antiseptic hand wash products.
- This rule only pertains to **consumer products**, and not those used in food handling environments or healthcare settings.
- This rule identifies Triclosan and 18 other active ingredients.
- None of the products that Best Sanitizers, Inc., sells contain any of these banned ingredients.
- Manufacturers have one year to sell through inventory, and stop selling by September 6, 2017.
- FDA has deferred ruling on consumer products using Benzethonium chloride, Benzalkonium chloride and PCMX (chloroxylenol) for a minimum of one year to allow suppliers more time to provide additional safety and efficacy data.

### For More Information:

- To visit the FDA’s website for more information on this rule, [click here](#).
- Contact your Best Sanitizers account representative.