

U.S. FDA Publishes Final Rule on Hand Sanitizer Active Ingredients

On April 12, 2019, the U.S. Food and Drug Administration (FDA) published the Final Rule for the *Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use*. The final rule outlines active ingredients that are not Generally Recognized as Safe and Effective (GRASE) and therefore, not permitted in consumer over-the-counter (OTC) hand sanitizers.

The final rule also outlines the active ingredients that currently require additional information to determine the safety and efficacy. The FDA has deferred rulemaking on Benzalkonium chloride, Ethyl alcohol (aka ethanol, alcohol), and Isopropyl alcohol for additional time to collect safety and efficacy data.



Effective April 13, 2020, manufacturers will need a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) to sell or distribute OTC hand sanitizers for consumer use containing one or more of the following 28 active ingredients:

- Benzethonium chloride
- Chloroxylenol
- Chlorhexidine gluconate
- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
- Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
- Methylbenzethonium chloride
- Nonylphenoxypoly (ethyleneoxy) ethanoliiodine
- Phenol (equal to or less than 1.5% or greater than 1.5%)
- Poloxamer iodine complex
- Povidone-iodine 5-10%
- Secondary amyltricrosols
- Sodium oxychlorosene
- Tribromsalan
- Triclocarban
- Triclosan
- Triple dye
- Undecoylium chloride iodine complex
- Polyhexamethylene biguanide
- Benzalkonium cetyl phosphate
- Cetylpyridinium chloride
- Salicylic acid
- Sodium hypochlorite
- Tea tree oil
- Combination of potassium vegetable oil solution, phosphate sequestering agent, and triethanolamine

Click to view the Federal Register posting of the final rule:

<https://www.federalregister.gov/d/2019-06791>

How Does this Impact You? Contact Us to Discuss

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