REGULATING AGENCIES

Understanding the FDA, EPA and CDC



Food and Drug Administration

- Antimicrobial hand hygiene, including hand sanitizers, antiseptic washes and antibacterial soaps, are regulated by the FDA.
- The FDA classifies these topical products as over-the-counter (OTC) drugs.
- OTC drugs must comply with the regulations (called "monographs") for certain categories of non-prescription drugs or requirements for new drug approval.
- Infection-prevention claims are considered false and misleading under the monograph. **Specifically, the FDA has stated that hand sanitizers are not proven to treat COVID-19.**
- Ethyl alcohol (an ingredient in some hand sanitizers) is classified by the FDA as a Category I active ingredient, which means it's recognized as safe and effective when used as directed.
- Many "soaps" on the market today are not just soap. They are cleansers, detergents or other types of products and are regulated as a cosmetic by the FDA.
- True soaps – made primarily from fats and alkalis and manufactured for consumer use – are regulated by the Consumer Product Safety Commission.



Environmental Protection Agency

- Surface disinfectants and sanitizers are regulated by the EPA.
- Surface disinfectants are subject to more rigorous EPA testing requirements than surface sanitizing products and must clear a higher bar for effectiveness.
- In March 2020, the EPA published List N: Disinfectants for Use Against SARS-CoV-2. The list includes products that meet EPA's criteria for use against SARS-CoV-2, the cause of COVID-19.
- The approved products on List N are for use on surfaces, not humans.
- There are no sanitizer-only products with approved virus claims. For this reason, sanitizers do not qualify for inclusion on EPA's List N.

The Food and Drug Administration (FDA) regulates hand care products based on their ingredients, how they are marketed for use and various other factors. But questions often come up about the role the Environmental Protection Agency (EPA) plays in regulating such products. In general, they don't. The EPA focuses on surfaces (counters, floors, etc) and the FDA oversees products relating to the skin.

The Centers for Disease Control and Prevention's (CDC) current recommendation to slow the spread of COVID-19 is to wash your hands often with soap and water for at least 20 seconds especially after you have been in a public place or after blowing your nose, coughing or sneezing. If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol.

Who Regulates What?

FDA SKIN | **EPA** SURFACES

Sources:
- https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces
- https://www.fda.gov/cosmetics/cosmetic-products/frequently-asked-questions-soap
- https://www.cpsc.gov/Soap
- https://www.cdc.gov/coronavirus/2019-ncov/about/prevention-treatment.html

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