



ALCOHOL-BASED HAND SANITIZERS

Use Caution when Purchasing Products from
Unlicensed Facilities



FOR CONSUMERS: The California Department of Public Health (CDPH) Food and Drug Branch (FDB) urges consumers to be cautious when using alcohol-based hand sanitizers from unlicensed manufacturers. Due to the ongoing Coronavirus Disease (COVID-19) pandemic, greater demand has resulted in a short-term decrease in the availability of hand sanitizers. This has made it difficult for consumers to access safe and effective products. Anyone with concerns or a complaint about a hand sanitizer product should contact FDB at **(800) 495-3232** or FDBinfo@cdph.ca.gov

Safety concerns with the use of unapproved hand sanitizers:

There are many risks in making alcohol-based hand sanitizers at home or using products made by unlicensed firms, including:

- The alcohol content may not be at the specific level needed to be effective at sanitizing; the target alcohol content can be difficult to achieve and confirm by untrained individuals who do not have adequate testing equipment.
- An insufficient alcohol content may result in an ineffective hand sanitizer, causing a false sense of security.
- Improper packaging (e.g. in beverage or liquor-like bottles) without proper identification and warnings on the labels could lead to accidental consumption.
- Ethanol used in hand sanitizers must be denatured to prevent adverse events (including deaths) from unintentional ingestion, particularly in young children.
- The addition of unsafe ingredients may lead to skin injuries.
- The lack of approved ingredients for skin care can lead to skin injuries after prolonged use.



FOR MANUFACTURERS: In California, licensed firms continue to manufacture hand sanitizers in an effort to meet the demand. **Any additional companies considering manufacturing hand sanitizers should contact FDB for guidance and assistance at (800) 495-3232 or FDBinfo@cdph.ca.gov.**

Regulation of hand sanitizers:

In the United States, alcohol-based hand sanitizers are considered over-the-counter (OTC) drugs, requiring the manufacturer register with the U.S. Food and Drug Administration (FDA). For manufacturers in California, they must also be licensed by the Department's **FDB**. This ensures drug products are made following Good Manufacturing Practices and they are safe and effective.

Recently, and only for the duration of the current COVID-19 emergency, the FDA has provided guidance for [alcohol manufacturers](#), [hand sanitizer manufacturers](#) and [compounding pharmacies](#) to allow for streamlined production of safe and effective hand sanitizers.

CDPH re-iterates the importance of following FDA guidances and that:

- Consumers making homemade alcohol-based hand sanitizers should follow FDA guidelines and have adequate testing equipment; and
- Manufacturers and compounding pharmacies follow the FDA guidance for [alcohol manufacturers](#), [hand sanitizer manufacturers](#), and [compounding pharmacies](#) during this public health emergency.

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