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 neededto 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 consideringmanufacturing 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). Manufacturers in California 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.

In March 2020, the FDA had issued temporary guidances for alcohol manufacturers, hand

sanitizer manufacturers and compounding pharmacies to manufacture safe and effective hand sanitizers for the duration of the Covid-19 emergency. However, on October, 12, 2021, the FDA announced that it intends to withdraw the above guidances, effective December 31, 2021.

Hand sanitizer manufacturers should note that:

- Effective Dec. 31, 2021, companies manufacturing alcohol-based hand sanitizers under the temporary policies must cease production of these products.
- Manufacturers wishing to continue producing hand sanitizers after the above date, must comply with the tentative final monograph for OTC topical antiseptics and other applicable requirements, including the FDA's Current Good Manufacturing Practice requirements.
- Manufacturers who no longer plan to produce these products are able to deregister by following the instructions on the Electronic Drug Registration and Listing Instructions page.
- Hand sanitizers manufactured before or on December 31, 2021 and produced under the temporary guidances can no longer be sold or distributed by manufacturers after March 31, 2022.

CDPH re-iterates the importance of complying with the appropriate, current FDA requirements for the manufacture and sale of hand sanitizers.

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