

SAFETY CONCERNS:

HAND SANITIZERS



The California Department of Public Health (CDPH)-Food and Drug Branch (FDB) is informing consumers about the dangers of using hand sanitizers that are improperly manufactured, labeled or packaged. Due to the ongoing Coronavirus Disease (COVID-19) pandemic, the demand for hand sanitizers has led to the production of these products by many different entities all over the world, raising concerns about the safety and effectiveness of some that are now offered for sale during this public health emergency.

Safety concerns with hand sanitizers:

To ensure safety of hand sanitizers, the U.S. Food and Drug Administration (FDA) has issued guidance policies^{1,2,3} for properly manufacturing alcohol-based hand sanitizers during the pandemic.

Be reminded that hand sanitizers must...:

- **be produced with** "<u>denatured</u>" alcohol, making the product bitter tasting and unpleasant to drink, especially by young children or those who cannot read labels. According to the FDA, even a small amount of hand sanitizer can result in alcohol poisoning or be lethal to young children.⁴ Some manufacturers are not following the FDA policies and are manufacturing products using non-denatured alcohol.
- <u>not</u> be produced with methanol (wood alcohol).⁵ Methanol is highly toxic and can be life-threatening if ingested or simply absorbed through the skin, especially by children. Symptoms of methanol poisoning include nausea, vomiting, headache, blurred vision, and seizures, and can lead to nervous system damage, coma and/or death. Recently, some hand sanitizers have tested positive for methanol contamination, so CDPH-FDB and the FDA urges consumers to be informed about the hand sanitizer products available on the market and to use caution with those purchased.
- **be properly** <u>labeled</u> as over-the-counter drugs, as this product is lawfully required to contain a "Drug Facts" panel, clear directions for use, and adequate warnings (especially warnings to protect children). Some manufacturers are not adhering to state and federal drug labeling requirements.

¹ U.S. Food and Drug Administration. 2020. <u>Temporary Policy for Manufacture of Alcohol for Incorporation into</u> <u>Alcohol Based Hand Sanitizer Products During the Public Health Emergency</u>.

² U.S. Food and Drug Administration. 2020. <u>Policy for Temporary Compounding of Certain Alcohol-Based Hand</u> <u>Sanitizer Products During the Public Health Emergency</u>.

³ U.S. Food and Drug Administration. 2020. <u>FDA Continues to Ensure Availability of Alcohol-Based Hand</u> <u>Sanitizer During the COVID-19 Pandemic</u>.

⁴ U.S. Centers for Disease Control and Prevention. 2017. <u>Reported Adverse Health Effects in Children from Ingestion of Alcohol-Based Hand Sanitizers, US, 2011–2014</u>. Morbidity and Mortality Weekly Report. 66(8): 223-226.

⁵ U.S. Food and Drug Administration. 2020. <u>FDA Updates on Hand Sanitizers with Methanol</u>.

• **be properly <u>packaged</u>** so as not to be confused with other commonly recognizable products (e.g.: beverage or liquor bottles) and accidentally consumed.

CDPH-FDB reminds everyone that hand sanitizers are OTC drugs, and are strictly for external use only and not for ingestion. CDPH-FDB further emphasizes compliance with FDA hand sanitizer manufacturing policies during the COVID-19 pandemic to prevent adverse health consequences.

Anyone with concerns or a complaint about a hand sanitizer product should contact CDPH-FDB at (800) 495-3232 or FDBinfo@cdph.ca.gov.

www.cdph.ca.gov