FDA Updates on Hand Sanitizers with Methanol

Methanol Contaminated Products List

Spanish version (/drugs/drug-safety-and-availability/la-fda-advierte-los-consumidores-sobre-los-riesgos-de-contaminacion-por-metanol-en-algunos)

7/2/2020: UPDATE - FDA warns consumers of risk of methanol contamination in certain hand sanitizers

[7-2-2020] FDA is warning consumers and health care providers that the agency has seen a sharp increase in hand sanitizer products that are labeled to contain ethanol (also known as ethyl alcohol) but that have tested positive for methanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin or ingested and can be life-threatening when ingested.

The agency is aware of adults and children ingesting hand sanitizer products contaminated with methanol that has led to recent adverse events including blindness, hospitalizations and death.

Methanol is not an acceptable active ingredient for hand sanitizers and must not be used due to its toxic effects. FDA's investigation of methanol in certain hand sanitizers is ongoing. The agency will provide additional information as it becomes available.

Consumers who have been exposed to hand sanitizer containing methanol and are experiencing symptoms should seek immediate treatment for potential reversal of toxic effects of methanol poisoning. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk for methanol poisoning, young children who accidently ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute, are most at risk.

FDA reminds consumers (/consumers/consumer-updates/safely-using-hand-sanitizer) to wash their hands often with soap and water for at least 20 seconds, especially after going to the bathroom; before eating; and after coughing,

sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html) (CDC) recommend consumers use an alcohol-based hand sanitizer that contains at least 60 percent ethanol (also referred to as ethyl alcohol).

FDA remains vigilant and will continue to take action when quality issues arise with hand sanitizers. The agency is especially concerned with:

- The dangers of drinking any hand sanitizer under any conditions. While hand sanitizers with possible methanol contamination are more life-threatening than those that are not contaminated, FDA urges consumers not to drink any of these products.
- Certain hand sanitizers that may not contain a sufficient amount of ethyl alcohol or isopropyl alcohol.
- Hand sanitizers that are sold or offered for sale with false and misleading, unproven claims that they can prevent the spread of viruses such as COVID-19, including claims that they can provide prolonged protection (e.g., for up to 24-hours).
- Products that are fraudulently marketed as "FDA-approved" since there are no hand sanitizers approved by FDA.
- Products packaged to appear as drinks, candy or liquor bottles, as well as products marketed as drinks or cocktails because their appearance could result in accidental ingestion or encourage ingestion. Children are particularly at risk with these products since ingesting only a small amount of hand sanitizer may be lethal in a young child.

FDA is aware of reports of adverse events associated with hand sanitizer products. FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) program (please provide the agency with as much information as possible to identify the product):

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm); or

- Download and complete the form (https://www.fda.gov/media/85598/download), then submit it via fax at 1-800-FDA-0178.

7/2/2020 PRESS RELEASE - FDA Takes Action to Warn, Protect Consumers from Dangerous Alcohol-Based Hand Sanitizers Containing Methanol

Go to FDA Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-warn-protect-consumers-dangerous-alcohol-based-hand)

6/19/2020 ALERT - FDA advises consumers not to use hand sanitizer products manufactured by Eskbiochem

Go to FDA Drug Alert (/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem)

FDA's testing and manufacturer/distributor recalls

The following chart outlines the information on hand sanitizer labels for consumers to use to identify a product:

- That has been tested by FDA and found to contain methanol.
- That is being recalled by the manufacturer or distributor.
- That is purportedly made at the same facility as products that have been tested by FDA and found to contain methanol.

FDA advises consumers not to use hand sanitizers from these companies, or products with these names or NDC numbers.

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Company	Date added to table	Product (s)	NDC(s)	Product status
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Clear Advanced Hand Sanitizer with 70% Alcohol	Not listed	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Advanced Instant Hand Sanitizer Clear Ethyl Alcohol 70%	Not listed	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Instant Hand Sanitizer Clear	60599-015-00 60599-015-01 60599-015-02	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020; product voluntarily recalled (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/4e-brands-north-america-issues-nationwide-voluntary-recall-hand-sanitizer-due-potential-presence) on 7/11/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	KLAR AND DANVER Instant Hand Sanitizer (labeled with Greenbrier International Inc.)	33992-8010-1	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	MODESA Instant Hand Sanitizer Moisturizers and Vitamin E	60599-007-33	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020

Company	Date added to table	Product (s)	NDC(s)	Product status
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Hand Sanitizer	60599-012-00 60599-012-01 60599-012-02 60599-012-03 60599-012-04 60599-012-05 60599-012-06 60599-012-07 60599-012-08 60599-012-10	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020; product voluntarily recalled (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/4e-brands-north-america-issues-nationwide-voluntary-recall-hand-sanitizer-due-potential-presence) on 7/11/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Hand Sanitizer Aloe	60599-013-00 60599-013-01 60599-014-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Instant Hand Sanitizer Lavender	60599-016-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Clear LEAR Advanced Hand Sanitizer	60599-017-00 60599-017-01 60599-018-00 60599-018-01	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020; product voluntarily recalled (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/4e-brands-north-america-issues-nationwide-voluntary-recall-hand-sanitizer-due-potential-presence) on 7/11/2020

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4E Global, SAPI de CV (Mexico)	07/08/2020	BLUEMEN Clear Advanced Hand Sanitizer	60599-018-02 60599-018-03 60599-018-04 60599-018-05 60599-018-06 60599-018-07 60599-018-08 60599-019-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020; product voluntarily recalled (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/4e-brands-north-america-issues-nationwide-voluntary-recall-hand-sanitizer-due-potential-presence) on 7/11/2020

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*public notification first occurred through CDER Alert (/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem) posted on 06/19/2020