

More Hand Sanitizer Warnings Posted by the FDA

Executive Summary:

There is an ongoing and escalating issue with hand sanitizers manufactured in some factories in Mexico, and sold in stores throughout the U.S, that pose a danger to those who use them. This is due to either methanol being added or substituted for ethyl or isopropyl alcohols, or subpotent percentages of appropriate alcohols in them. The former can and has led to toxic poisonings via ingestion or absorption through the skin with known serious adverse events including blindness, heart problems, central nervous system effects, hospitalizations and death. The latter can lead to not be strong enough to kill the virus that is on the hands/arms. The FDA has posted an updated list as they test and find these dangerous hand sanitizers. The list has grown to over 100 products since the first FDA alert went out June 19, 2020. The impact to First Responders is potentially threefold. First, work supplies may contain some of these brands of hand sanitizers, putting personnel at professional risk. Secondly, they may come across those that have used these products and are displaying symptoms of methanol toxicity and need urgent medical care. And, third, they may have these hand sanitizers in their homes and be at risk for significant illness in themselves or their family.

Additionally, Health Canada is recalling certain hand-sanitizers that contain ingredients that are not approved for Canadian hand sanitizers, such as methanol, industrial-grade ethanol, and alcohol denaturants. They are updating their lists as more products not meeting approval guidelines for hand sanitizers are found. They also are providing lists of those hand sanitizers authorized for sale in Canada as well as a list of approved products in other jurisdictions that have been accepted for use by Canada during the COVID-19 Pandemic. Note: More information and links for Canadians are found below the info for the U.S.

United States:

Several times, since the original posting of toxic hand sanitizers on June 19th, the FDA has added names to the list, as they have tested, and detected, the presence of methanol alcohol in hand sanitizers made by some manufacturers in Mexico and, in an abundance of caution, have also added the names of all the hand sanitizers made by those manufacturers, since they may also contain methanol. Unfortunately, in many cases, the manufacturer and the active ingredient methanol are not included on the label. **Typically, the label will indicate Ethyl alcohol (Ethanol) or Isopropyl alcohol, and even give a percentage of 60, 70, or an even higher percentage of the alcohol listed, when some or all of it is actually methanol.** These hand sanitizers have been sold in retail and big box stores throughout the U.S.

Although ingesting any alcohol can be toxic, none is as life threatening as methanol, also known as wood alcohol. **Exposure through ingestion, either intentionally (often in teens or adults desperately wanting alcohol) or accidentally (in younger children) is most likely to cause serious toxicity.** However, it can also be absorbed through the skin in large enough doses to cause toxicity, particularly in young children that are affected by low toxic levels.

Although the majority of products on the list contain, or are suspected of containing methanol, **another group of names were added to the list because testing revealed that they contain too low levels of either ethyl or isopropyl alcohols and these subpotent hand sanitizers are not capable of killing the SARS-CoV-2 virus or other viruses or bacteria that they are used to eliminate.**

The FDA reminds **consumers that hand washing with soap and running water for at least 20 seconds is still the preferred method of decontaminating hands and arms (or other contaminated skin).** In the absence of proper handwashing, hand sanitizers may be used until handwashing can occur.

In June's posting, the FDA stated that no adverse events had been reported regarding hand sanitizers containing methanol. **Since then, the FDA has been made aware of both adults and children ingesting methanol-containing hand sanitizers which have led to adverse events such as hospitalizations, heart trouble, damage to central the nervous system, blindness, and death.**

According to the FDA, those who have been exposed to methanol-containing hand sanitizers and are having symptoms, **"Should seek immediate treatment for potential reversal of the 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, and/or death."** Although anyone using these products can develop toxicity from methanol poisoning, **young children who typically ingest these products accidentally or older children, teens, or adults who drink these products as their alcohol (ethanol) substitute, have the greatest risk.** The lethal dose for a child can be quite small, depending on the percentage of methanol in the sanitizer.

Adverse events or quality issues with hand sanitizer use should be reported by consumers, patients, and health care professionals to the FDA's MedWatch Adverse Event Reporting site @ <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

The FDA will continue to monitor the situation and test products, taking action when any quality issues are found with hand sanitizers. Specifically:

1. The danger in drinking/ingesting any hand sanitizer for any reason.
2. **Certain hand sanitizers may not contain enough ethyl or isopropyl alcohol to effectively kill viruses and bacteria.**

3. Hand Sanitizers that are offered for sale which have false, misleading, or unproven claims to prevent the spread of viruses such as SARS-CoV-2 and/or claims that the sanitizers provide prolonged protection (up to 24 hours).
4. **No hand sanitizers are approved by the FDA so those that have the claim of “FDA-Approved” on the label, through marketing or otherwise, are fraudulently doing so.**
5. **“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 at particular high risk with these products since ingesting only a small amount of hand sanitizer may be lethal for a young child.”**
6. Products that are labeled with harmful or poisonous ingredients (e.g. methanol).

The initial post (6/24) on our Health Intelligence page, on this topic, can be found here:

<https://www.firstwatch.net/fda-warning-about-hand-sanitizers-containing-methanol/>

July 31, 2020 -- FDA Updates on Hand Sanitizers Consumers Shouldn't Use:

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use#products>

The above link has labeled “buttons” for links to:

1. Hand Sanitizers Consumers Should Not Use
2. A Spanish Version
3. FDA MedWatch Adverse Event Reporting System

Healthline Article on the FDA Expanded Warning on Hand Sanitizers (7/29/20):

<https://www.healthline.com/health-news/fda-says-avoid-9-hand-sanitizers-that-contain-toxic-methanol>

USA Today (Aug 1st)

<https://www.usatoday.com/story/money/2020/08/01/hand-sanitizer-warning-methanol-risk-fda-avoid-these-sanitizers/5562366002/>

July 27, 2020 -- FDA Warning Letter about Toxic Hand Sanitizers:

Please note the link to the

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reiterates-warning-about-dangerous-alcohol-based-hand-sanitizers#:~:text=The%20U.S.%20Food%20and%20Drug,the%20skin%20as%20well%20as>

July 2nd FDA Hand Sanitizer Update

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-warn-protect-consumers-dangerous-alcohol-based-hand>

FDA Initial Warning Alert and the Update 6/19/20 & 6/29/20:

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem>

DO NOT USE Hand Sanitizer List (link updated as needed):

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol>

Canada:

Health Canada had posted initially (6/17), and continues to update, a list of recalled brands of hand sanitizers that do not meet ingredient requirements for hand sanitizers. Specifically, these recalled products contain industrial-grade ethanol, alcohol denaturants (additives that make the product unpalatable to drink) and even some with methanol. These products are being recalled because they have not been approved for use in hand sanitizers, therefore the Department has not reviewed them for safety and efficacy.

Use of these products, per the Health Canada posting, may cause “Possible adverse reactions to the ingredients in these products may include dermatitis, skin irritation and cracking, eye irritation, upper respiratory irritation; and headaches”.

Health Canada makes the following recommendations:

1. **Stop using any products on both of these lists** & follow municipal or regional guidelines for disposal of these products or return them to your local pharmacy for proper disposal:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73385a-eng.php>

<https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73421a-eng.php>

2. Consult your health care provider for assistance if you have symptoms or health concerns after use of any of these products.

3. To help prevent the spread of COVID-19, wash your hands with soap and water for at least 20 seconds. Use the alcohol-based sanitizers if soap & water are not available.

4. Use hand sanitizers that are found on the list of those authorized for sale in Canada: <https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/hand-sanitizer.html> .

5. “Consult the list of hand sanitizers authorized or registered in other jurisdictions that may not display an NPN or DIN, but have been accepted for use in Canada during the COVID-19 pandemic” found here: <https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/products-accepted-under-interim-measure.html>

6. Report any health product adverse event or complaint to Health Canada:

Adverse Events: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

Complaints: <https://healthy Canadians.gc.ca/apps/radar/MD-IM-0005.08.html>