

Hand sanitizers – dangers of methanol contamination

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Risk Solution Services provides technical insight related to existing and potential insured risk at Markel. The team partners with our customers, claims, and underwriters to educate on both current and future risk trends and supports our clients with a broad offering of risk management solutions.

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Hand sanitizers

Hand sanitizers are defined as a type of antimicrobial agent that kills or permanently inactivates at least 99.9 percent of microorganisms when used on the hands. Microorganisms include: viruses, fungi, and bacteria; however, most hand sanitizers currently on the market list only bacteria.



Unfortunately, it has been recently reported some hand sanitizers currently in the stream of commerce may contain methanol (wood alcohol).

Methanol formula

CH₄O, CAS-No. 67-56-1 is generally utilized as a solvent and laboratory chemical. **Methanol is not intended for food, drug, or household use, is toxic, and can be lethal.**

Hand sanitizers typically use toxic chemicals, particularly alcohol, as their active ingredient, which can also be hazardous if ingested. However, if alcohol is properly used (and particularly not ingested) according to the World Health Organization (WHO), there is no reported or likely resistance to alcohol-based hand rubs.

To complicate the issue of use of hand sanitizers, hand hygiene is and has become an important part of the response to the international emergence of COVID-19. Practicing hand hygiene, which includes the use of alcohol-based hand rub (ABHR or hand sanitizers) or handwashing, is a simple yet effective way to help prevent the spread of pathogens and infections.

However, attempts to wash hands utilizing hand sanitizers containing methanol as a main ingredient or as a contaminant due to poor manufacturing practices pose major health problems. According to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) methanol is highly flammable both in liquid and vapor form (flammable liquid Category 2), it is toxic if swallowed (acute toxicity (oral) Category 3), it is toxic in contact with skin (acute toxicity (dermal) Category 3), toxic if inhaled (acute toxicity (inhalation) Category 3), and causes damage to organs (liver, kidneys, central nervous system, optic nerves, etc.) with specific target organ toxicity (single exposure) Category 1.

GHS, the Globally Harmonized System of Classification and Labeling of Chemicals, was developed by the United Nations (UN) and supported by the US as a way to bring into agreement the chemical regulations and standards of different countries. GHS includes criteria for the classification of health, physical, and environmental hazards, as well as specifying what information should be included on labels of hazardous chemicals, as well as, safety data sheets. (UNECE - GHS, Rev.8, UN, 2019, UNECE - GHS Rev.7, UN 2017)

Under GHS, US and other professionally generally accepted chemical categorizations methanol is not an acceptable ingredient for hand sanitizers and must not be used for this purpose due to its toxic effects.

As of July 2020, there are over 100 different hand sanitizer products on the FDA listing under review because they contain methanol. According to some sources, this number is increasing.

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Sample recent recalls include:

- Maquiladora Miniara S.A. de C.V. Issues Voluntary Nationwide Recall of Shine and Clean Hand Sanitizer and Due to Potential Presence of Undeclared Methanol (Wood Alcohol)
- Real Clean Distribuciones SA de CV Issues Voluntary Nationwide Recall of Four Hand Sanitizer Due to Potential Presence of Undeclared Methanol (Wood Alcohol)
- LIQ-E S.A. de C.V. Issues Voluntary Recall of the Optimus Instant Hand Sanitizer Due to the Potential Presence of Undeclared Methanol

In most cases, methanol will not appear on the product label. Regardless, of the ingredient listings, methanol is not an acceptable ingredient in any drug, including hand sanitizers. FDA maintains a listing of FDA-tested and recalled hand sanitizers on the Food and Drug Administration’s website: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol>

The FDA listing is continually updated as dangerous products are discovered; and, FDA’s investigation of methanol in certain hand sanitizers is ongoing. Earlier in July 2020 at least four (4) additional people died in New Mexico after reportedly drinking hand sanitizer products.

No products on the FDA listing of suspect or confirmed hand sanitizers with potential methanol contamination should be used. And, regular review of the listing is advised as the listing is updated daily. The agency will provide additional information as it becomes available.

Methanol in hand sanitizers

The FDA is currently 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 it can be life-threatening when ingested.

Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, and 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 accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute, are most at risk. In the FDA’s ongoing investigation of methanol in certain hand sanitizers, testing has found methanol contamination in hand sanitizer products ranging from 1% to 80%.



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Proper use of hand sanitizers

The US Centers for Disease Control and Prevention (CDC) advises that the best way to prevent the spread of infections and decrease the risk of getting sick is by frequently washing hands with plain soap and water for at least 20 seconds on a regular basis; and, when there is reason to believe that added washing is needed to decrease risk of getting sick. The FDA further adds that:



- If soap and water are unavailable, the CDC recommends using an alcohol-based hand sanitizer that contains at least 60% alcohol.
- An adequate amount of sanitizer should be used during each application to cover **all** hand surfaces.
- Once applied, hands should be rubbed together until they feel dry (approximately 20 seconds). Typical method is by counting one thousand and one...one thousand and two... one thousand and three...etc. until the number one thousand and 20 is reached.
- If hand sanitizer is rinsed or wiped from hands before it is dry, it may not be effective in killing the targeted bacteria, fungi, or virus.
- Young children should always be supervised when using hand sanitizers to prevent swallowing.



In the event any hand sanitizer believed to contain methanol may have been utilized and ingested whether by accident or intentionally, methanol poison ingestion controls and countermeasures should be practiced immediately including but not limited to contacting the nearest medical facility, poison control facility, and/or physician for guidance.

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For evaluating hand sanitizers some useful terms include:

- Alcohol-based (hand) rub – An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients with excipients, and humectants.
- Antiseptic agent – An antimicrobial substance that inactivates microorganisms or inhibits their growth on living tissues (e.g. alcohols, chlorhexidine gluconate (CHG), chlorine derivatives, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan).
- Antiseptic hand wipe – A piece of fabric or paper pre-wetted with an antiseptic used for wiping hands to inactivate and/or remove microbial contamination. They are not a substitute for using an alcohol-based hand rub or antimicrobial soap.
- Efficacy/efficacious – The (possible) effect of the application of a hand hygiene formulation when tested in laboratory or in a vivo situation.
- Effectiveness/effective – The clinical conditions under which a hand hygiene product has been tested for its potential to reduce the spread of pathogens.
- Humectant – Ingredient(s) added to hand hygiene products to moisturize the skin.
- Persistent activity – The prolonged or extended antimicrobial activity that prevents the growth or survival of microorganisms after application of a given antiseptic; also called “residual”, “sustained”, or “remnant” activity. Both substantive and non-substantive active ingredients can show a persistent effect significantly inhibiting the growth of microorganisms after application. (WHO – Patient Safety – ISBN 978 92 4 159790 6, WHO, 2009)



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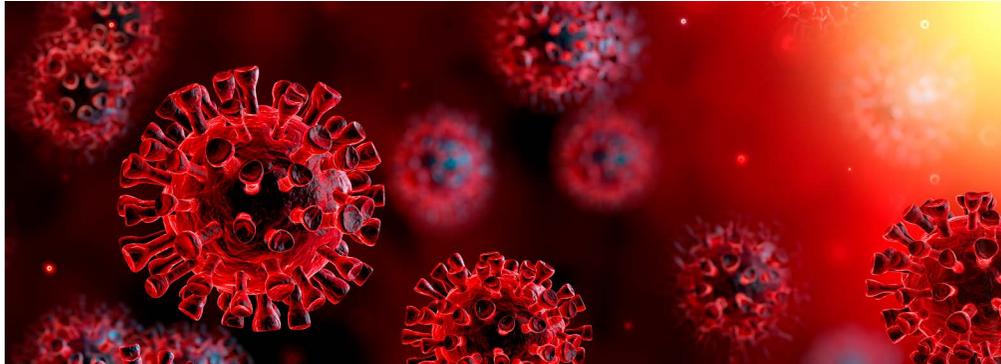
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Additional published FDA concerns for hand sanitizers include:

- Certain hand sanitizers may not contain a sufficient amount of ethyl alcohol or isopropyl alcohol to eliminate viruses and bacteria.
- Hand sanitizers may be sold or offered for sale with false, 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 may be fraudulently marketed as “FDA-approved;” there are no hand sanitizers approved by FDA.
- Some products are packaged to appear as drinks, candy, or liquor bottles; their appearance could result in accidental ingestion or encourage ingestion.
- Products may contain with harmful or poisonous ingredients, such as methanol.

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Risk management issues to consider:

- To help increase the availability of hand sanitizers, FDA has issued guidance for the temporary preparation of alcohol-based hand sanitizers by some companies and pharmacies during the public health emergency posed by COVID-19.
- The guidance documents describe circumstances under which the FDA does not intend to take action when these companies prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the COVID-19 public health emergency.
- FDA has also issued guidance for the temporary manufacture of alcohol by alcohol producers to use as the active ingredient in hand sanitizer products.
- 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. The agency is aware of people ingesting hand sanitizer products contaminated with methanol that has led to recent adverse events including blindness, hospitalizations, and death.
- A MedWatch safety alert was added to the FDA Recalls webpage.
- FDA is advising importers, consignees, distributors, retailers, and others not to distribute or sell certain hand sanitizers, even if the manufacturer of the product has not recalled it, due to the dangers of methanol contamination, including death.



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- The FDA has posted a “do-not-use” list of dangerous hand sanitizer products, which is being updated regularly. If any of the identifiers (name, company, or national drug code (NDC)) match a product on the list, the FDA urges consumers to immediately stop using the hand sanitizer.
- FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA’s MedWatch Adverse Event Reporting program. Reporting involves completing and submitting an online report or submitting the form by facsimile.
- 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.
- Per the FDA’s temporary policies for preparation and compounding of certain alcohol-based hand sanitizer products during the public health emergency, entities that are not registered drug manufacturers currently have the ability to temporarily register as over-the-counter (OTC) drug manufacturers and prepare or compound alcohol-based hand sanitizers during the COVID-19 public health emergency. These facilities may not employ best practices for production of OTC drug manufacturing or preparation, and pose an elevated risk.
- Consumers are encouraged to keep hand sanitizers out of the reach of children and, in case of ingestion, to get medical help or contact a poison control center immediately. Very small amounts of hand sanitizer can be toxic, even lethal, to young children.

- All alcohol-based products are potentially flammable and therefore they should be stored away from high temperatures and flames. The WHO suggests that all health care organizations currently using alcohol-based hand rubs should undertake local risk assessments.
- Used containers and dispensers will contain gel residues and flammable vapors. Rinsing out used containers with large quantities of cold water will reduce the risk of fire and the containers may then be recycled or disposed of in general waste.



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For risk management purposes, the following questions should be asked:

- Is the insured an importer, distributor, or retailer of hand sanitizers? Are specific hand sanitizer products and manufacturers of hand sanitizer products imported, distributed, or sold by the insured regularly cross-referenced against the published FDA “do-not-use” list? Products should be checked for manufacturer name, product name, and NDC number.



- Is the insured a health care facility or high-traffic facility that offers hand sanitizer for customer use?
- Has the facility had to file any adverse events through the FDA’s MedWatch reporting program?
- Have users of hand sanitizer products at the insured’s facility reported symptoms consistent with methanol exposure or sought treatment for methanol poisoning?
- Has the insured altered manufacturing or other business operations to manufacture, produce, or compound alcohol-based hand sanitizers during the COVID-19 public health emergency? If so, have best industry practices been researched and implemented? Are batches tested to ensure adequate alcohol content and ensure that methanol is not included as an ingredient?

- Are GMP guidelines being employed?
- Are hand sanitizers kept out of the reach of children or any other protected group? Are means of contacting the poison control center posted in the facility? This is a heightened concern for schools and other child care, elderly, and confinement facilities.
- Are adequate fire-prevention measures employed if the insured stores a stockpile of hand sanitizer products (storage away from high temperatures, flames, etc.)? The risk of significant facility fires associated with ignition of a hand sanitizer stockpile is highest at facilities that store large quantities of the product. Quantities of hand sanitizer above 5 gallons should be stored in a flammable liquids cabinet or in areas protected by an automatic sprinkler system.
- How does the insured dispose of used hand sanitizer containers? Are they rinsed with large quantities of cold water prior to disposal as general waste?

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