FDA warns that vapors from alcohol-based hand sanitizers can have side effects
Apply hand sanitizer in a well-ventilated area

6-16-2021 FDA Drug Safety Communication

What safety concern is FDA announcing?
The U.S. Food and Drug Administration (FDA) is warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin. These symptoms are likely to have occurred because of vapors from the hand sanitizer, potentially from exposure in enclosed spaces or places with poor air circulation. We have received increasing reports of these side effects since the start of the COVID-19 pandemic. Most people experienced minor or minimal effects; however, some cases required treatment by a health care professional.

What is FDA doing?
We are continuing to monitor reports of adverse events that occur with hand sanitizers. At this time, we are not making any changes to the Drug Facts label for hand sanitizers but will inform the public if additional information becomes available.

What are hand sanitizers and how can they help me?
Hand sanitizers are over-the-counter (OTC) drug products that can help consumers reduce bacteria on their hands. However, the best way to prevent the spread of infections and decrease the risk of getting sick is by washing your hands with plain soap and water, advises the Centers for Disease Control and Prevention (CDC). Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the restroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not available, the CDC recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol. Hand sanitizers are left on the skin to dry.

What should consumers do?
Consumers should use hand sanitizers in a well-ventilated area. If you are using hand sanitizer in an enclosed area such as a car, open a window to improve ventilation until the hand sanitizer is dry and the vapors have cleared. Make sure your hands are completely dry and vapors have cleared before doing any activities involving heat, sparks, static electricity, or open flames. Read and follow the directions and warnings on the OTC Drug Facts label.

Some hand sanitizers may be contaminated with harmful ingredients so check FDA's "do-not-use" list to learn more. If you experience side effects from hand sanitizer or if someone accidentally ingests it, contact your health care professional or poison control at 1-800-222-1222 or online. Call 911 if the person has trouble breathing or becomes unconscious.

Store hand sanitizers and all other OTC and prescription medicines up and away and out of children's reach and sight. Swallowing even a small amount of hand sanitizer can cause alcohol poisoning in children, which may cause serious illness or death.

What should health care professionals do?

Health care professionals should use hand sanitizer in a well-ventilated area, especially when using it frequently throughout the day. Also check FDA's "do-not-use" list before recommending or using a specific hand sanitizer. Educate consumers about the appropriate use of hand sanitizers, and encourage them to read and follow the directions and warnings on the OTC Drug Facts label.

What did FDA find?

We reviewed case reports submitted to FDA* and cases from calls to U.S. poison control centers of adverse events after applying alcohol-based hand sanitizers to the skin. Commonly reported symptoms included headache, nausea, and dizziness, likely because of vapors from the hand sanitizer product, and potentially from exposure in enclosed spaces.

For cases reported to FDA in the 11 years between January 1, 2010, and December 31, 2020, we identified 50 cases† of serious adverse events after applying alcohol-based hand sanitizers. All were reported after March 2020 and coincided with the marked increase in the use of hand sanitizer during the COVID-19 pandemic. Most of the 50 cases were in adults, with four in children.

For cases from U.S. poison control center calls, in the 3 years between January 1, 2018, and December 31, 2020, we identified 299 cases† of skin and inhalation/nasal exposures that resulted in symptoms from exposure to hand sanitizer products. The number of exposures rose significantly after March 2020 during the COVID-19 pandemic. Most cases were in adults, with children 5 or younger accounting for 12 percent. Most cases resulted in minor or minimal effects; however, some required treatment by a health care professional.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.
†In analyses of FAERS and poison control center data, we excluded cases involving alcohol-based hand sanitizer with confirmed or suspected methanol contamination.

How do I report side effects from hand sanitizers?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving hand sanitizers or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

How can I get new safety information on medicines I'm prescribing or taking?

You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about hand sanitizers

- Hand sanitizers are regulated by FDA as over-the-counter (OTC) drug products.
- Hand sanitizers help reduce bacteria on the hands and are intended to be used when soap and water are not available. They are left on the skin to dry and not rinsed off with water.
- Many hand sanitizers contain alcohol, such as ethanol, as an active ingredient.

- The Centers for Disease Control and Prevention (CDC) recommends using an alcohol-based hand sanitizer that contains at least 60 percent alcohol when soap and water are not available.
- Hand sanitizers do not reduce all types of germs, do not work as well when hands are visibly dirty or greasy, and may not remove harmful chemicals.

Additional Information for Consumers

- FDA is warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin and breathing in the vapors.
- Use hand sanitizer in a well-ventilated area. When using hand sanitizer in an enclosed area, such as a car, open a window to improve ventilation until the hand sanitizer is dry and the vapors have cleared.
- Store hand sanitizers and all other over-the-counter (OTC) and prescription medicines up and away and out of children's reach and sight. Youngsters, especially toddlers, may be attracted by the pleasant smell or brightly colored solutions, bottles, pouches, or other containers of hand sanitizer.
- Hand sanitizers are intended to be used when soap and water are not available. Leave the hand sanitizer on the skin to dry and do not rinse it off with water. The best way to prevent the spread of infections and decrease the risk of getting sick is by washing your hands frequently with plain soap and water for at least 20 seconds.
- Adults should always supervise young children using hand sanitizer.
- Do not drink hand sanitizers. Drinking even a small amount of hand sanitizer can cause alcohol poisoning in children, while larger amounts may be toxic in older children and adults.
- Do not use hand sanitizer in or near the eyes because it can cause burning and damage. Watch young children around dispensers containing hand sanitizer, which are often mounted at eye level and can splash. In case of contact, rinse eyes thoroughly with water.
- Some hand sanitizers may be contaminated with harmful ingredients. Before you buy or use hand sanitizer, check FDA's "do-not-use" list.
- Store hand sanitizer away from heat and flames because it contains alcohol and is flammable. When using hand sanitizer, rub your hands until they feel completely dry and allow the vapors to clear before performing activities that may involve heat, sparks, static electricity, or open flames.
- To help FDA track safety issues with medicines, report side effects from hand sanitizers or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin and breathing in the vapors that linger.
- Use hand sanitizer in a well-ventilated area.

- Store hand sanitizer away from heat and flames. When using hand sanitizer, rub your hands until they feel completely dry and allow the vapors to clear before performing activities that may involve heat, sparks, static electricity, or open flames.
- Some hand sanitizers may be contaminated with harmful ingredients. Before recommending hand sanitizer or using hand sanitizer, check FDA's "do-not-use" list.
- Educate consumers about the appropriate use of hand sanitizers, and encourage them to read and follow the directions and warnings on the OTC Drug Facts label.
- To help FDA track safety issues with medicines, report adverse events involving hand sanitizers or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Data Summary

We reviewed case reports submitted to FDA and cases from U.S. poison control center calls of systemic symptoms after applying alcohol-based hand sanitizers to the skin.* This is likely to have occurred because of vapors from the hand sanitizer, potentially from exposure in enclosed spaces or those with poor air circulation. In both data sources, the number of cases increased substantially after the start of the COVID-19 pandemic.

We searched the FDA Adverse Event Reporting System (FAERS) database between January 1, 2010, and December 31, 2020, and identified 50 cases of serious adverse events with alcohol-based hand sanitizer, following dermal application and inhalation of vapors that linger. Although our search spanned an 11-year timeframe, all cases of such serious adverse events were received after March 2020. Commonly reported adverse events included headache, nausea, and dizziness. Most cases involved adults; there were 4 cases in children ages 5 to 16 years. In FAERS cases, information about the settings in which the hand sanitizers were applied was rarely reported.

We also searched the American Association of Poison Control Centers' (AAPCC) National Poison Data System (NPDS) database between January 1, 2018, and December 31, 2020, and identified 299 cases of dermal (n=138) and inhalation/nasal exposures (n=161) to alcohol-based hand sanitizer with a related clinical effect. The number of exposures rose significantly after March 2020. Most cases were in adults, with children 5 or younger accounting for 12 percent. Clinical effects included headache, nausea, and dizziness/vertigo from ethanol. While the majority of cases resulted in minor or minimal effects, a small number of moderate effects from dermal exposure (n=12) and inhalation/nasal exposure (n=2) were documented.

Published literature describes inhalation of vapors as a route of alcohol absorption after applying alcohol-based hand sanitizer to the skin.[1, 2] In a study by Arndt et al.,[3] with use of alcohol-based hand sanitizer on the skin in a confined space, inhalation of vapors caused elevations in a urine test for alcohol use.

*In analyses of FAERS and poison control center data, we excluded cases involving alcohol-based hand sanitizer with confirmed or suspected methanol contamination.

References

1. Brewer C, Streel E. Is alcohol in hand sanitizers absorbed through the skin or lungs? implications for disulfiram treatment. Alcohol 2020;55:354-6.

2. Emerson BL, Whitfill T, Baum CR, Garlin-Kane K, Santucci K. Effects of alcohol-based hand hygiene solutions on breath alcohol detection in the emergency department. Am J Infect Control 2016;44:1672-4.

3. Arndt T, Schröfel S, Güssregen B, Stemmerich K. Inhalation but not transdermal resorption of hand sanitizer ethanol causes positive ethyl glucuronide findings in urine. Forensic Sci Int 2014;237:126-30.

Related Information

FDA Consumer Update: Safely Using Hand Sanitizer

FDA updates on hand sanitizers consumers should not use

Lock it Up: Medicine Safety in Your Home

CDC: Put Your Medicines Up and Away and Out of Sight

OTC Drug Facts Label

The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective

Think It Through: Managing the Benefits and Risks of Medicines