

FDA warns that getting alcohol-based hand sanitizer in the eyes can cause serious injury Immediately and thoroughly rinse eyes with gently running water if this occurs

# 11-2-2021 FDA Drug Safety Communication

### What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) is warning that getting alcohol-based hand sanitizer in the eyes from splashing or touching the eyes after use of hand sanitizer can result in serious injury, including severe irritation and damage to the surface of the eye. Eye exposure to hand sanitizer has been reported in all age groups; however, it has occurred most often in children. Such eye injuries have become much more frequent, likely due to the marked increase in the use of alcohol-based hand sanitizer during the COVID-19 pandemic.

# What is FDA doing?

We are continuing to monitor safety with use of alcohol-based hand sanitizers. The <u>Drug Facts</u> <u>label</u> for these hand sanitizers currently warns that the product should not be used in or near the eyes. At this time, we are not making any changes to the Drug Facts label but wanted to make the public aware of this growing safety issue, and we will follow up 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. 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 <u>Centers for Disease Control and Prevention (CDC)</u>. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not available, the CDC recommends consumers use a hand sanitizer that contains at least 60 percent alcohol.

# What should consumers and caregivers do?

Do not use alcohol-based hand sanitizers in or near your eyes. After applying alcohol-based hand sanitizer to your hands, avoid touching your eyes because the alcohol in the hand sanitizer can cause severe irritation and damage to the surface of the eye. Adults should always supervise young children, particularly those younger than 6 years old, using alcohol-based hand sanitizers, especially around dispensers containing these hand sanitizers, which often are at children's eye level and can splash. Store alcohol-based hand sanitizers and all other OTC and prescription medicines up and away and out of children's reach and sight.

If alcohol-based hand sanitizer does accidentally splash or get in your eyes, or those of a child, immediately and thoroughly rinse them under gently running water such as from a sink tap, water bottle, or emergency shower for at least 15 to 20 minutes. Do not delay rinsing your eyes, as immediate rinsing is the most important thing you can do to reduce the risk of serious eye injury. If symptoms such as redness, pain, irritation, visual impairment, blurred vision, or light sensitivity persist after rinsing, seek an urgent eye examination.



Always read and follow the directions and warnings on the <u>OTC Drug Facts label</u>. Also, before buying hand sanitizer, check <u>FDA's "do-not-use" list</u>, as some hand sanitizer may contain or be contaminated with harmful ingredients.

# What should health care professionals do?

If alcohol-based hand sanitizer gets into a patient's eyes, urge them to immediately and thoroughly rinse their eyes under gently running water such as from a sink tap, water bottle, or emergency shower for at least 15 to 20 minutes. After rinsing, if symptoms such as redness, pain, irritation, visual impairment, blurred vision, or light sensitivity persist, advise the patient to seek an urgent eye examination.

Check <u>FDA</u>'s "do-not-use" list before recommending or using a specific hand sanitizer, as some hand sanitizer may contain or be contaminated with harmful ingredients. Counsel consumers about the appropriate use of hand sanitizers, and encourage them to read and follow the directions and warnings on the <u>OTC Drug Facts label</u>.

#### What did FDA find?

We reviewed cases from calls to U.S. poison control centers and publications in the medical literature<sup>1,2</sup> of serious side effects resulting from eye exposure to alcohol-based hand sanitizers. For cases from U.S. poison control center calls between January 1, 2018, and April 30, 2021, we identified 3,642 cases of side effects resulting from eye exposure to these hand sanitizers. The most common side effects were eye irritation/pain and red eye/conjunctivitis. This included 58 cases of a more serious injury to the surface of the eye. All 58 cases were treated by rinsing with water or saline with 26 also receiving antibiotics. Half of the 58 (n=29) occurred in children and teens 19 years and younger.

We reviewed two publications describing a total of 18 cases of eye exposure to alcohol-based hand sanitizer in children younger than 18 years, which required treatment in a hospital or by a health care professional. In 10 cases, the child had damage to the surface of the eye.<sup>1,2</sup>

#### How do I report side effects from alcohol-based hand sanitizers?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving alcohol-based 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 <u>email alerts</u> 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 specific kinds of alcohol, such as ethanol, as an active ingredient.
- The <u>Centers for Disease Control and Prevention (CDC)</u> recommends using an alcoholbased 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 and Caregivers**

- FDA is warning that getting alcohol-based hand sanitizer in the eyes can result in serious injury, including severe irritation and damage to the surface of the eye.
- Do not use alcohol-based hand sanitizers in or near your eyes. After applying alcohol-based hand sanitizer to your hands, avoid touching your eyes.
- Adults should always supervise young children, particularly those younger than 6 years old, using alcohol-based hand sanitizers, especially around dispensers containing these hand sanitizers, which often are located at children's eye level and can splash.
- If alcohol-based hand sanitizer accidentally splashes or gets in your eyes or those of a child, immediately and thoroughly rinse them under gently running water such as from a sink tap, water bottle, or emergency shower for at least 15 to 20 minutes. Do not delay in rinsing the eyes, as immediate rinsing is the most important thing you can do to reduce the risk of serious eye injury.
- After rinsing, if symptoms such as redness, pain, irritation, visual impairment, blurred vision, or light sensitivity persist, seek an urgent eye exam.
- 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.
- Store hand sanitizers and all other over-the-counter (OTC) and prescription medicines <u>up</u> 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 that contain hand sanitizer.
- Do not drink alcohol-based hand sanitizers. Drinking even a small amount can cause alcohol poisoning in children, while larger amounts may be toxic in older children and adults.
- Use alcohol-based hand sanitizer in a <u>well-ventilated area</u>. When using it 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.
- Some hand sanitizers may contain or be contaminated with harmful ingredients. Before you buy or use hand sanitizer, check <u>FDA's "do-not-use" list</u>.
- Store alcohol-based hand sanitizer away from heat and flames because it contains alcohol, which is flammable. When using alcohol-based 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 alcohol-based 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 <u>email alerts</u> about Drug Safety Communications on medicines or medical specialties of interest to you.

#### **Additional Information for Health Care Professionals**

- FDA is warning that getting alcohol-based hand sanitizer in the eyes can result in serious injury, including corneal abrasions and injury.
- If someone seeks medical advice about alcohol-based hand sanitizer splashing or getting in their eyes, urge them to immediately and thoroughly rinse their eyes under gently running water such as from a sink tap, water bottle, or emergency shower for at least 15 to 20 minutes. After rinsing, if symptoms such as redness, pain, irritation, visual impairment, blurred vision, or light sensitivity persist, advise them to seek an urgent eye examination.
- Use alcohol-based hand sanitizer in a well-ventilated area.
- Some hand sanitizers may contain or be contaminated with harmful ingredients. Before recommending or using hand sanitizer, check <u>FDA's "do-not-use" list</u>.
- To help FDA track safety issues with medicines, report adverse events involving alcohol-based 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 <u>email alerts</u> about Drug Safety Communications on medicines or medical specialties of interest to you.

### **Data Summary**

We reviewed cases from U.S. poison control center calls and published articles in the medical literature 1,2 of serious ocular adverse events following accidental ocular exposure to an alcohol-based hand sanitizer.

We searched the American Association of Poison Control Centers' (AAPCC) National Poison Data System (NPDS) database between January 1, 2018, and April 30, 2021, and identified 3,642 cases of ocular-only exposures to an alcohol-based hand sanitizer with related ocular adverse effects. The most common related effects were eye irritation/pain and red eye/conjunctivitis. There were 58 cases of corneal abrasions and 160 cases of blurred vision. Of the 58 corneal abrasions, 51 were treated and released. The remainder were either unknown, lost to follow-up, or refused referral/did not arrive at the health care facility. Of the 51 cases treated and released, 27 had a moderate effect (more pronounced than minor symptoms but not life-threatening and without residual adverse effect), two had a major effect (life-threatening or resulted in residual adverse effect), and the remainder were either not followed or were minor. All 58 cases were treated with dilution/irrigation/wash and 26 of them also received antibiotics. Half of the corneal abrasion cases (n=29) occurred in children and teens 19 years and younger, and 21 percent (n=12) occurred in children 5 years and younger. In children 5 years of age and



younger, most exposures occurred at home. In children 6 to 19 years of age, most exposures occurred in school settings.

We reviewed two publications describing a total of 18 cases of eye exposure to alcohol-based hand sanitizer in children, which required treatment in a hospital or by a health care professional. Martin et al. described a case series of 16 children who were hospitalized at a pediatric ophthalmology referral center in 2020, an increase from one case in 2019. The average age of the children was 3.5 years. Eight of the 16 cases had a corneal and/or conjunctival ulcer. The median time between exposure and complete re-epithelialization for children with corneal ulcers was 13 days.

Yangzes et al.<sup>2</sup> described two pediatric cases of eye injury following ocular exposure to alcohol-based hand sanitizers. The first involved a 4-year-old girl who had an eye exposure while attempting to use a hand sanitizer dispenser at a shop. She complained of severe photophobia and had right eyelid edema. Findings included conjunctival ischemia and a large corneal epithelial defect. Treatment consisted of irrigation with saline solution, and oral and topical medications. The corneal defect resolved completely, and conjunctival ischemia resolved in 2 weeks. The second case involved a 5-year-old boy in whom ocular exposure to alcohol-based hand sanitizer resulted in conjunctival congestion with superficial punctate keratopathy. Treatment consisted of saline wash and topical medications, with ocular adverse events resolving by day 5.

#### References

- 1. Martin GC, Le Roux G, Guindolet D, Boulanger E, Hasle D, Morin E, et al. Pediatric eye injuries by hydroalcoholic gel in the context of the coronavirus disease 2019 pandemic. JAMA Ophthalmol 2021;139:348-51.
- 2. Yangzes S, Grewal S, Gailson T, Grewal SPS. Hand sanitizer-induced ocular injury: a COVID-19 hazard in children. JAMA Ophthalmol 2021;139:362-4.

#### **Related Information**

FDA Drug Safety Communication: FDA warns that vapors from alcohol-based hand sanitizers can have side effects

FDA Consumer Update: Safely Using Hand Sanitizer

FDA updates on hand sanitizers consumers should not use (FDA's "do-not-use" list)

FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Q&A for Consumers | Hand Sanitizers and COVID-19



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