Soapmaking Studio

Understanding Hand Sanitizer: Its Use, Formulation, Manufacture, and Sale

By Kerri Mixon

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Contents

How to Use Hand Sanitizer (According to the Centers for Disease Control)

The comprehensive CDC article, "Show Me the Science–When & How to Use Hand Sanitizer in Community Settings," below, thoroughly explains the precise use of hand sanitizers. The article was last accessed April 25, 2020, through the following URL.
https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html

> "CDC recommends washing hands with soap and water whenever possible because handwashing reduces the amounts of all types of germs and chemicals on hands. But if soap and water are not available, using a hand sanitizer with at least 60% alcohol can help you avoid getting sick and spreading germs to others. The guidance for effective handwashing and use of hand sanitizer in community settings was developed based on data from a number of studies. Alcohol-based hand sanitizers can quickly reduce the number of microbes on hands in some situations, but sanitizers do not eliminate all types of germs.
>
> Why? Soap and water are more effective than hand sanitizers at removing certain kinds of germs, like Cryptosporidium, norovirus, and Clostridium difficile. Although alcohol-based hand sanitizers can inactivate many types of microbes very effectively when used correctly, people may not use a large enough volume of the sanitizers or may wipe it off before it has dried.
>
> Hand sanitizers may not be as effective when hands are visibly dirty or greasy.
>
> Why? Many studies show that hand sanitizers work well in clinical settings like hospitals, where hands come into contact with germs but generally are not heavily soiled or greasy 16. Some data also show that hand sanitizers may work well against certain types of germs on slightly soiled hands. However, hands may become very greasy or soiled in community settings, such as after people handle food, play sports, work in the garden, or go camping or fishing. When hands are heavily soiled or greasy, hand sanitizers may not work well. Handwashing with soap and water is recommended in such circumstances.
>
> Hand sanitizers might not remove harmful chemicals, like pesticides and heavy metals, from hands.
>
> Why? Although few studies have been conducted, hand sanitizers probably cannot remove or inactivate many types of harmful chemicals. In one study, people who reported using hand sanitizer to clean hands had increased levels of pesticides in their bodies. If hands have touched harmful chemicals, wash carefully with soap and water (or as directed by a poison control center).
>
> If soap and water are not available, use an alcohol-based hand sanitizer that contains at least 60% alcohol.
>
> Why? Many studies have found that sanitizers with an alcohol concentration between 60–95% are more effective at killing germs than those with a lower alcohol concentration or non-alcohol-based hand sanitizers. Hand sanitizers without 60-95% alcohol 1) may not work equally well for many types of germs; and 2) merely reduce the growth of germs rather than kill them outright.
>
> When using hand sanitizer, apply the product to the palm of one hand (read the label to learn the correct amount) and rub the product all over the surfaces of your hands until your hands are dry.
>
> Why? The steps for hand sanitizer use are based on a simplified procedure recommended by CDC. Instructing people to cover all surfaces of both hands with hand sanitizer has been found to provide similar disinfection effectiveness as providing detailed steps for rubbing-in hand sanitizer.
>
> Swallowing alcohol-based hand sanitizers can cause alcohol poisoning.
>
> Why? Ethyl alcohol (ethanol)-based hand sanitizers are safe when used as directed, but they can cause alcohol poisoning if a person swallows more than a couple of mouthfuls. From 2011–2015, U.S. poison control centers received nearly 85,000 calls about hand sanitizer exposures among children. Children may be particularly likely to swallow hand sanitizers that are scented, brightly colored, or attractively packaged. Hand sanitizers should be stored out of the reach of young children and should be used with adult supervision. Child-resistant caps could also help reduce hand sanitizer-related poisonings among young children. Older children and adults might purposefully swallow hand sanitizers to become drunk."

Formulating an Effective Hand Sanitizer Recipe

Additional information about hand sanitizer formulation is available from the CDC in the article, "CDC Statement for Healthcare Personnel on Hand Hygiene during the Response to the International Emergence of COVID-19," which was last accessed April 25, 2020, and is available through the following URL.
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/hcp-hand-sanitizer.html

> "CDC recommends the use of alcohol-based hand sanitizers with greater than 60% ethanol or 70% isopropanol as the preferred form of hand hygiene in healthcare settings, based upon greater access to hand sanitizer."

A mixture of alcohol and water has a greater efficacy than pure alcohol; the water facilitates the denaturing of microbial proteins. Keep in mind the following information about alcohol's shortcomings from the CDC website.
https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html

> "Alcohols are not recommended for sterilizing medical and surgical materials principally because they lack sporicidal action and they cannot penetrate protein-rich materials. Fatal postoperative wound infections with *Clostridium* [*difficile*] have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores."

While alcohol is very effective against viruses, for some specific bacteria in the *Clostridium* genus, particularly the *difficile* species, alcohol is bactericidal (it destroys the bacteria) but it is not sporicidal (it does not destroy the endospores—the rugged dormant form of the bacteria when in a sort of hibernation). Therefore, the World Health Organization's guide to sanitizer formulations includes the addition of a 3% hydrogen peroxide solution (because it is sporicidal) at the rate of about 1%.
https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

With this scientific information from the CDC, hand sanitizers should be formulated and made with the following goals.

- ☑ Include 3% hydrogen peroxide solution as 1% to 2% of the hand sanitizer formula.
- ☑ Don't use pure alcohol; some water is needed to help denature microbial proteins.
- ☑ Hand sanitizers are less effective if hands are dirty, oily, or greasy; therefore, the hand sanitizer product should not contain added oils, unnecessary powders, nor large quantities of other additives. Additives should be minimal.
- ☑ According to the CDC, fats or oils added to a hand sanitizer may make the product less effective because triglycerides may fortify the phospholipid membrane that encapsulates virulent microbes. Never add oils, such as coconut oil or avocado oil, to a hand sanitizer.
- ☑ To reduce the risk of alcohol poisoning among children, hand sanitizer products should neither be brightly colored nor scented as appealing foods, such as candy.

☑ To make hand sanitizer, a gelling agent (e.g. carbomer, acrylates, hydroxyethyl-cellulose, or xanthan gum) must first be thickened with distilled water and then added to the alcohol. If rheology agents and other additives approximate 10% of the volume, then a stronger alcohol is required because its strength will be diluted by the additives. For example, when making 10 ounces of hand sanitizer starting with 60% alcohol (which is 60% alcohol and 40% water) and adding 10% additives, the finished hand sanitizer will not contain the required minimum 60% alcohol.

10% additives	1 ounce additives	**10% additives**
90% liquid from 120 proof alcohol bottle (which contains 60% alcohol and 40% water)	5.4 ounces alcohol (from alcohol bottle)	**54% alcohol**
	3.6 ounces distilled water (from alcohol bottle)	**36% water**
The final product does **not** meet the minimum CDC recommendation of 60% alcohol by volume.		

Similarly, adding some isopropyl alcohol to an aloe vera gel will not produce an effective hand sanitizer because the alcohol content will not meet the minimum requirement set by the CDC. Do not add alcohol to aloe vera gel.

☑ The CDC recommends at least 60% (by volume) of the hand sanitizer product should be alcohol if using **ethyl alcohol**, **ethanol**, or **grain alcohol**. To achieve a hand sanitizer with a minimum of 60% ethanol, the ethanol must be 70% (140 proof) to accommodate additives. This is not possible because the California Department of Alcoholic Beverage Control (ABC) code § 23403 makes it illegal to sell non-denatured ethanol stronger than 60% alcohol (120 proof) within the state of California. Therefore, ethanol cannot be used because it cannot be purchased with a strong enough alcohol content. For more information, refer to the following URL and CA ABC article. https://www.abc.ca.gov/high-proof-alcoholic-beverages

Likewise, vodkas do not contain enough alcohol. Most vodkas, including Tito's® Handmade Vodka, are 80 proof, which means they contain only 40% ethanol. The strongest popular vodka, Smirnoff™ Recipe No. 57 Vodka (blue label), is 100 proof, which is 50% ethanol, and is not strong enough to meet CDC guidelines. Do not use vodka as hand sanitizer.

☑ The CDC recommends at least 70% of the hand sanitizer product be alcohol if using **isopropyl alcohol**, **isopropanol**, or **rubbing alcohol**. Isopropyl alcohol may be purchased in different strengths (e.g. 70%, 91%, or 99%) and the un-listed percentage is always water. So, 91% isopropyl alcohol is not pure alcohol; it contains 9% water. Due to necessary additives, 70% isopropyl alcohol will result in a hand sanitizer containing less than 70% alcohol, so it is not strong enough. Either 91% or 99% isopropyl alcohol may be used to achieve a hand sanitizer containing a minimum of 70% alcohol. Use 91% or 99% isopropyl alcohol.

☑ Home crafters cannot advertise or sell hand sanitizer because it is a drug. Hand sanitizer is a drug because it is intended to prevent disease. It is illegal to advertise or sell hand sanitizer unless the manufacturer, product, and ingredients have all

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been registered with and pre-approved by the FDA. Homemade hand sanitizer may be created for personal use or to give away.

For example, on March 6, 2020, the FTC fined Teami (a small tea company in Seminole, Florida) $15.2 million for making drug-like claims about their teas. The company claimed the various teas would promote weight loss, detoxify the body, reduce food cravings, improve blood circulation, increase red blood cells, strengthen the immune system, rejuvenate the body, and other claims. None of these claims were substantiated by the FDA, nor was the company registered with the FDA to sell drugs. The FTC fines totaled $15.2 million but the company's net worth was evaluated below a million, so the minimum payment was reduced to $1 million. Teami cannot resume business until it pays the minimum $1 million fine. For more information, refer to the suit brought by the FTC at the following URL.
https://www.ftc.gov/system/files/documents/cases/1823174teamicomplaint_exhibits1-26.pdf

Similarly, November 25, 2019, the FDA issued an official warning to companies selling CBD products with drug-like advertising claims. The following quote is from the FDA website.
https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details

> "CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, food products such as chocolate bars and teas, and topical lotions and creams. …The FDA has previously sent warning letters to other companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act. Some of these products were in further violation because CBD was added to food, and some of the products were also marketed as dietary supplements despite products which contain CBD not meeting the definition of a dietary supplement.
>
> Under the FD&C Act, any product intended to treat a disease or otherwise have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body."

Ingredients

91% or 99% isopropyl alcohol is a flammable liquid also referred to as isopropanol or rubbing alcohol and is the main ingredient in hand sanitizer. The diluted 70% version contains 70% alcohol and 30% water; it is not strong enough. The hand sanitizer formula must contain at least 78% of the 91% isopropyl alcohol or at least 71% of the 99% isopropyl alcohol to yield a product containing the recommended minimum volume of 70% alcohol.

3% hydrogen peroxide solution is not entirely necessary to yield a hand sanitizer to destroy viruses (alcohol is the star ingredient) but it is recommended by the World Health Organization because it has the sporicidal effect that alcohol lacks. Add the hydrogen peroxide solution to the hand sanitizer formula at 1% to 2% by volume.

Distilled water is needed to denature the protein structures found in virulent microbes. Water also hydrates the rheology agents (the thickening powders). Some gelling agents

will not thicken in alcohol. For example, xanthan gum powder thickens water to form a gel that can be added to alcohol, but xanthan gum powder alone will not thicken pure alcohol; instead, xanthan gum powder will sink to the bottom of pure alcohol and remain a separate powder. Any water (deionized, reverse osmosis, or tap) will work, but only distilled water consists of pure water (without dissolved salts and trace minerals that may promote oxidation of the finished product). The quantity of water changes depending on the purity of isopropyl alcohol used. 91% isopropyl alcohol contains 9% water, so less water is needed than when using 99% isopropyl alcohol (which is 1% water).

Hydroxyethylcellulose (HEC) powder is a natural wood cellulose that absorbs water to form a smooth gel. Hydroxyethylcellulose may not be used as the sole thickener because it will settle to the bottom of the bottle and form a layer of gel below the less-dense alcohol. Another thickener, such as xanthan gum, must be added to keep the finished product homogenous and prevent settling over time. Hand sanitizer may be made with other thickeners, but the hydroxyethylcellulose has a smooth, velvety soft finish. Hydroxyethylcellulose takes from 20 minutes to an hour to become fully hydrated and thick. It should be 1% to 2% of the formulation, depending on the desired thickness of the finished product.

Panthenol (pro-vitamin B) powder is not a necessary additive. It is one of the few conditioning agents compatible with alcohol. (Both panthenol and propanediol end in “ol” due to the OH functional group, which denotes an alcohol). People with dry hands who frequently use hand sanitizers appreciate the conditioning power of a mere 0.5% panthenol powder.

Propanediol liquid is best described as a non-sticky glycerin. With “tri” meaning 3 and “di” meaning 2, scientifically speaking, glycerin is “propane-tri-ol” and is a larger stickier molecule than “propane-di-ol.” Either propanediol or glycerin may be used at 0.5%, but glycerin may feel sticky with repeated use of the hand sanitizer. Both are clear liquids valued as humectants and skin conditioning agents and both easily dissolved in water; neither one is necessary.

Xanthan gum powder is a food-grade powder often used to thicken soups, sauces, and salad dressings. While it is much easier to thicken hand sanitizer with carbomers or acrylates, it is more desirable to use a natural non-petroleum-derived thickener, such as xanthan gum or hydroxyethylcellulose. Xanthan gum thickens water to form a gel on contact, so mechanical mixing with an immersion blender is required to achieve even hydration (and avoid dry clumps of powder from forming). When used in conjunction with hydroxyethylcellulose, use xanthan gum at the rate of 0.5% of the hand sanitizer product. Xanthan gum may be used as the sole thickening agent, but it has a mucousy snoty finish when used alone to form a gel. If using xanthan gum without adding hydroxyethylcellulose powder, increase the xanthan gum to 0.7% to 0.8% and be satisfied with a slightly thinner product to avoid the snoty feel.

Formulas and Recipes

Remember, the bottle of 91% rubbing alcohol is not 100% alcohol; it is 91% alcohol and 9% water. Use caution when calculating formula percentages and recipe weights; make certain the finished hand sanitizer product will contain at least 70% isopropyl alcohol.

The following formula and recipe require 91% isopropyl alcohol. The alcohol content of the finished hand sanitizer product is 70.98%.

Hand Sanitizer Formula		To make 20 oz	Hand Sanitizer 20-oz Recipe	
distilled water	17.5%	× 20 =	3.50 oz	distilled water
hydrogen peroxide	1.0%	× 20 =	0.20 oz	hydrogen peroxide
hydroxyethylcellulose	1.5%	× 20 =	0.30 oz	hydroxyethylcellulose
panthenol	0.5%	× 20 =	0.10 oz	panthenol
propanediol	0.5%	× 20 =	0.10 oz	propanediol
xanthan gum	0.5%	× 20 =	0.10 oz	xanthan gum
91% isopropyl alcohol	78.0%	× 20 =	15.60 oz	91% isopropyl alcohol
9% water in alcohol bottle				9% water in alcohol bottle
fragrance	0.5%	× 20 =	0.10 oz	fragrance
Total of percentages	= 100.0%		20.00 oz	= Total recipe weight

The following formula and recipe require 99% isopropyl alcohol. The alcohol content of the finished hand sanitizer product is 70.29%

Hand Sanitizer Formula		To make 20 oz	Hand Sanitizer 20-oz Recipe	
distilled water	24.5%	× 20 =	4.90 oz	distilled water
hydrogen peroxide	1.0%	× 20 =	0.20 oz	hydrogen peroxide
hydroxyethylcellulose	1.5%	× 20 =	0.30 oz	hydroxyethylcellulose
panthenol	0.5%	× 20 =	0.10 oz	panthenol
propanediol	0.5%	× 20 =	0.10 oz	propanediol
xanthan gum	0.5%	× 20 =	0.10 oz	xanthan gum
99% isopropyl alcohol	71.0%	× 20 =	14.20 oz	99% isopropyl alcohol
1% water in alcohol bottle				1% water in alcohol bottle
fragrance	0.5%	× 20 =	0.10 oz	fragrance
Total of percentages	= 100.0%		20.00 oz	= Total recipe weight

Adjustments to the Formula

Adjustments to the formula may be made to accommodate the availability of ingredients and depend on the desired thickness of the product, as determined by the dispenser or packaging. Adjustment guidelines are covered in the Ingredients chapter.

If the crafter chooses not to include the hydrogen peroxide, panthenol, propanediol (or glycerin), or fragrance, then increase the distilled water so the total percentage will equal 100%. For example, if not adding 0.5% panthenol powder, then increase the distilled water from 24.5% to 25.0%.

Similarly, if adjusting the percentage of hydroxyethylcellulose, increase or decrease the distilled water as needed to total 100%. If omitting hydroxyethylcellulose, slightly increase the xanthan gum from 0.5% to 0.7% and make up the missing portion by increasing the water. The example of omitting hydroxyethylcellulose from the 91% isopropyl alcohol formula follows.

Hand Sanitizer Formula without HEC	
distilled water	18.8%
hydrogen peroxide	1.0%
~~hydroxyethylcellulose~~	
panthenol	0.5%
propanediol	0.5%
xanthan gum	0.7%
91% isopropyl alcohol	78.0%
9% water in alcohol bottle	
fragrance	0.5%
Total of percentages	= 100.0%

The necessary ingredients are distilled water, xanthan gum (or carbomers or acrylates), and 91% or 99% isopropyl alcohol; these 3 ingredients are mandatory for creating a hand sanitizer gel. Although thinner, less appealing, and lacking the World Health Organization's recommendation of hydrogen peroxide, the following formula works.

Minimal Hand Sanitizer Formula	
distilled water	21.2%
xanthan gum	0.8%
91% isopropyl alcohol	78.0%
9% water in alcohol bottle	
Total of percentages	= 100.0%

Manufacture

Create a clean work environment free of clutter and take precautions to protect against accidental biological, chemical, or physical contaminants. Keep in mind alcohol is extremely flammable and acts as a solvent that may damage or mar surfaces.

Using a scale, weigh out the distilled water. Add the correct weight of 3% hydrogen peroxide solution to the distilled water and stir. Next, add the correct weight of hydroxyethylcellulose powder and stir to wet the powder. The hydroxyethylcellulose should be completely wet but it will take from several minutes to an hour to form a gel. Do not wait for the hydroxyethylcellulose to gel. Continue to add the correct weight of panthenol powder and stir until the panthenol powder is dissolved (the hydroxyethylcellulose remains a gritty solid powder). Add the correct weight of propanediol and stir (the hydroxyethylcellulose should still be gritty). While mechanically mixing with an immersion blender to create a strong vortex in the liquid, slowly sprinkle the correct weight of xanthan gum powder into the vortex. Briefly continue to blend the mixture until the xanthan gum has gelled. Next, add the correct weight of isopropyl alcohol and blend the mixture until it is smooth.

The hydroxyethylcellulose may take up to an hour to become fully hydrated and form a gel. Tightly cover the mixture to prevent alcohol evaporation and allow the mixture to set for an hour while the hydroxyethylcellulose powder finishes gelling. (If hydroxyethylcellulose was not used, then there is no need to wait). After waiting for an hour, blend again because the hydroxyethylcellulose gel may be thicker at the bottom of the container.

Examine the mixture for clumps of xanthan gum. If clumps formed, first try blending the mixture with an immersion blender to chop the clumps into smaller bits and allow the smaller bits 5 to 10 minutes to absorb water. Blend again. If xanthan gum clumps remain large and unsightly, remove them; a metal strainer works better than a cheese cloth for removing xanthan gum clumps (a small portion of the finished gel will also be removed and discarded). Add the correct weight of fragrance and blend again.

Packaging and Labeling

Depending on the viscosity of the finished hand sanitizer gel product, package the gel in pump bottles, airless pump bottles, or squirt bottles for dispensing. Correctly label the product with the name of the commodity, the net weight of the product, the name and address of the manufacturer, an ingredient declaration (in order of predominance), directions for use, and warning statements. Warning statements should include information that the product is flammable and is not for ingestion. A sample ingredient declaration for either of the recipes from page 8 (without adjustments) follows.

> Ingredients: Isopropyl alcohol, water, hydroxyethylcellulose, hydrogen peroxide, xanthan gum, panthenol, propanediol, fragrance.

Although the hand sanitizer cannot be sold, it is pertinent the product is correctly labeled, especially if giving it away to anonymous community groups, such as homeless shelters. An ingredient declaration will help prevent someone who is allergic to a specific ingredient or avoiding a specific ingredient from using the product. Directions for use (and how much product to apply) may vary depending on product thickness or hand size.

Selling Hand Sanitizer

Again, home crafters cannot advertise or sell hand sanitizer because it is a drug. Hand sanitizer is a drug because it is intended to prevent disease. See page 5. In addition to sharing your hand sanitizer product with family and friends, consider donating some free bottles to help your local community. Schools, hospitals, doctors' offices, nursing homes, battered women's shelters, homeless shelters, law enforcement stations, court houses, and prisons all appreciate receiving hand sanitizer.

Erroneous information is available online, on social networks and in blog posts, falsely explaining, "due to the public health emergency, the FDA is temporarily allowing anyone to make and sell hand sanitizer because it is essential." This information is false. The FDA's "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry" is available through the following URL and was last accessed April 25, 2020.
https://www.fda.gov/media/136118/download

The FDA guidance document explains "temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities" will be allowed. The step was taken by the FDA to allow pharmacists in state-licensed pharmacies or pharmacists in federal facilities and FDA-registered facilities who to not normally manufacture hand sanitizer to do so to help meet demand. Unfortunately, this obviously does not include home crafters.

"My wish is for you to have fun, create, give, and stay healthy!"
—Kerri Mixon

About Kerri Mixon

Kerri Mixon is a professional cosmetic formulator, master soapmaker, and author in San Diego, California. She opened her first soap company, Pallas Athene Soap, in 1999 and joined the Handcrafted Soap and Cosmetic Guild in 2003. Kerri teaches soap and cosmetic making classes throughout the United States and has regularly taught at the Soapmaking Studio in Lemon Grove since 2008. Honored and humbled by receiving a lifetime membership award from the Soap Guild in 2019, Kerri sought to give back to the soapmaking community. Early in 2020, Kerri Mixon officially registered the last Sunday in September, annually, as National Soapmaking Day. She is thankful for abundant creativity and health; her hobbies include gardening and fashion. A 16th-generation soapmaker now in her 50s, she revels at the opportunity to make impossible custom soap creations for clients and enjoys spending time with her husband and their cats and cockatoo.

This information about hand sanitizer was prepared by Kerri Mixon for the Soapmaking Studio. Located near San Diego, the Soapmaking Studio is a school of product formulation and handmade cosmetics. Hand sanitizer manufacture is taught in the Serum Making Class. To promote better public hygiene and reduce the spread of virulent microbes, this booklet is made available to Soapmaking Studio students and to the public indefinitely.

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