Hand Sanitizer Primer

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During the last year, the use of hand sanitizer has exponentially increased from an occasional preventive during the flu season, to multiple daily applications throughout the day. The hand sanitizer we know has origins in waterless hand cleaners, which have been in production since the 1940s. Gel hand cleaners were created in the late 1980s, but they were not released until the late 1990s. It has only been in the last decade that hand sanitizers became common products in every home or pocket. The current 2020 pandemic fueled massive sales of all types of hand sanitizers. The purpose of hand sanitizers is to disinfect your hands when soap and water are unavailable, by killing infectious biological agents, such as bacteria and viruses.

What are Viruses and Bacteria

The term virus comes from the Latin word for poison. A virus is a very small infectious agent that can only replicate inside living cells of another organism (microorganisms, plants and animals). Most viruses range in size from 20 to 300 nanometers (Figure 1). Viruses are essentially parasites that cannot exist and replicate outside the host cells. For this reason, most scientists do not consider viruses to be living entities. They lack the cellular machinery required to replicate on their own. Viruses hijack the host cell's replication process, forcing the host to produce more copies of that virus.

Viruses are often the cause of common diseases or can be the catalyst for other diseases. Many childhood illnesses are caused by viruses like measles, mumps, pertussis, and chickenpox. There are many widespread persistent viruses that humans deal with continually. These common illnesses, such as the common cold or flu. Then there are viruses that we deal with more sporadically such as herpes, HIV, papilloma virus, or chickenpox (shingles).

Bacteria, unlike viruses, are prokaryotic, single-celled microbes that are much larger than viruses, and are able to live outside a host organism. There are very few bacteria that cause human disease or infection, but when they do, bactericides (or antibacterials or antibiotics) can treat those infections. These agents do not work against viral infections. Bacteria can be responsible for some commonly known infections like strep throat, staph and tuberculosis.

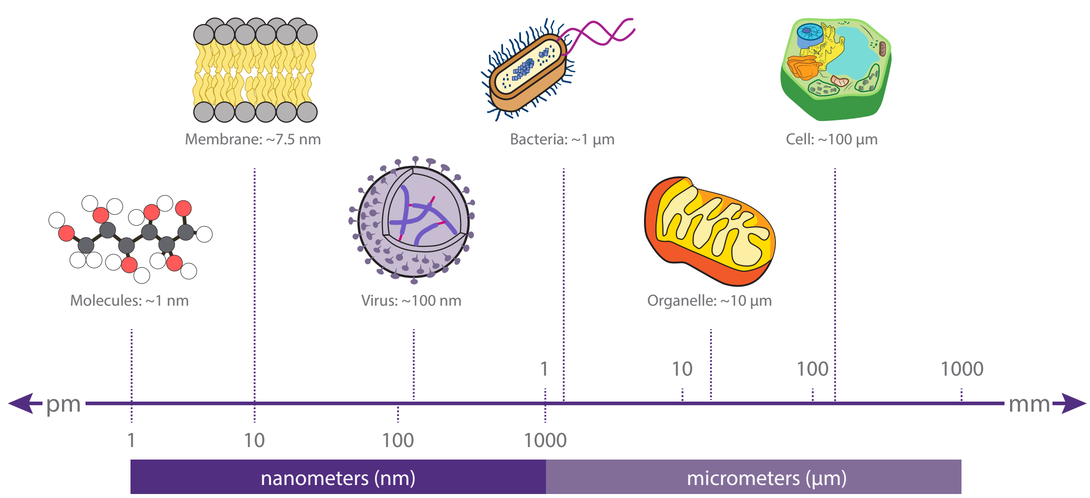


Figure 1. Relative sizes of common microorganisms, molecules and cellular components

Stopping Transmission of Viruses and Bacteria with Disinfectants

The primary goal of a disinfectant is to kill the biological agent, or render it unable to reproduce. In order to accomplish that goal, usually the disinfectant must attack the physical structure of a virus or bacteria, usually either the outer membrane or the genetic material inside the agent (Figure 2).

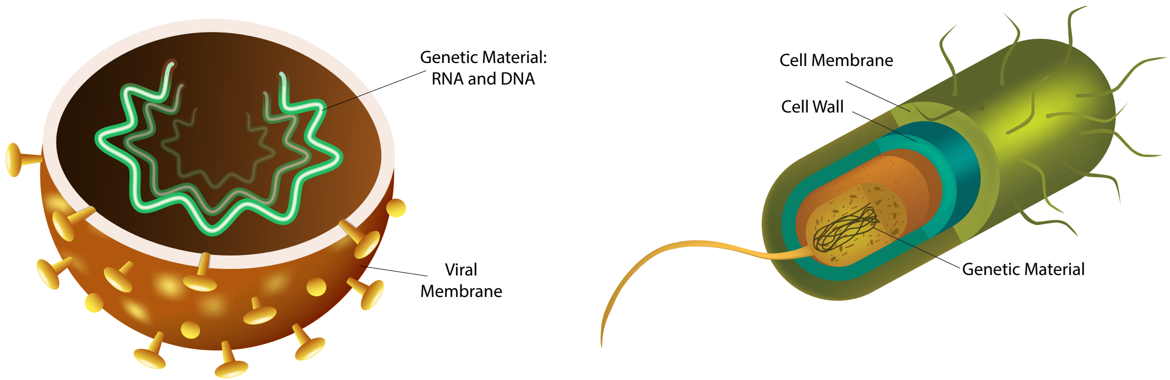


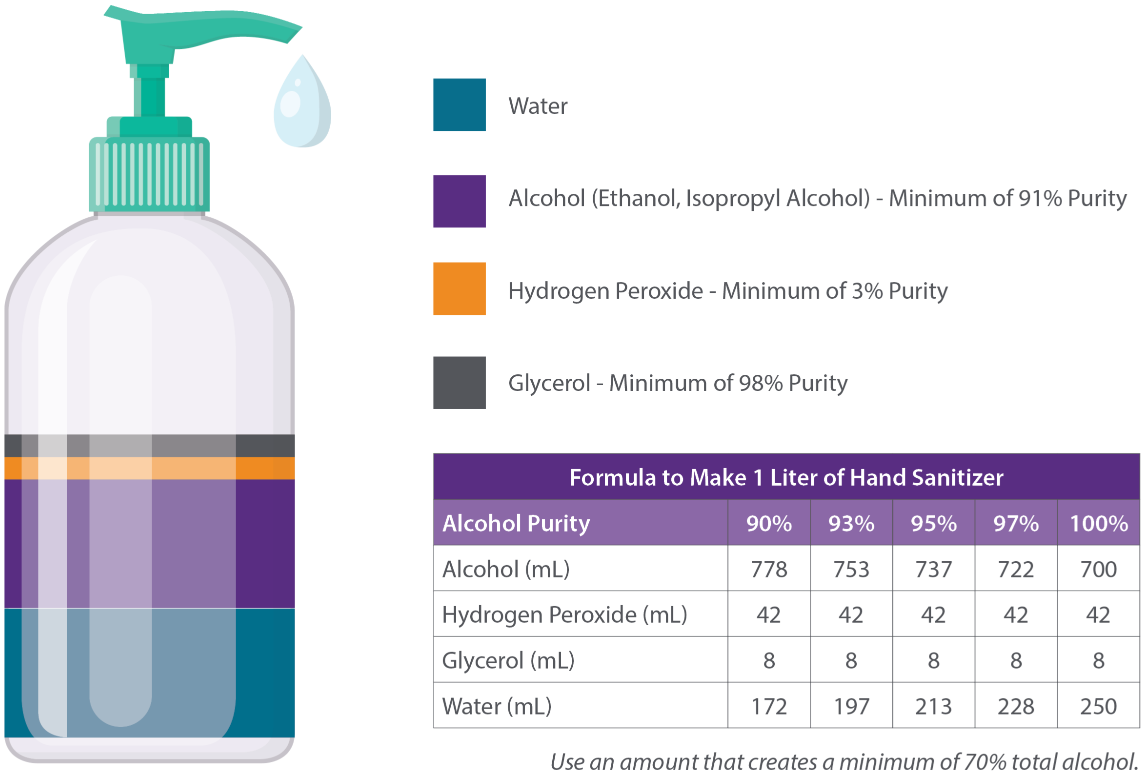
Figure 2. Virus structure and bacterium structure

There are many commercial products for all types of settings such as home, health care facilities and laboratory. Most of these products contain familiar active chemical agents such as alcohols, acids, chlorides, etc. In general, these products work through one of three processes. The first mode of interaction is dehydration where the active ingredient inactivates the biological agent by removing water from its surroundings. The second mode of interaction is disruption of the cell, or capsule, by denaturing proteins, or dissolving lipid capsules, thereby spilling out the cell contents. This ultimately also has the effect of drying out the biological agents before they can replicate. The final mode disrupts the generic machinery of the cell, inhibiting replication of the biological agent.

The common theme for all of these products is that the products must be physically applied and allowed to make contact for a period of time, before being wiped away. This is called the dwell time, or contact time. Surfaces must be wet to be effective. Very few of these products are instantaneously effective, and the solution needs to be applied for several minutes and allowed to dry.

Hand Sanitizer Ingredients

Hand sanitizers are a mix of four to ten ingredients depending on the manufacturer. The basic four ingredients are water (wetting agent to keep disinfectant in contact with skin and infectious agent), an alcohol (to kill biological agents), hydrogen peroxide (to stop mold growth in the bottle), and glycerol (an emollient to soften skin and slow drying). Other additional ingredients can include colorants, fragrances, and skin conditioners, such as aloe vera or vitamin E. Figure 3 shows the most common ingredients for hand sanitizer and gives you the proportions to make your own in-house product for your personal use.



Formula to Make 1 Liter of Hand Sanitizer					
Alcohol Purity	**90%**	**93%**	**95%**	**97%**	**100%**
Alcohol (mL)	778	753	737	722	700
Hydrogen Peroxide (mL)	42	42	42	42	42
Glycerol (mL)	8	8	8	8	8
Water (mL)	172	197	213	228	250

Use an amount that creates a minimum of 70% total alcohol.

Figure 3. Ingredients and proportions in hand sanitizer

Most of the ingredients are fairly straightforward. The biggest issue is the choice of an alcohol. The most commonly used alcohol for hand sanitizer is ethanol. Ethanol is commonly imbibed in our wine and other spirits, and is the base for synthetic fuels. Ethanol is often produced through fermentation processes of plant material such as corn. It can also be produced from petrochemical reactions of the hydration of ethylene (synthetic ethanol). Due to its use in alcoholic beverages, the fuel industry and the cosmetic industry, ethanol is a highly traded commodity with highly fluctuating prices that have only increased with the greater need for disinfectants.

A second choice of alcohol for hand sanitizer is isopropyl alcohol (IPA), commonly known as rubbing alcohol. IPA has been widely used as an industrial solvent and biological disinfectant for over a hundred years. IPA is produced by an industrial hydration process which tends to make it more expensive to produce than alcohols such as ethanol or methanol. This raises a dangerous trend in hand sanitizers. Methanol, often referred to as wood alcohol, is one of the cheapest alcohols to produce. Methanol is a common by-product of many chemical processes and can create many dangerous by-products like aldehydes.

Of the three alcohols that have been discussed, methanol is the most toxic. It can cause blindness, convulsions, and death if consumed or excessively absorbed. Historically, some bootleggers would spike methanol into their ethanol spirits to increase the volume of product they were selling. But, the contaminated spirits caused the death or blindness of those unfortunate enough to drink the tainted beverages. Lately, the FDA has issued many recalls on hand sanitizer for the use of methanol instead of the accepted ethanol or isopropyl alcohols. Manufacturers of these sanitizers are using methanol in the same way that early bootleggers did to reduce their cost and bulk up their product.

The safest hand sanitizer products contain either ethanol or isopropanol and are free of methanol (Figure 4).

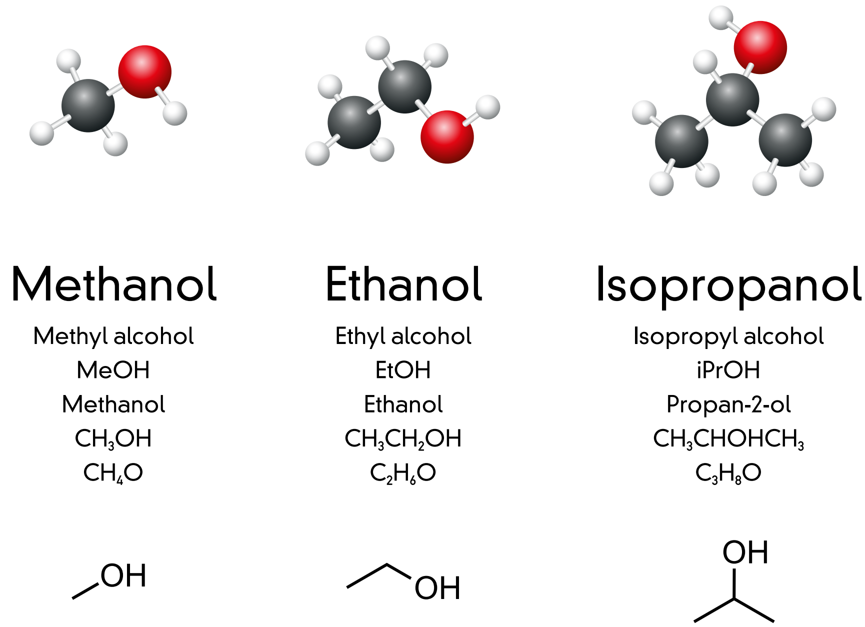


Figure 4. Different small alcohols found in hand sanitizer

Contamination in Hand Sanitizer

The issue of contamination and adulteration of hand sanitizer has peaked over the last few months resulting in numerous recalls. The FDA has issued guidance for laboratory testing of hand sanitizers to determine if they contain any of the targeted contaminants including methanol, other unacceptable alcohols, and all their breakdown and impurity products (Table 1). For the full testing and target methodology from the FDA, go to: https://www.fda.gov/media/141501/download.

Table 1. Hand Sanitizer Impurity Targets

Compound	CAS #	FDA Level
Methanol	67-56-1	1
Benzene	100-41-4	1
Acetaldehyde	75-07-0	1
1,1-Diethoxyethane	105-57-7	1
Acetone	67-64-1	2
1-Propanol	71-23-8	2
Ethyl Acetate	141-78-6	2
2-Butanol	78-92-2	2
Isobutanol	78-83-1	2
1-Butanol	71-36-3	2
3-Methyl-1-Butanol	123-51-3	2
Amyl Alcohol	71-41-0	2

Final Thoughts

During this pandemic, the use of hand sanitizers has skyrocketed. A product that may have only been used occasionally, or when thought of, has become entrenched in daily use. The consumers have created a need for sanitizers and manufacturers have responded, but some have used inferior products or illegal additives to boost their sales and reduce their costs. The FDA has stepped in and not provides guidance for the safety testing of hand sanitizer that laboratories can now use to weed out the contaminated materials. SPEX CertiPrep is, as always, proud to be at the forefront of laboratory needs by offering its hand sanitizer impurity standards. Our standards contain all of the impurities targeted by the FDA testing method and help laboratories in their testing and validation processes during this increased time of need and awareness.