



Making Sense of the COVID-19 PPE and Hand Sanitizer Frenzy

“Are All Hand Sanitizers Effective Against COVID-19?”

A Technical White Paper to Help Guide Healthcare Clinicians and Users on the Key Regulations, Guidelines, Technologies and False or Misleading Products on the Market.

Authored and Co-Authored by
Five diverse, qualified subject matter experts.



Table of Contents

1. Background & Problem Statement
2. Regulatory Organizations and Their Differing Roles
3. Why Are Alcohol Sanitizers Preferred?
4. The FDA's Temporary Policy for Manufacturing Alcohol Based Hand Sanitizers
5. Key FDA Vigilance, Guidelines and Limitations
6. Hydromer's First Responder™ Hand Sanitizer
7. Conclusion
8. About the Authors and Subject Matter Experts
9. References

Making Sense of the COVID-19 PPE and Sanitizer Frenzy

“Are all Hand Sanitizers Effective Against COVID-19?”

A Technical White Paper to Help Guide Healthcare Clinicians and Users on the Key Regulations, Guidelines, Technologies and False or Misleading Products on the Market.

Noted below are just a few critical issues being faced by employers, consumers, clinicians and first responders who need to rely on a long-term supply of quality hand sanitizer during this extended battle with COVID-19.

- In January of 2020 as COVID-19 was spreading, the FDA issued the hand sanitizer market leader a warning letter for **making unproven claims** that their hand sanitizer helps eliminate Ebola, MRSA, and the flu.
- Since March of 2020, the FDA has issued **sixty-six (66) warning letters to firms selling fraudulent products with claims to prevent, treat, diagnose or cure COVID-19** – with three (3) of those being actual hand sanitizer manufacturers.
- Recently the FDA notified **several fuel ethanol companies that their product does not meet the safety standards required** for use in hand sanitizer production.
- In one case, the FDA said it found significant levels of the carcinogen acetaldehyde in ethyl alcohol supplied to a company for use in its hand sanitizer.
- In Canada, Health Canada has already **recalled six (6) hand sanitizers because they contained an industrial grade ethanol (alcohol)**.
- Over 1,500 new manufacturers have registered with the FDA to produce alcohol-based hand sanitizers and rubs - including businesses that have never operated in the healthcare field - such as gasoline producers, beverage distilleries and perfume manufacturers. While this has been good to ensure that the supply meets the demand, how do you know that the product quality is sufficient to work on COVID-19?
- Over 1,000 Chinese medical suppliers have recently been caught using bogus registration data submitted to FDA (false addresses and non-working phone numbers) to sell their products into the U.S.

Some alarming information for sure, but what does this all mean? With multiple reputable agencies involved such as FDA, CDC, WHO, and EPA providing conflicting guidelines on PPE and sanitizers - along with the potential bad-practices and exploitation currently taking place (and the probabilities of more to come), is anyone watching over the consumer and clinicians who need high quality hand sanitizers the most?

1. Background

With the Coronavirus (COVID-19) becoming the worst pandemic the world has seen in our lifetime, we can only look back into history to give us direction as to how to proceed to overcome this terrible disease. However, as with many diseases - over time we will eventually learn how to overcome and /or live functionally with the virus - but at the cost of losing many family and friends along the way.

Meanwhile, there are many websites available, articles and blogs being published by “experts in their field” and television programs being broadcasted, which all provide us with information about what we should do to help prevent the spread of this virus. However, some information is contradictory - while others only tell us only part of the story and some just do not make sense. With all this data being provided to us by these “experts”, how can we sort out reality from half-truths? In this article, we will attempt to provide some clarification, at a level that we can all understand – layman’s terms. So, let us start from the beginning.

First, we must understand that there are two distinct ways to transmit the COVID-19 virus; one is via person-to-person contact and the other is by touching surfaces contaminated with COVID-19.

Person to person contact: When someone infected with the virus coughs, sneezes, or speaks, they spray small droplets from their nose and mouth, that may contain the COVID-19 virus. If you are too close (less than six feet apart), you can breathe in the droplets.ⁱ It is for this reason that social distancing and face masks are being suggested, and in some cases required – especially when in stores, hospitals, nursing homes and other public areas. However, it is probably not for the reasons that most people think.

According to Dr. Aaron Hamilton, MD of the Cleveland Clinic, a cloth mask will not prevent you from breathing in respiratory droplets that carry a virus, but it will help protect others

from you - if you happen to be infected, with or without symptoms. Therefore, properly wearing a face mask, social distancing and frequent hand washing, may ultimately help slow how far the virus spreads.ⁱⁱ

Contact with a contaminated surface:

According to a recent New York Times article, the CDC issued a news release stating that it may be possible for a person to become infected with COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly eyes, based on lab studies on COVID-19. Therefore, washing your hands often is suggested. However, they do not think that this method is the main way the virus spreads.ⁱⁱⁱ

So, we see that face masks, social distancing and frequent hand washing are essential to limit the spread of the virus. Now, that we have discussed how COVID-19 can be transmitted, next we need to know what each agency’s responsibility to the public are.

2. Regulatory Organizations and Their Role

Over the past few months, you have probably heard acronyms like WHO, CDC, FDA and EPA being discussed. So, let us briefly discuss what they mean and what their role is in providing guidance and help in controlling the spread of the virus.

World Health Organization (WHO): The World Health Organization plays an essential role in the governance of health and disease due to its core global functions of establishing, monitoring, and enforcing international norms and standards, and coordinating multiple actors toward common goals.^{iv}

The WHO monitored COVID-19 in its early stages in China by collecting and analyzing data and eventually providing advice and helping countries prepare for the disease globally. Finally, in

February 2020, the WHO announced a name for the disease – COVID-19 (CO = corona, VI = virus, D= disease, 19 = of 2019).^v

Center for Disease Control and Prevention

(CDC): The Centers for Disease Control and Prevention serves as the national focus for developing and applying disease prevention and control, environmental health, health promotion, and education activities designed to improve the health of the people of the United States.^{vi} The CDC is responding to the pandemic by preparing healthcare workers, learning more about how the disease spreads, and supporting the state, local, tribal and territorial governments on the front lines of the outbreak.^{vii}

Food and Drug Administration (FDA): The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; as well as ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.^{viii} The major areas of the FDA's focus is to increase the availability of tests, therapeutics, and other devices such as ventilators and personal protection equipment. They also monitor the human and animal food supply.^{ix} They are the key regulatory group for our first responders and front-line workers in hospitals and home care environments.

Environmental Protection Agency (EPA): The Environmental Protection Agency is a federal government agency whose mission is to protect human and environmental health by regulating the manufacturing, processing, distribution, and use of chemicals and other pollutants through fines, sanctions, and other procedures. It oversees programs to promote energy efficiency, environmental stewardship, sustainable growth, air and water quality, and pollution prevention.^x The EPA registers antimicrobial pesticides, which include disinfectants for use on pathogens that cause COVID-19. They also ensure the availability of these disinfectants and take-action against fraudulent products.^{xi}

As you can see, each of these agencies play specific roles in fighting the spread of the

COVID-19 virus; however, in many cases they try to work together to educate and protect the public and to provide professional guidance through the varying news media outlets. Unfortunately, at times these agencies seem to provide confusing, if not contradictory, guidelines when it comes to PPE and sanitizers.

But what about the effectiveness of the hand sanitizer products currently on the market? What works; and why? How come there is such a limited supply? Why do most products have to be made with alcohol? Confusion about these topics is completely understandable. Let's work through it.

3. Why Are Alcohol Hand Sanitizers Preferred

Although we are starting to see a growing supply of items that the FDA, WHO and CDC are telling us we need to use in order to help reduce the spread of the virus, it wasn't too long ago that all of these items were extremely scarce – especially hand sanitizers.

The WHO provided studies suggesting that alcohol-based hand sanitizers - or hand rubs (which are interchangeable terms) consisting of very specific grades of raw materials, were to be one of the most effective means of minimizing the spread of the virus, especially in absence of frequent hand washing with soap and water.

Alcohol attacks and destroys the envelope protein that surrounds viruses such as this coronavirus and is vital to its survival and multiplication. A hand sanitizer needs to be at least 60% alcohol, in order to kill most viruses and must be used properly by covering your hands and lower wrists fully and rubbing it in for at least 20 seconds.^{xii}

Hand sanitizers are classified as an non-prescription, over-the-counter drug, which is controlled by the FDA. This means that any label claims made must be backed up with safety and efficacy information, which the FDA must review and approve prior to marketing the product. This FDA labeling requirement may be a major compliance challenge for many non-healthcare

companies to properly manage and adhere to over the long run.

4. The FDA's Temporary Policy for Manufacturing Alcohol Based Hand Sanitizers

In March of this year, the FDA provided a temporary ruling, allowing entities not currently regulated by the agency to produce alcohol-based hand sanitizers for consumers and for healthcare personnel, for the duration of the public health emergency. Providing they remain within the guidelines of the FDA's policy, with no deviation.

According to the FDA's temporary ruling, all components of the formulation are required to meet a specific grade and purity for the finished product to meet efficacy specifications:

<u>Component</u>	<u>Specification</u>
Ethyl Alcohol by Volume	Not less than 94.9% Ethanol Meets USP or FCC Grade Requirements Must be screened for any potentially harmful impurities Must be denatured
Isopropyl Alcohol	USP Grade
Glycerin (glycerol)	USP or FCC Grade
Hydrogen Peroxide	USP or Technical Grade
Water	Purified USP Grade

However, in addition to efficacy, safety concerns were also considered. **To prevent human consumption** of the finished product, the ethyl alcohol used must be denatured. In addition - label warnings, reminding the user to keep the product out of the reach of children must be present to prevent poisoning by ingestion. Unfortunately, too many reports have been reported where children and young adults consuming the "undenatured" hand sanitizer have died.

To meet the demand, over 1,500 manufacturers registered with the FDA to produce the alcohol-based hand sanitizers for BOTH retail and hospital use, while other companies started

producing the raw materials required to make the finished products meet the defined specifications. Businesses such as gasoline producers, distilleries and perfume makers ramped up their ethyl alcohol production to meet the new demands set by the hand sanitizer manufacturers. Prior to the COVID-19 outbreak, the global market for hand sanitizers were estimated to be \$1.35 billion. However, with the demand increasing due to the virus, it is predicted to reach \$1.87 billion this year.

^{xiii} However, some of this product is being manufactured by entities who have never worked under the stringent guidelines of the FDA, and as a result, the FDA has begun to cite, fine, and force some manufacturers out of the market in an effort to remain diligent.

5. FDA Vigilance

As of the most recent FDA news release, there have been 42 letters sent to companies making products found to have false information that the government agency said was being used to capitalize on the COVID-19 outbreak. This included claims that their product could treat and even cure COVID-19. ^{xiv} There is even a report that some Chinese medical suppliers are using bogus registration data (false addresses and non-working phone numbers) in order to sell their products into the U.S. ^{xv} With the FDA's temporary policy for manufacturing alcohol based hand sanitizers, as well as the registration process being so straightforward, you have to wonder why this type of deceit is even necessary. Is this deception reflected in their products?

In addition to this, on April 15, 2020 the FDA issued limits on certain chemicals permitted to be used in alcohol-based hand sanitizers. The crackdown was meant to protect consumers from potentially dangerous impurities in the finished product. In one case, the FDA said they found significant levels of the carcinogen acetaldehyde in ethyl alcohol supplied to a company for use in the hand sanitizer. ^{xvi} Recently there have been instances of some companies being shut down by FDA, due to using prohibited substances like methyl alcohol as a

replacement for ethyl alcohol in large amounts of hand sanitizers, which is extremely dangerous and toxic to humans.

So far, we have only discussed alcohol-based hand sanitizers. However, there are also alcohol-free products on the market as well – some containing chemicals such as quaternary compounds (usually benzalkonium chloride). However, until more data is provided to the FDA, ethyl alcohol, isopropyl alcohol, and benzalkonium chloride are the only active ingredients approved for use in consumer hand sanitizers. ^{xvii}

Alcohol-based hand sanitizers are a necessity in the absence of soap and water. As with any alcohol hand sanitizers, be sure to follow the directions for use. Due to the alcohol content, the product is flammable - so do not use it near an open flame. However, be assured that the reports of the alcohol hand sanitizer being dangerous to store in small vessels in automobiles is false and since has since been corrected.

6. Hydromer's First Responder® Alcohol Hand Sanitizer

One example of a properly formulated and controlled hand sanitizer is being manufactured by Hydromer Inc.; Hydromer is based in North Carolina and is FDA registered (over forty years) and ISO certified (over seventeen years) as a medical manufacturer. Hydromer's First Responder® Alcohol Hand Sanitizer is manufactured, following the FDA's temporary hand sanitizer production guidelines to fight against COVID-19 - which stipulates a minimum of 80% ethanol content, along with a defined list of permissible additional additives.

The FDA has clearly stated that this formulation should not be altered in any way (no thickening agents /no diluting agents /no smell enhancing agents etc.) that may reduce its actual efficacy against fighting COVID-19.

Thus, proper hand sanitizer formulations tend to have a more noticeable alcohol smell and are more of a thin liquid by nature. This is due to the

FDA's strict formulation and intent for the hand sanitizer to easily spread over the surface area of your hands, fingers, and lower wrist. Hydromer's sanitizer is made under strict GMP compliance. Every batch of product produced is inspected by trained Quality Assurance personnel in order to guarantee that it meets the stringent requirements of the FDA's temporary ruling.

Hydromer uses quality packaging, approved for the intended use of storing hand sanitizer and is purchased from trusted and reliable suppliers. This ensures that there is no cross contamination or migration of unwanted ingredients into the hand sanitizer that may create adverse effects to the end user. Like others, Hydromer also has a pledge program that donates free product to many local first responders, daycare centers and civic centers. See <https://www.hydromer.com/our-pledge/>

7. Conclusion

As a result, consumers must be cognizant of the fact that there are products on the market that do not meet the established requirements, may contain dangerous impurities, or make labeling claims that are untrue. If you are ever unsure, **request a copy of the manufacturers Safety Data Sheet (SDS)**. This document contains various bits of information about the product and is readily available upon request.

So, when purchasing any brand of hand sanitizer, note that all brands are not the same. Pay attention to the label and ask yourself: does it contain a minimum of 80% alcohol as described by the FDA's temporary ruling? Are there unbelievable claims being made (like cures COVID-19)? Are the instructions clear and large enough to read? Is it made in the USA? Is it readily available and in quantities to meet your needs? What is the cost? These are all things to keep at the forefront of your mind when shopping for a hand sanitizer.

In conclusion, rest assured that all global governmental agencies are working together to overcome the COVID-19 virus by eventually developing a vaccination. But until then, it is our responsibility to follow the recommendations

already established. However, the most important thing to remember is that the virus is real - and until a vaccine is developed, we can help reduce the spread of the virus by following some basic precautionary measures:

- Washing hands for the prescribed 20 seconds and often with soap and warm water **(or use an alcohol-based hand sanitizer if soap and water is not available)** even after immediately removing gloves.
- Avoiding close contact with people who are sick
- Practicing social distancing by staying six feet away from anyone
- Avoid touching you face, especially with unwashed hands or gloves
- Wear a cloth face covering (or mask) when you need to go out in public or as required by law ordinances
- Covering your mouth and nose with a tissue or your sleeve when coughing and sneezing, not your hands

- Clean and disinfect frequently touched surfaces on a regular basis
- **Healthcare Institutions and business owners should take extra care to lock in only highly qualified, FDA grade suppliers of hand sanitizers for six to twelve months, due to market instability and the seemingly lasting effects of COVID-19 around the globe.**

Meanwhile, stay safe!

8. About the Authors & Contributors

- **John Konar, Vice President Quality & Regulatory Initiatives at Hydromer, Inc.**, is a well-rounded professional with over thirty years of expertise in the regulatory, technology and quality assurance fields, specializing in human and animal medical and drug products.
- **Peter M. von Dyck, Chief Executive Officer at Hydromer, Inc.**, is a medical technology entrepreneur with over twenty-five years of medical device and infection control experience. He has invented, patented, developed, and commercialized several life-saving specialty medical devices for the global market. Peter is an industry recognized leader and was named Entrepreneur of the Year® in the area of healthcare and life sciences by Ernst and Young, awarded the Business Diversification Award for Entrepreneurship in 2003 and in 2004 and was named by the Medical Device and Diagnostic Industry Magazine as one of the 100 Most Notable People.
- **Shan Wickramanayake, Ph.D., Director of Manufacturing at Hydromer, Inc.**, is an R&D manufacturing process development expert with over ten years of industrial experience in composite polymer compounding/formulating and processing. His academic background includes a Ph.D. and M.S. in Engineering from the University of Michigan and was a Chemical Engineering postdoctoral research fellow at Georgia Institute of Technology.
- **Michelle Robbins is a Healthcare Supply Chain expert and supply chain professional** with extensive hospital supply chain management, consulting, technology, and sales experience. Practiced in product launch and management and achieving optimized market penetration.
- **Ravi Rangarajan is Vice President of Business Development at Hydromer, Inc.**, and is a senior chemical manufacturing industry professional of chemical technologies. His academic background includes an MBA in Finance from the University of Memphis, an M.S. in Chemical Engineering from Oregon State University, and a B.S. in Technology from Anna University.



9. References

- i World Health Organization (April 29, 2020) Coronavirus Disease (COVID-19) advice for the public. Available online at <https://www.who.int/emergencies/disease/novel-coronavirus-2019/advice-for-public>
- ii Cleveland Clinic (April 7, 2020) Unsure About Actually Wearing a Face Mask? Here's How (and Why) to Do it. Available online at: <https://health.clevelandclinic.org/unsure-about-actually-wearing-a-face-mask-heres-how-and-why-to-do-it/#:~:text=The%20following%20people%20should%20NOT,face%20mask%20without%20help.>
- iii New York Times (May 28, 2020) What's the Risk of Catching Coronavirus From a Surface? Available online: <https://www.nytimes.com/2020/05/28/well/live/whats-the-risk-of-catching-coronavirus-from-a-surface.html>
- iv Jennifer Prah Ruger, Derek Yach (April 9, 2014) The Global Role of the World Health Organization. Available online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3981564/>
- v World Health Organization (June 1, 2020). Events as they happen. Available online: <https://www.who.int/emergencies/disease/novel-coronavirus-2019/events-as-they-happen>
- vi Centers for Disease Control and Prevention (CDC) (September 25, 2018) Center for Disease Control and Prevention. Available online: www.cdc.gov/maso/pdf/cdcmiss
- vii Centers for Disease Control and Prevention (May 31, 2020). Coronavirus Disease 2019, CDC in Action. Available online: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cdc-in-action.html>
- viii US Food and Drug Administration (March 28, 2018) What We Do. Available online: <https://www.fda.gov/about-fda/what-we-do>
- ix FDA U.S. Food & Drug Administration (May 21, 2020). FDA COVID-19 Response At-A-Glance Summary. Available online: www.fda.gov
- x Investopedia.com. Understanding the Environmental Protection Agency. Available online: <https://www.investopedia.com/terms/e/environmental-protection-agency.asp>
- xi EPA.gov (June 1, 2020). Disinfectant Use and Coronavirus (COVID-19). Available online: <https://www.epa.gov/coronavirus/disinfectant-use-and-covonavirus-covid-19>
- xii The Conversation. Manal Mohammed (March 13, 2020) Coronavirus: not all hand sanitizers work against it- here's what you should use. Available online: <https://theconversation.com/coronavirus-not-all-hand-sanatizers-work-against-it-heres-what-you-should-use-133277>
- xiii Fortune Business Insights (May 19, 2020). Impact of COVID-19 on Hand Sanitizer Market to Reach USD 1.87 Billion by 2020. Available online: <https://www.globenewswire.com/news-release/2020/05/11/2030895/0/en/Impact-of-COVID-19-on-Hand-Sanitizer-Market-to-Rreach-USD-1-87-Billion-by-2020>

^{xiv}Lyle Muller, Iowa Watch (May 11, 2020) We didn't do it, says first US hand sanitizer maker accused of false claims to treat, cure COVID-19. Available online: <https://www.desmoinesregister.com/story/news/2020/05/11/we-didn't-do-it-says-first-us-hand-sanitizer-maker-accused-false-claims-treat-cure-covid-19>

^{xv}Austen Hufford, Mark Maremont, Liz Lin, The Wall Street Journal (June 12, 2020). Over 1,300 Chinese Medical Suppliers to U.S. – Including Mask Providers – Use Bogus Registration Data.

^{xvi}Stephany Kelly, US Legal News (April 30, 2020) U.S. calls ingredients in some ethanol-based hand sanitizers unsafe. Available online: <https://www.reuters.com/article/us-health-coronavirus-ethanol-sanitizer/us-cracks-down-on-ethanol-based-hand-sanitizer-hitting-supply-as-demand-soars-idUSKBN22COLG>

^{xvii}FDA Federal Register Document No. 2019-06791 (Effective April 13, 2020) Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use



About Hydromer® First Responder® Sanitizer



40+ years of trusted experience in innovative medical products.



Kills harmful bacteria and viruses that cause illness

FDA registered formulation 80% v/v

Faster and more effective at killing germs, than gels

About Hydromer's® First Responder® Antiseptic Hand Rub

We offer FDA registered "alcohol-based" sanitizers, which are widely used across the entire spectrum of healthcare, safety, first response, and many other critical functions. Hydromer's First Responder® alcohol-based hand sanitizers for personal and public use can be distributed to a variety of industries, including commercial establishments, hospitals, retail, manufacturing facilities, and more. Our alcohol-based formulations meet the **80% v/v Denatured Ethyl Alcohol** minimums required by the FDA.

Benefits include:

- FDA registered formulation
- Kills viruses and bacteria that may cause illnesses
- Manufactured with our long standing medical industry expertise in our ISO certified facility
- Quick and effective
- Can be labeled with Hydromer® First Responder™ brand
- Can be privately labeled



Commercially available in 55 gallon drums, 1 gallon and 1/2 gallon containers, w/pump dispenser, and other packaging available by request.

hydromer.com • (888) 90-HYDRO • info@hydromer.com