



HAND SANITIZER

70% (v/v) ISOPROPYL ALCOHOL
70% (v/v) ETHYL ALCOHOL
liquid & gel formulations

AS OF JUNE 29, 2020

FREQUENTLY ASKED QUESTIONS

General FAQs:

Q: Is hand sanitizer effective against COVID-19?

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 bathroom; 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% alcohol.**

The FDA OTC Monograph <https://federalregister.gov/d/2019-06791> Table 3 - Classification of OTC Consumer Antiseptic Rub Active Ingredients provides the guidance below:

Active ingredient	1994 TFM proposal ¹	2016 Proposed rule
Alcohol 60 to 95 percent	I ²	III SE ³ .
Isopropyl alcohol 70 to 91.3 percent	III E	III SE.
Benzalkonium chloride	III SE	III SE.

OTC Monograph Part 333A

Shotwell hand sanitizers contain 70% alcohol by volume at a minimum meeting the CDC recommendation. Our isopropyl alcohol hand sanitizers contain 70% isopropyl alcohol as required by the monograph. Our ethyl alcohol, which in the regulations is defined as “alcohol,” formulations contain 70% ethyl alcohol (alcohol) which also meets the requirements of the FDA monograph and CDC.

All of our products meet the CDC recommendations and the FDA OTC monograph requirements.

Q. Does the FDA regulate all hand sanitizers? Do hand sanitizers come with product information on their labeling?

A. Hand sanitizers are over-the-counter (OTC) drugs regulated by FDA.

Hand sanitizers that meet FDA’s OTC drug review conditions or that are manufactured under the conditions in FDA’s temporary policy, will include a “Drug Facts” label similar to the ones found at the end of the guidance: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). Consumers should assure they are following the warnings and precautions described on this label, particularly regarding use in children. The Drug Facts label also will describe the ingredients in the product. [Labels and Drug Facts](#) for all Shotwell Hydrogenics hand sanitizer formulations can be found on DailyMed, the official provider of FDA label information.

Q. Do hand sanitizers have an expiration date? Are they still effective after the expiration date?

A. OTC drug products generally must list an expiration date unless they have data showing that they are stable for more than 3 years. FDA does not have information on the stability or effectiveness of drug products past their expiration date (See 21 CFR 211.137). Hand sanitizer produced under the temporary policies for hand sanitizer production and compounding may not have an expiration date listed because they are expected to be used during this public health emergency.

Q. Are you FDA registered?

A. We registered our labels with the FDA and received approved NDC Label codes for Shotwell. Our FDA Establishment Number is **3016819525**.



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HAND SANITIZER FORMULATIONS

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General FAQs Continued:

Q. What are denaturants and why are they added to hand sanitizer?

A. Denaturants are added to alcohol to make it less appealing to ingest. Denatured alcohol is used in hand sanitizer to deter children from unintentional ingestion – the denatured alcohol makes the hand sanitizer taste bad so children will not want to continue once they have had a taste. There are a number of adverse events every year resulting from intentional or unintentional ingestion of hand sanitizer, which is a particular concern for young children.

Q. How can I find hand sanitizers listed with the FDA, or verify that a company has listed its product with the FDA?

A. FDA publishes product listing information provided by the companies that make the drug on the National Drug Code (NDC) Directory. This listing does not mean the drug is approved by FDA. Anyone can look up a drug product and download the information by searching on its NDC, company name or drug name. For a list of all hand sanitizers, choose the proprietary name search, and search for the term “hand sanitizer.”

https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

In summary, we are following the rules and regulations established by the CDC and the FDA under the OTC Monograph part 333A and our products contain the minimum required active concentrations.

Financial FAQs:

Q. What forms of payment can you send other than wire transfer, ACH, etc.?

A. Check and Credit Card payments can be arranged if the customer incurs the associated processing fees.

Packaging FAQs:

Q. What packaging does Shotwell's hand sanitizer come in?

A. Shotwell Hydrogenics utilizes 330-gallon Mauser totes that measure 48" Length X 40" Width X 53" Height. The Mauser 330-gallon tote is on the preferred list for tote recycling companies, and the cost of the tote is included in wholesale pricing.

Q. What is the weight of a 330-gallon capacity tote?

A. An empty tote weighs 155 pounds. When filled with Shotwell Hydrogenics hand sanitizer, the weight of the tote ranges from 2,578 to 2,586 pounds.

Q. How many totes can fit on a truck?

A. A box van can carry up to 17 totes. Consult the weight of the carrier's equipment to determine how much weight to carry. Typically, a “full truckload” consists of 14 totes, each holding 330 gallons, for a total of 4,620 gallons.

Q. What size connectors are on the tote?

A. A 6" threaded with 2" bung connector is on the top and a 2" valve with a male quick disconnect coupler with cap is on the bottom.

Q. How can I pump the hand sanitizer out of the top?

A. Consult a supply warehouse (like Uline or others) for a 330-gallon manual or powered IBC pump.

Q. How can I drain the hand sanitizer out of the bottom?

A. Using the bottom 2" valve

Q. Do you sell in drums?

A. No, we do not sell drums at this time.

Q. Do you bottle Hand Sanitizer?

A. Shotwell does not currently bottle hand sanitizer, but we have relationships with bottlers we can refer you to.

Q. What sample sizes do you have?

A. Samples of 8-fluid ounces or 1-gallon jugs are available.

Q. How quickly can you get the samples to me?

A. Samples normally ship within 48 hours and are sent via either overnight or regular mail based on urgency and size of sample.



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Logistics / Supply Chain FAQs:

Q. Can I pickup the totes?

A. Our products are Ex Works Shotwell Hydrogenics from Midland, Texas. Customers can schedule a dock time and send a certified hazmat endorsed carrier to pick up hand sanitizer orders at the scheduled time.

Q. Can you ship in ISO Tanks?

A. ISO Tanks must be deemed certified clean and will incur additional charges. We do not currently offer this option out of our Midland facility. If an ISO tank is required, we would need to work with you to source it from another location.

Q. Can you ship internationally?

A. Yes, International UN-Rated totes are required and will incur additional charges. The customer will need to have the totes shipped to their preferred freight forwarder to have the totes properly loaded into IBC cargo containers for ocean freight.

Q. What lead time do you have to get product in?

A. Plant throughput is based on customer demand, in addition to current on-hand inventory to fill immediate needs. With our current product mix, the facility has capacity to produce an estimated 1MM+ gallons per month. Our average batch size is around 6,500 gallons.

Q. How do you ensure you have a quality product?

A. Our state-of-the-art chemical manufacturing facility, located in Midland, Texas, is ISO9001:2015 certified, NSF (National Sanitation Foundation) certified, and FDA registered. We conduct multiple quality checks using approved test methods. Batches must pass quality control testing prior to being allocated as finished good inventory. Currently we perform FTIR analysis and each batch has to meet at >95% match to the alcohol in our product library. We also perform specific gravity testing on inbound raw materials to ensure specification match as well as quality. We also look at color, appearance, smell, and pH. Customers receive a Certificate of Analysis with every shipment ensuring quality product is delivered.

Product FAQs:

Q. Does your Hand Sanitizer have a scent added?

A. SHSNH6-4601 is an ethyl-alcohol gel product that is infused with aloe, Vitamin E, and eucalyptus spearmint scent.

Q. Does your Hand Sanitizer have aloe?

A. Most Shotwell formulations contain glycerin to provide a smooth-touch finish. SHSNH6-4601 does contain aloe in addition to glycerin.

Q. What is the difference between Isopropyl (IPA) and Ethyl alcohol?

A. Both isopropyl and ethyl alcohol are both approved antiseptic ingredients per the CDC and FDA. Ethyl alcohol is most commonly derived from corn and isopropyl alcohol is derived from propene, which can come from fossil fuels like coal, petroleum or natural gas.

Q. What is the difference between the Gel & Non-Gel hand sanitizer formulas?

A. The addition of a gelling agent and the viscosity of the finished product. The Non-Gel (liquid) can be used in a spray bottle and is sold as hand sanitizer.

Q. Why does the product not have hydrogen peroxide in it?

A. Hydrogen peroxide is not required because Shotwell Hydrogenics is utilizing DI water.

Q. What is the Viscosity Measurement (Centipoise) of your products?

A. Viscosity is measured with a C Golden Wall NDJ-5S - Digital rotational viscosity meter that has a range of 10 centipoise to 100,000 centipoise with an accuracy of +3% or -3%

- SHSNH6-3000: 1-400 centipoise
- SHSNH6-3500: 400-2000 centipoise
- SHSNH6-4000: 1-400 centipoise
- SHSNH6-4500: 3600-6600 centipoise

Q. Where can I get a SDS sheet?

Technical Data Sheets/Safety Data Sheets are available upon requests through:
qualitysupportshotwell@shotwellhydrogenics.com



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