



Guidance for DSP Production of Hand Sanitizer and Sanitary Spray

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Craft distilleries around the country are stepping in to help alleviate our national shortage of sanitizing solutions. Two products in particular are in high demand: 60% ABV hand sanitizer and 70% ABV sanitary spray for surface disinfection. ACSA is working closely with TTB and FDA to ensure DSPs have the appropriate regulatory guidance and other information needed to ensure proper production and distribution guidelines are followed, as well as standards for safety and efficacy.

TTB

On March 18, 2020 at 6:00p.m. the TTB released this special edition guidance for DSPs and Industrial Alcohol User permittees on producing ethanol-based hand sanitizers.

Due to the Coronavirus 2019 (COVID-19) pandemic, the Acting Administrator of the Alcohol and Tobacco Tax and Trade Bureau (TTB) has found that it is necessary or desirable to waive provisions of internal revenue law with regard to distilled spirits, and therefore is providing certain exemptions and authorizations to distilled spirits permittees who wish to produce ethanol-based hand sanitizers to address the demand for such products during this emergency. Any existing DSP therefore can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer, as described below, without having to obtain authorization first. These measures are generally authorized under authorities that apply in disaster situations, and as a result, are initially approved through June 30, 2020, with the possibility for

extension as necessary.

Permit guidance for alcohol fuel plants (AFPs) and beverage distilled spirits

plants: TTB is exempting AFPs and beverage DSPs from the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the manufacture of hand sanitizer to other TTB permittees who are authorized to receive such distilled spirits. TTB is authorizing this exemption under the authority of 26 U.S.C. 5562. AFPs and beverage DSPs must continue to keep records of their operations, including any undertaken as authorized under this exemption.

Tax guidance for the manufacture of hand sanitizer: Hand sanitizer products are not subject to Federal excise tax if made with denatured ethanol. However, if made with undenatured ethanol, Federal excise tax applies. For information regarding denaturants, please contact TTB's [Scientific Services Division](#).

Formula guidance for the manufacture of hand sanitizer: TTB is authorizing the manufacture of hand sanitizer products consistent with [World Health Organization \(WHO\) guidance](#). All TTB-permitted DSPs (including AFPs and beverage DSPs) may manufacture hand sanitizer products that are comprised of denatured or undenatured ethanol, glycerol (not less than 1.45% of the finished hand sanitizer product on a volume basis), and hydrogen peroxide (not less than 0.125% of the finished hand sanitizer product on a volume basis), without first obtaining formula approval from TTB.

Guidance for industrial alcohol users: Industrial alcohol user permittees may also use denatured ethanol to manufacture hand sanitizer consistent with [World Health Organization \(WHO\) guidance](#) without first obtaining formula approval. During the period of this guidance, TTB is also exempting industrial alcohol user permittees from the requirement to request approval from TTB to increase the quantities of denatured ethanol that they may procure (see 27 CFR 20.42(a)(3) and 20.56). TTB is authorizing

these exemptions under its authority in 27 CFR 20.22(b) to approve emergency variations from regulatory requirements.

This information is available on our [Public Guidance page](#).

FDA

FDA Guidance for Industry has been released. A summary follows, and the complete document is available here: [Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#)

Per the guidance, the FDA does not intend to take action against firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand runs for the duration of the public health emergency provided the following are adhered to:

- Hand sanitizer is manufactured using United States Pharmacopoeia (USP) grade ingredients in the preparation of the product consistent with WHO recommendations:
 - Alcohol (ethanol) – 80% volume/volume in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations or Isopropyl Alcohol (75% v/v) in an aqueous solution
 - Glycerol (1.45% v/v)
 - Hydrogen peroxide (.125 % v/v)
 - Sterile distilled water or boiled water
 - **Firm doesn't add other active or inactive ingredients**
- Make sure that you are keeping a record to document key steps and controls to assure each batch matches the formula developed for the product
- Labeled consistent with Appendix A in the guidance doc
- You will need to register in the FDA Drug Registration and Listing System: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls>
 - Any SPL authoring software may be used to create registration and listing SPL files. The FDA website offer two SPL authoring tools -- [CDER Direct](#) and [Xforms](#). One of the simplest ways to submit SPLs is through the use of CDER Direct, a free tool from the FDA. You can create an account at <https://direct.fda.gov>. After you sign up for an account and it is confirmed,

you can begin creating and sending SPL submissions to the FDA.

- FDA recommendation is to follow this sequence of steps:
 1. Obtain a DUNS number if you do not have one
 - <https://www.dnb.com/duns-number/get-a-duns.html>
 2. Create a CDERDirect account
 - <https://direct.fda.gov>
 3. Register the establishment if you are a manufacturer or performing manufacturing processes
 - Electronic Code of Federal Regulations Link -
<https://www.ecfr.gov/cgi-bin/text-idx?SID=db44a05bff49df1b148f18db961172bd&mc=true&node=pt21.4.207&rgn=div5>
 4. Request a labeler code (Labeler codes are only used for generating **National Drug Code** (NDC) numbers for drugs)
 5. List the product

[Here is a link](#) to the instructions page. On the page you will find guidance on how to register your establishment, request a labeler code and list a drug product.

- You will need to have a way to accept adverse event reports for manufactured products.
NOTE: ACSA is putting together guidelines on how to meet the adverse effects reporting requirements and it will be posted as soon as possible.

World Health Organization: Guide to Local Production of Hand Rub Formula

For DSPs producing hand sanitizer, WHO has published a [guide to production including ingredients, formulas and process](#).

Insurance

Please check with your insurance provider about coverage for potential liability. You may or may not need additional coverage. Each provider will likely have a range of requirements and they will vary for every DSP and every specific case. The following **are not requirements** but are some restrictions we have seen:

- Labels are part of the product: Manufacturers cannot state a hand sanitizer kills specific viruses or bacteria without testing verification and FDA approval.
- Child-resistant closures must be used to make the product less accessible to children.
- Product labels and containers should be reviewed by an attorney familiar with FDA requirements and regulations.

- Remove all ignition sources in the immediate area of any ethanol production and distribution such as non-classified standard electrical appliances such as lights, radios, and extension cords.
- Avoid plastic intermediate bulk containers for flammable liquid storage. Metal bulk containers are safer.
- To reduce the risk of static discharge ignition, bonding and grounding measures should be implemented on all flammable liquids stored and distributed in metallic containers.
- Ensure fire protection systems are maintained and active. Keep Class B fire extinguishers readily available.

Again, please check with your insurance provider for detailed guidance.

**THIS DOCUMENT WILL BE CONTINUALLY UPDATED AS NEW INFORMATION
CONTINUES TO ARRIVE**

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