

Production of Hand Sanitizer for Donation or Sale

Please read this fact sheet in its entirety to understand the permitting process for ethanol/alcohol production and transportation, and the manufacture of hand sanitizers for donation or sale.

Who Regulates Hand Sanitizer Products and the Process for Making Them?

Minnesota Pollution Control Agency (MPCA) regulates Ethanol Plants that will produce ethanol/ethyl alcohol to sell to other companies that will make the final sanitizer product.

Minnesota Department of Public Safety (DPS) regulates Distilleries/Micro Distilleries/Liquor Manufacturers that are purchasing (but not transporting) ethanol/ethyl alcohol for sanitizer production.

Minnesota Board of Pharmacy oversees regulation of hand sanitizer as a drug under the U.S. Food and Drug Administration (FDA) regulations.

For Ethanol Plants - Pollution Control Agency Guidance

Operation Authorized before Determination on the Need of an Air Permit Amendment When

- Your permit allows you to ship 190 proof or 200 proof ethanol without added denaturant.
- Your alternative denaturant meets the following conditions:
 - » denaturant is a chemical with equal or lower vapor pressure than gasoline,
 - » denaturant is added in equal or lower mass ratio than the allowed gasoline/ethanol ratio in the air emissions permit, and
 - » denaturant does not have a higher human toxicity than gasoline
- You must notify the MPCA within 7 days of beginning production and shipment that you have started production and shipment of 190 proof or 200 proof ethanol for hand sanitizer or surface sanitizer under the conditions described above.

Determine if You Need an Air Permit Amendment

- It is the responsibility of the facility to determine if the process change will require a permit amendment.
- If a permit amendment or notification is required, within 60 days of beginning production and shipment of 190 proof or 200 proof ethanol for hand sanitizer or surface sanitizer you must submit the required permit application or notification.

- Within 30 days of beginning production and shipment of 190 proof or 200 proof ethanol for hand sanitizer or surface sanitizer you must either determine if a permit amendment is required for the necessary physical or operational modifications at your facility **OR** submit an Applicability Determination request for a site-specific analysis. Either way, please consider the following as you read and analyze your air emission permit conditions:
 - » Most fuel-ethanol Air Quality permits allow for the facility to produce and ship “ethanol” without regard to its final destination or purpose.
 - » The permit will specify hourly and annual limits on ethanol production, as well as the method required to document the amount shipped and/or produced.
 - » Current permits likely include flexibility language that authorizes the Permittee to add additional equipment without a permit amendment.
 - » Additional equipment may be required to produce pharmaceutical-grade ethanol.
 - » Change of denaturant may require a permit amendment or a notification.
 - » Changes that would require a permit amendment include any increase in annual throughput amounts, and addition of equipment not pre-authorized by flexibility language.
- If you determine you are not required to obtain a permit amendment or submit a notification, you must maintain documentation of this determination on-site.

Determine if You Need a Water Permit Modification

It is the responsibility of the facility to determine if the process change will require a permit amendment. Please use your consultants to determine the next step. The MPCA will review the proposal.

- Your first step should be to read your permit. Water permits allow for specific discharges from facilities, and if the discharges remain consistent with what is currently permitted, a modification would not be required. If changes to your discharge or by-product characteristics are anticipated as a result of this process change, please consult your assigned permit contact.
- If the request is time-sensitive, please contact the MPCA at MPCA.COVID19REGFLEX@state.mn.us, or discuss this with the assigned permit engineer after submission of any required permit amendment.

For Distilleries – Minnesota Department of Public Safety Guidance

Micro distillers and liquor manufacturers must apply for and submit the \$20.00 fee for an ethyl alcohol permit. <https://dps.mn.gov/divisions/age/forms-documents/AlcoholDocuments/ethylAlcoholDistilledSpirits.pdf>.

A DPS permit is not required to transport bulk ethyl alcohol to ethyl alcohol permit holders who would make hand sanitizer.

Other Guidance

Minnesota Board of Pharmacy

The Board of pharmacy will exercise enforcement discretion and allow ethanol producers and distilleries to produce and sell hand sanitizers without being licensed as drug manufacturers, as long as they follow relevant guidelines issued by the (FDA).

Food and Drug Administration (FDA)

On March 27, 2020 the FDA updated its three guidance documents on the production of hand sanitizers and alcohol for use in hand sanitizers:

- [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#)
- [Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#)
- [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency “](#)

Send questions about hand sanitizers during the COVID-19 pandemic to COVID-19-Hand-Sanitizers@fda.hhs.gov.

Sales and Use Tax

Minnesota is a member of the Streamlined Sales and Use Tax Agreement (SSUTA). This is a multi-state agreement that creates uniform definitions of products for sales tax purposes. Hand sanitizer qualifies as a “drug” based on the SSUTA definition, and therefore it is exempt from sales and use tax.

Sales tax is not owed on hand sanitizer sales so retailers should code it as exempt in their systems. DOR is aware that not all retailers are charging for this product, but those that are charging will need to make sure they are not collecting sales tax.

Special Taxes

Several taxes administered by the Special Taxes Division were flagged for potential tax liability. These taxes are petroleum, liquor, MinnesotaCare, and environmental taxes. None of these taxes apply to hand sanitizer.

- Hand sanitizer contains ethanol, but it is not gasoline or a special fuel, so the petroleum taxes do not apply.
- Minnesota imposes two types of special taxes on alcoholic beverages: excise tax and gross receipts tax. Hand sanitizer is defined as a drug and not an alcoholic beverage, so these taxes do not apply.
- The MinnesotaCare tax applies to drugs that require a prescription. Hand sanitizer does not require a prescription, so the MinnesotaCare tax does not apply.
- The environmental taxes collected apply to specific products or waste management. Hand sanitizer does not qualify under either of these categories.

Resources Offering

The [Minnesota Department of Homeland Security’s State Emergency Operations Center \(SEOC\)](#) is coordinating offers of resources, supplies or personnel for the COVID-19 response for the State of Minnesota. You can find information under the “[Taking Action: How you can help](#)” heading on the website. They have an [on-line form](#) you can complete or you can email them at hsem.ppp@state.mn.us. Your submission will be reviewed by personnel in the State Emergency Operations Center. Businesses will be contacted if there is a need for the identified resources.