



# HAND SANITIZER RESOURCE GUIDE FOR OREGON

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# HAND SANITIZER RESOURCE GUIDE FOR OREGON

## INTRODUCTION

The Oregon Liquor Control Commission, Oregon Health Authority, Oregon Board of Pharmacy, Business Oregon, and Oregon Department of Agriculture, with the help of Moda Health, have set up a coordinated effort to address the need for making hand sanitizer in Oregon.

Businesses in Oregon that already have an OLCC-issued distillery license and a permit from the Federal Alcohol and Tobacco Tax and Trade Bureau (TTB) can work together to coordinate sourcing of raw materials, production of ethanol, and procuring containers for finished hand sanitizer product.

## SITUATIONAL-BASED GUIDANCE

### ALREADY HAVE OLCC LICENSE AND TTB PERMIT

*I already have an OLCC-issued distillery license and a permit from the federal Alcohol and Tobacco Tax and Trade Bureau (TTB). May I make hand sanitizer in Oregon?*

Businesses that already have an OLCC-issued distillery license and a permit from the TTB have met the standards of all requiring agencies are allowed to make hand sanitizer.

#### *Guidance regarding OLCC:*

- You may make the ethanol used to make the hand sanitizer.
- You may purchase or acquire bulk ethanol from other Oregon distillery licensees, and they may sell or provide bulk ethanol to you, in containers having a capacity greater than one U.S. gallon.
- You may import bulk ethanol into Oregon.
- Oregon manufacturers and wholesalers of beer, wine, and cider may sell or donate beer, wine, and cider to you, and then you may distill that product to the necessary specifications.
  - Oregon manufacturers and wholesalers of beer, wine, and cider must still follow OLCC privilege tax reporting and payment requirements.
  - Email for general inquiries about privilege taxes: [olcc.privilegetax@oregon.gov](mailto:olcc.privilegetax@oregon.gov)
- You may not import into Oregon the beer, wine, or cider under the privilege of your OLCC-issued distillery license. However, if you have another type of OLCC-issued alcohol license that allows the import of beer, wine, or cider, you may import the type of alcoholic beverage that the license allows.
- There are no OLCC tax issues and you don't have to file any reports with the OLCC.
- You don't need any other OLCC license or approval to make a hand sanitizer.
- You must follow the requirements of other agencies. Failure to follow those requirements could lead to serious OLCC-related regulatory issues. There are also BOP regulatory implications that include civil penalties and criminal penalties.

### ***Guidance regarding other agency requirements.***

See later in this document for information on other agencies.

- You must be registered with the U.S. Department of Health and Human Services Food and Drug Administration (FDA).
- You must obtain a license from the Oregon Board of Pharmacy (BOP). Note that the BOP licensure requires a site visit/inspection, and that may take longer than same day.
- Moda Health is helping with the coordination effort in Oregon. You are welcome to contact Moda Health at: [handsanitizer@modahelath.com](mailto:handsanitizer@modahelath.com)

### **DO NOT HAVE OLCC LICENSE**

#### ***I do not already have an OLCC-issued distillery license. May I make hand sanitizer in Oregon?***

The best path would be to obtain both an OLCC-issued distillery license and the required TTB permit.

- If you tell the TTB that you want the permit because it is related to making hand sanitizer, it may be the TTB would be able to expedite your application.
- At this time, to obtain a distillery license from the OLCC will take about three to four months.
  - Link to distillery license information on the OLCC website: [https://www.oregon.gov/olcc/LIC/pages/distillery\\_license.aspx](https://www.oregon.gov/olcc/LIC/pages/distillery_license.aspx)
  - To submit an application for a distillery license: [OLCC.LiquorLicenseApplication@oregon.gov](mailto:OLCC.LiquorLicenseApplication@oregon.gov)

Here is what we know about making hand sanitizer in Oregon without an OLCC-issued distillery license.

#### ***Denatured Alcohol***

- “Denatured alcohol” means alcohol with additives for the purpose of making it unfit for human consumption.” Denatured alcohol is not considered an alcoholic beverage in Oregon.
- Isopropyl alcohol is denatured alcohol.
- If you obtain and use only already denatured alcohol, the OLCC has no requirements.
- You may be able to make hand sanitizer with already denatured ethanol; however, you will still need to meet the requirements of other agencies. Here are the agencies we know about at this time:
  - U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB).
  - U.S. Department of Health and Human Services Food and Drug Administration (FDA).
  - Oregon Board of Pharmacy.

#### ***Non-denatured Ethanol***

- “Non-denatured ethanol” means “alcoholic beverage” and “alcoholic liquor” as defined in Oregon Revised Statute (ORS) 471.001(1).
- Note that if you already hold an OLCC-issued license that allows for the manufacture of malt beverages (beer), wine, or cider, you will need to check that the TTB allows you to have non-denatured ethanol in your TTB-bonded area.

- An OLCC-issued Industrial Alcohol Authority (IAA) will allow you to acquire, but not make, ethanol. If you obtain an IAA, you must not do anything with the non-denatured alcohol that requires an OLCC license or TTB permit. Examples of prohibited activities include manufacturing, distilling, rectifying, and blending the non-denatured alcohol.
- An individual with an IAA may:
  - Import into Oregon and store 190 to 200 proof non-denatured alcohol without an OLCC-issued distillery license.
  - Acquire 80 to 200 proof non-denatured alcohol that is already in Oregon, but must acquire it from the holder of an IAA. Note that to obtain non-denatured alcohol from a business with an OLCC-issued distillery license, both you and the Oregon distillery licensee must have an OLCC-issued IAA.
  - Convert non-denatured alcohol into denatured alcohol.
  - Sell or transfer 80 to 200 proof non-denatured alcohol to the holder of an IAA.
  - Use 80 to 200 proof non-denatured alcohol for scientific, pharmaceutical, manufacturing, mechanical, and industrial purposes. This may allow you to make hand sanitizer, provided you meet the requirements of all other agencies.
- For questions about an IAA or to obtain an application: [OLCC.licenseservices@oregon.gov](mailto:OLCC.licenseservices@oregon.gov)
- You may be able to make hand sanitizer with an IAA; however, you will still need to meet the requirements of other agencies. Here are the agencies we know about at this time:
  - U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB).
  - U.S. Department of Health and Human Services Food and Drug Administration (FDA).
  - Oregon Board of Pharmacy.

## OTHER AGENCIES AND THEIR CONTACT INFORMATION

The OLCC cannot answer questions about the allowances and requirements of other agencies or organizations. You must contact each agency or organization. As of the date of this document, here are other agencies and organizations OLCC knows about that have a part in the making or regulation of hand sanitizer:

### STATE OF OREGON: BOARD OF PHARMACY

- Manufacturer Application: [Manufacturer application](#)
  - At this time, there is no fee and generally can process on the day received.
- General questions and to email the completed application: [pharmacy.licensing@oregon.gov](mailto:pharmacy.licensing@oregon.gov)

### STATE OF OREGON: BUSINESS OREGON

- Business Oregon may be able to assist distilleries in expanding their capital to increase the production of raw materials utilized for hand sanitizer.
- Visit <https://www.oregon4biz.com> for more information.
- Questions can be emailed to: [stephen.richardson@oregon.gov](mailto:stephen.richardson@oregon.gov)

### FEDERAL: THE U.S. DEPARTMENT OF TREASURY ALCOHOL AND TOBACCO TAX AND TRADE BUREAU (TTB)

The TTB has a COVID-19 page, which includes the TTB's March 26, 2020 newsletter giving guidance on the production of hand sanitizer. This page will have the most recent updates. Here is a link to that page.

<https://www.ttb.gov/coronavirus>

### FEDERAL: THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION (FDA)

Hand sanitizers are over-the-counter (OTC) drugs regulated by the FDA. The FDA has published information. The FDA guidance should be referenced and followed by all parties manufacturing hand sanitizer. Here are some essential links:

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost>

<https://www.fda.gov/media/136118/download>

<https://www.fda.gov/media/136289/download>

<https://www.fda.gov/about-fda/contact-fda>

### WORLD HEALTH ORGANIZATION (WHO)

The World Health Organization (WHO) has published the following guide to production of hand sanitizer (hand rub):

[https://www.who.int/qpsc/5may/Guide\\_to\\_Local\\_Production.pdf](https://www.who.int/qpsc/5may/Guide_to_Local_Production.pdf)