

GUIDANCE DOCUMENT

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This guidance document may change with updated information or added examples. The Nebraska Liquor Control Commission recommends you check this document for the most up to date information regarding this guidance.

HAND SANITIZER GUIDELINES:

Due to the Coronavirus 2019 (COVID-19) pandemic, the Nebraska Liquor Control Commission is issuing guidance to all DSP licensees in the State of Nebraska regarding the production of hand sanitizer. On March 18, 2020, the Alcohol Tax and Trade Bureau issued a public guidance waving the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the manufacture offhand sanitizer to other TTB permittees who are authorized to receive such distilled spirits. Please see [TTB G 2020-1](#) for the full TTB guidance on this subject. On March 27, 2020, the TTB issued an amendment to TTB G 2020-1, in the form of [TTB G 2020-1A](#). This document has been updated on that date to reflect that update.

On March 24, 2020, the [Federal Food and Drug Administration issued a guidance for creating alcohol-based hand sanitizer products during the public health emergency \(COVID-19\)](#). The Nebraska Liquor Control Commission is recommending that all DSPs in the State of Nebraska follow this guidance when producing alcohol for alcohol-based hand sanitizer products.

Only those entities that hold a DSP issued by the Alcohol Tax and Trade Bureau are permitted to produce hand sanitizer for sale in the State of Nebraska.

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For formulation and tax guidance for the manufacture of hand sanitizer the NLCC will be following the guidance laid out by the TTB in TTB G 2020-1A. For Nebraska specific guidelines see the following:

Tax guidance for the manufacture of hand sanitizer:

Hand sanitizer products are not subject to Federal or State excise tax if made with denatured ethanol. However, if made with undenatured ethanol, Federal and State excise tax applies. For any questions regarding denaturants, please contact the FDA.

As updated in TTB G 2020-1A nonbeverage products made with ethanol, including hand sanitizer, are not subject to federal excise tax. The NLCC will not be collecting excise tax on any ethanol produced by DSPs in the state that is used to produce hand sanitizer. NLCC requires that documentation of production of hand sanitizer be kept for audit purposes. Please be aware that the FDA specifies the use of denatured alcohol in their formulations.

Documentation of production of denatured alcohol is required to be kept per Chapter 7 of the Rules and Regulations.

Formula guidance for the manufacture of hand sanitizer:

TTB is authorizing the manufacture of hand sanitizer products by DSPs using a formulation in the FDA guidance cited above without first obtaining formula approval from TTB. Please be aware that the FDA specifies the use of denatured alcohol in their formulations.

Guidance for industrial/nonbeverage alcohol users:

Industrial alcohol user permittees may also use denatured ethanol to manufacture hand sanitizer consistent with FDA guidance stated above without first obtaining formula approval. During the period of this guidance, the 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.

FDA Temporary Policy for manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products:

The FDA provided a framework by which an alcohol (ethanol) producer to produce alcohol-based hand sanitizer products during the public health emergency (COVID-19). The NLCC recommends following the guidelines laid out by the FDA as the FDA is the regulatory agency for over-the-counter (OTC) drug manufacturers. As alcohol-based hand sanitizers are classified by the FDA as an OTC drug the NLCC is requesting that any DSP in the State of Nebraska follow the guidelines laid out by the FDA here:

<https://www.fda.gov/media/136390/download>

Document last updated on March 27, 2020.