



CORONAVIRUS (COVID-19) UPDATE: ACSA RESPONSE ON UPDATED FDA GUIDANCE

March 24, 2020

Today, the American Craft Spirits Association (ACSA) received additional guidance from the Food and Drug Administration (FDA) concerning the production and processing of alcohol for use as the active ingredient in FDA approved hand sanitizer. You can find that guidance on our COVID-19 site [here](#).

This document applies specifically to DSPs producing or purchasing ethanol for use in the production of hand sanitizer. **Note:** this new guidance does not change or impact the FDA guidance regarding the formula or process for making hand sanitizer (published Friday, March 20, 2020). Please carefully review the entire FDA guidance and remember to compare.

Today's FDA guidance has the following principal takeaways:

- DSPs must distill to a minimum of 94.9% ABV to meet the purity requirements of the USP or FCC standard. However, your product will not need to be officially certified.
- Ethanol used as the active ingredient in hand sanitizer must be denatured. The appendix in this document offers two denaturing formulas that you “may” use. It is noted that this guidance highly recommends these formulas but they are stated as NON-BINDING.
- Clarifies that the ethanol may be denatured at the point of production, or may be delivered as undenatured to an appropriate third party (i.e. compounder) and may be denatured by the third party making the hand sanitizer product.
- Clarifies that no ingredients other than ethanol, water (boiled, distilled, RO), and approved denaturants may be used in the alcohol. Note: this does not remove the requirement in the hand sanitizer formula that water must be boiled or distilled. This is water only in relation to the distillation of the ethanol.

We are painfully aware of the continuing inconsistencies between the TTB, FDA, and WHO and are working diligently to clarify, resolve, and report information back to you as quickly, efficiently, and accurately as possible. As you might imagine, this new guidance detoured the task force from completing the responses to the Sanitizer FAQs we received on the ACSA webinar yesterday. If you were unable to attend, please find the [archived webinar here](#). We are now realigning to respond to the number of questions and hope to have that FAQ out to our members shortly.

If you are producing either hand sanitizer or sanitizing solution, and you haven't yet let us know, please confirm the same at news@americancraftspirits.org. We are receiving multiple requests from federal and state entities and are referring them to the [list of DSPs](#) currently producing.

Finally, please continue to send your questions to legislation@americancraftspirits.org

ACSA is the only 501(c)(6) national trade group representing craft producers in the U.S.

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