DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

Distilled Spirits Council Guidance on Distiller Production of Hand Sanitizer to Address COVID-19 Pandemic

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Distilled Spirits Council Guidance on Distiller Production of Hand Sanitizer to Address COVID-19 Pandemic

DISCUS has worked throughout the COVID-19 pandemic to gain regulatory clarity for distillers wishing to produce hand sanitizer to help address the nationwide shortage during the COVID-19 pandemic. Included below is a summary of the current available guidance and policies that have been released in relation to the production of hand sanitizer in response to COVID-19, as well as other helpful resources for navigating these issues. Thus far, the following federal agencies have released relevant guidance on the production of hand sanitizer in response to COVID-19: The Tax and Trade Bureau, The Federal Drug Administration, and The Department of Transportation. **NOTE: Government Issued guidance documents are included in full in the appendices. Please carefully review them in full and follow each requirement to ensure compliance.**

The Department of Labor (OSHA) also has released helpful information that we provide below. Several states have released notices related to compliance with state laws and regulations. Summaries and copies of those communications are included in this document, which we will continue to update as we gain more clarity from regulators.

Please note that this document is meant to assist in collecting information being released as it relates to the COVID-19 pandemic and is not intended to be an exhaustive list of laws and regulations that may apply to your operations.

Some of the other helpful resources we have collected include sample Material Safety Data Sheets for the WHO Hand Sanitizer Formula and Ethanol SDA Formula 40-B, sample Certificate of Analysis for ethanol denatured with denatonium benzoate, guidance on redistilling fuel ethanol and beer, and relevant webinars that have been hosted on these topics.

DISCUS is incredibly proud of the distillers jumping in to help the country win this fight against COVID-19. Thank you all! #DistillersUnited4aCause

Risk to Children: FDA has expressed concern about the risk to children consuming sanitizers and has pointed to increased calls to poison control centers during the COVID-19 pandemic. *See* FDA's recent press announcement.

We encourage all distillers to closely review and adhere to all FDA policies, and also consider taking a few additional steps to address concerns about children inadvertently consuming sanitizers, including: (1) add an overt warning to packaging that product be kept out of reach of children; (2) use packaging and labeling that makes it clear that the product is sanitizer and NOT a beverage; and (3) continue to spread awareness that these products be kept out of reach of children (see below).

Given the increase in use of this product in response to COVID-19, DISCUS launched a public education campaign to remind adults to keep hand sanitizer out of reach of children. The campaign features public education images created by DISCUS that will be shared on our website and highlighted across social media platforms. We encourage all distillers to visit the campaign webpage and help share this message.

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU (TTB) GUIDANCE

On March 26, TTB revised its public guidance on "Production of Hand Sanitizer to Address the COVID-19 Pandemic," which supersedes TTB's prior guidance from March 18 (See Appendix A, TTB G 2020-1). Of note, this new guidance (1) directs permittees to follow the FDA Guidance, which includes the WHO Formula and additional FDA requirements (see section below for FDA Policies); (2) provides additional guidance on uses of undenatured or denatured alcohol that are not subject to the Federal Excise Tax (FET); (3) exempts distilled spirits plants (DSPs) from requirements to request approval to receive spirits in bond or to obtain additional bond coverage; and (4) restates the remaining provisions of the earlier guidance (such as waiving prior authorization).

- TTB announced on December 18 that they are extending any exemptions, waivers, or other authorizations currently provided in TTB G 2020-1B **through June 30, 2021**.

Formula Guidance

TTB is authorizing the use of the formulations in the FDA guidance documents to manufacture hand sanitizer products and denatured alcohol for use in hand sanitizer by DSPs without first obtaining formula approval from TTB. The formulations authorized in current FDA guidance are those made with specially denatured alcohol (SDA) Formula No. 3-C, SDA Formula No. 40-A (with or without tert-butyl alcohol), SDA Formula No. 40-B (with or without tert-butyl alcohol), and alcohol containing 3% triethyl citrate (w/w). TTB is authorizing these exemptions to approve emergency variations from regulatory requirements, and to approve variations in formula requirements related to denatured alcohol and products made with such alcohol.

Waiver of Prior Authorization Requirements

- ***Permit Guidance for AFPs and DSPs***: 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."

- ***Industrial Alcohol Users: "***Industrial alcohol user permittees may also use denatured ethanol to manufacture hand sanitizer using a formulation in the FDA guidance . . . without first obtaining formula approval from TTB. . . . 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."

- ***Transfer In Bond:*** "[F]or transfers of either denatured or undenatured distilled spirits between domestic DSPs, TTB is exempting DSPs from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits from another DSP and to obtain additional bond coverage." Required to keep record of information that would normally be submitted on TTB F 5100.16.

- Please see TTB Guidance in Appendix A for complete details.

Tax Liability

Alcohol used to produce hand sanitizer is not subject to the FET, if it is denatured OR for the other exceptions noted below. See TTB Guidance in Appendix A for complete details.

- ***Denatured Alcohol Following FDA Guidance:*** "Tax-free ethanol may be used to produce hand sanitizer if it is denatured according to TTB regulations and Food and Drug Administration (FDA) guidance." *See* FDA Policies below.

- ***State and Local Government Exemptions:*** "Alcohol, whether or not denatured, may be delivered tax-free to state and local governments for non-beverage purposes."

- ***Hospitals, Clinics, Laboratories, etc.:*** Undenatured alcohol may also be provided to "hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale."

    - Note: DISCUS has clarified that it is current TTB policy that undenatured alcohol donated or sold to a government entity or any of these institutions, not for resale or use in the manufacture of any product for sale, either in the form of hand sanitizer or alcohol to be made into hand sanitizer is not subject to FET, provided all the requirements in 27 C.F.R. Part 22 are satisfied. TTB will determine whether an institution qualifies for this provision prior to providing them a Tax-Free Alcohol user permit.

- See TTB Guidance in Appendix A for additional guidance related to providing alcohol to state and local governments, as well as hospitals, clinics, laboratories, etc.

- On May 19th, TTB released Guidance 2020-4: Tax-Free Withdrawal of Distilled Spirits and Products Containing Distilled Spirits for Hand Sanitizer Purposes under the CARES Act and TTB Guidance. This document provides guidance in a question-and-answer format about tax-free withdrawals of distilled spirits and hand sanitizer under the CARES Act and TTB's exemptions.

Trade Practice Enforcement During COVID-19 Pandemic – Hand Sanitizer

On May 8th, TTB published trade practice guidance, which included the following regarding hand sanitizer: Industry members have asked TTB whether providing hand sanitizers to consumers violates the trade practices provisions of the FAA Act. There are no trade practice restrictions on industry members selling hand sanitizers directly to consumers or providing hand sanitizers, free of charge, directly to consumers. *See* 27 CFR 6.96(b). Additionally, packaging and distributing distilled spirits, wine or malt beverage products in combination with other non-beverage items, such as hand sanitizer, for sale to consumers is allowable. *See* 27 CFR 6.93. **This Circular was in effect until September 30th.**

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Hand Sanitizer-Related Production Recordkeeping/TTB Monthly Reports

DSPs (including AFPs) should use existing TTB report forms to document their tax-free withdrawals under the CARES Act. In cases where the transaction field for the line is blank, the proprietor should write the phrase "CARES Act" in the blank space to indicate that the products were produced for withdrawal tax-free under the CARES Act. Product quantities should be reported in proof gallons or wine gallons in accordance with the instructions on each form. Below is a summary of the report forms and lines to be used:

Permit Type and Operational Report		Operational Report Lines to be Used
DSP	Monthly Report of Production Operations (TTB Form 5110.40)	line 13
DSP	Monthly Report of Storage Operations (TTB Form 5110.11)	line 21
DSP	Monthly Report of Processing Operations (TTB Form 5110.28)	lines 21 and 41
DSP (Industrial Only)	Monthly Report of Processing (Denaturing) Operations (TTB Form 5110.43),	lines 2 and 12, and section III
AFP	Alcohol Fuel Plant Report (TTB Form 5110.75)	line 15

Please review TTB's guidance in full and follow each requirement to ensure compliance.

FOOD AND DRUG ADMINISTRATION (FDA) TEMPORARY POLICIES

Hand sanitizers are an over-the-counter (OTC) product regulated by the FDA. FDA has issued two temporary policies of note, one related to Preparation of Hand Sanitizers and another related to Manufacture of Alcohol to be used in hand sanitizers.

Questions for FDA? Please reach out to: covid-19-hand-sanitizers@fda.hhs.gov.

Preparation of Hand Sanitizers

On February 10, 2021, FDA revised the *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry* for a fifth time (previous versions were published on June 1, April 15, March 27, March 19, and August 7), which covers entities not currently licensed and registered as drug manufacturers that want to produce hand sanitizer to help respond to the COVID-19 pandemic. *See* Appendix B-1. This guidance states that FDA does not intend to take action against facilities that prepare alcohol-based hand sanitizers for the duration of the public health emergency provided their guidance is followed.

Please review the Temporary Policy in full (Appendix B-1), but included below are some highlights:

- ***Formula:*** This policy provides the required formula, which is based on the World Health Organization (WHO) guidance and also includes other FDA requirements. The WHO Formula No. 1 is linked here in a scalable format, courtesy of the Brown Forman team. (password jb).
    - **FDA requests producers not add any active or inactive ingredients other than those specified in this guidance, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.**
    - **Ethanol:** Alcohol (ethanol) that is produced using fermentation and distillation processes typically used for consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer. Ethanol made using wet milling, fermentation, and distillation processes used for consumable goods (like alcoholic beverages made by distilleries) generally does not contain impurities above the limits listed in FDA's Attachment 1. However, all ethanol made for use in hand sanitizer should meet the limits in Attachment 1, if tested. Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if it meets USP or FCC grade. 17 FCC grade alcohol should be tested for impurities using the methods recommended in USP and confirmed to meet the limits in Attachment 1, Table 1.
        - **Fuel or Technical Grade Ethanol**: Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) may be considered for use in hand sanitizer provided the following circumstances are present:

i. the alcohol is produced using fermentation and distillation processes typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol;

ii. the alcohol meets USP or FCC grade requirements or the conditions in Attachment 1 of this guidance; and

iii. the alcohol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements but potentially present based on the specific manufacturing environment.

- Fuel grade ethanol that does not meet USP or FCC requirements may be considered for use in hand sanitizer under this temporary policy only if the following circumstances are present:

1. Fuel or technical grade ethanol does not contain gasoline or any of its components (e.g., n-heptane).

2. Impurities meet the interim limits listed in Table 1 below and no other potentially harmful impurities are present other than those addressed in Table 1. If a firm wishes to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should test the ethanol (or have a third party laboratory conduct testing) to identify the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment. These impurities and their interim limits in ethanol for use in hand sanitizer under this policy are provided in Table 1 below. These interim limits take into account the expected clinical usage and administration of hand sanitizers described under this temporary policy. We recommend using test methods described in USP.

Table 1

Impurity	Interim Limit under this policy
Methanol	NMT 630 ppm
Benzene	NMT 2 ppm
Acetaldehyde	NMT 50 ppm*
Acetal (1,1-diethoxyethane)	NMT 50 ppm
Sum of all other impurities	NMT 300 ppm

3. In cases where fuel or technical grade ethanol that does not meet the interim limits in Table 1 because the sum of all other impurities exceeds the interim limit of 300 ppm, all individual impurities are identified and meet the interim limits in Table 2 below.

The interim impurity limits provided in Table 2 are generally based on ICH Q3C *Guideline on Impurities: Guideline for Residual Solvents*, considering the expected clinical usage and administration that has been defined for hand sanitizers under this policy.

Table 2

Impurity	Interim Limit under this policy
Acetone	NMT 4400 ppm
n-propanol (1-propanol)	NMT 1000 ppm
Ethyl acetate	NMT 2200 ppm
Sec-butanol (2-butanol)	NMT 6200 ppm
Iso-butanol (2-Methyl-1-propanol)	NMT 21700 ppm
n-butanol (1-butanol)	NMT 1000 ppm
iso-amyl alcohol (3-Methyl-1-butanol)	NMT 4100 ppm
Amyl alcohol	NMT 4100 ppm

4. For any impurity identified not listed in Table 1 or Table 2, the firm submits data with the level for each individual impurity with information regarding the safety of each impurity, if available, for FDA's assessment regarding whether the ethanol is suitable for use under this policy.

- **NOTE**: Submissions should be sent to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line for FDA's assessment regarding the use of the ethanol under this policy.

- **NOTE: Additional Considerations for Testing Stemming from Recent Methanol Substitution or Contamination in Hand Sanitizers:** Recent FDA sampling and test results demonstrating methanol substitution for ethanol in hand sanitizer products have raised serious safety concerns. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, adolescents and adults who drink these products as an alcohol (ethanol) substitute and young children who accidentally ingest these products are most at risk for methanol poisoning.

  Accordingly, methanol cannot safely be used as an ingredient, or as a denaturant, in hand sanitizer. FDA is continuing to investigate methanol substitution and/or contamination to help safeguard consumers from hand sanitizers that may cause harm.

- Use of alcohol (ethanol) or IPA procured from another source, rather than manufactured in-house by the firm, is consistent with this policy if the hand

sanitizer manufacturer tests, or has tested, each lot of the active ingredient (either ethanol or IPA) for methanol content prior to use, regardless of the process used by the outside source in manufacturing the alcohol. For both alcohol (ethanol) and IPA, FDA recommends the test methods described in the USP monograph for alcohol (ethanol). Given the risks to consumers (including death) associated with methanol substitution, FDA strongly recommends the test for methanol be conducted in a laboratory that has been previously inspected by FDA and found in compliance with Current Good Manufacturing Practice (CGMP). As part of the Agency's evaluations of laboratory data, FDA may consider whether the laboratory has been previously inspected by FDA and found to be in compliance with CGMP.

- Any alcohol (ethanol) or IPA that contains more than 630 ppm methanol is not consistent with this temporary policy and may be considered evidence of substitution and/or contamination. Hand sanitizers containing methanol-contaminated alcohol (ethanol) or IPA are subject to adulteration charges under the FD&C Act. Such alcohol (ethanol) or IPA material should be destroyed, and the manufacturer should contact FDA regarding the material and its source. For more information, contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "METHANOL" in the subject line.

- **NOTE**: FDA notes that acetaldehyde appears to be genotoxic, and potentially carcinogenic, when in direct contact with tissues. Given the large number of applications of this product expected by consumers and health care personnel during the public health emergency, exposure to hand sanitizer with high levels of acetaldehyde poses a significant safety concern. FDA is aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers and that the CDC recommends consumers use hand sanitizer containing at least 60% alcohol when soap and water are unavailable. Therefore, FDA is temporarily willing to consider ethanol containing acetaldehyde above that permitted by USP at an interim level no higher than 50 ppm, for use in hand sanitizer under this temporary policy. An interim upper limit of 50 ppm is based on available toxicity data for acetaldehyde considering the expected clinical usage and administration of hand sanitizers under this policy. FDA is continually assessing the needs and circumstances related to the COVID-19 temporary policies, including the use of ethanol containing acetaldehyde at an interim level no higher than 50 ppm, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw these policies as appropriate.

- **Isopropyl Alcohol**: WHO Formulation 2 uses isopropyl alcohol rather than ethanol and FDA has stated that, when used as the active ingredient, isopropyl alcohol should be USP grade.

        - **NOTE**: If a firm wishes to use other sources of isopropyl alcohol as an active ingredient, provide analytical data of the isopropyl alcohol tested against all of the elements of the USP monograph, including listed impurities, to COVID-19-Hand-Sanitizers@fda.hhs.gov and include "ISOPROPYL ALCOHOL DATA" in the subject line, for FDA's assessment regarding the use of this ingredient under this policy.

    - **Glycerin and Glycerol:** FDA has specified that both USP and FCC grade glycerin is acceptable.

    - **Hydrogen peroxide**: Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP, or technical grade hydrogen peroxide may be used and the hand sanitizer formula should be adjusted based on the actual concentration of hydrogen peroxide used. FDA requests that firms formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP (in the latter case provided the alcohol (ethanol or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol).

    - **Sterile Water**: Water for hand sanitizer production should be sterilized by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP. Water should be used as quickly as possible after it is rendered sterile or purified.

    - **American Chemical Society (ACS) Grade Ingredients**: Ingredients that are described as only meeting American Chemical Society (ACS) grade standards should generally not be used in hand sanitizers. Where an ingredient is described as meeting both ACS grade and USP or FCC grade, use of that ingredient is consistent with this policy.

        - **NOTE**: If a firm wants to use an ingredient that is described only as ACS grade, the firm should submit relevant information on the ingredient's concentration and impurity profile to COVID-19-Hand-Sanitizers@fda.hhs.gov with "*name of ingredient* DATA" in the subject line for FDA's assessment regarding the use of the ingredient under this policy.

- ***Denatured:*** FDA's guidance requires the use of denatured alcohol and mandates the use of one of three TTB denaturing formulas: 40-A and 40-B (both of which can be used with or without the tert-butyl alcohol), and 3-C, which contains isopropyl alcohol.

    - The August 7 update includes an additional denaturant, triethyl citrate, though FDA notes that TTB has not approved this material as a denaturant under the Internal Revenue Code through its regulations at 27 CFR Part 21. When referring to this denaturant, FDA points to TTB's recognition that, through December 31, 2020, distilled spirits plants may withdraw distilled spirits tax-free for use in hand sanitizer that is produced and distributed consistent with this guidance.

- FDA is continuing to evaluate other potential formulas for denaturing. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov with "DENATURANTS REQUEST" in the subject line.

- For formula 3-C, using technical grade isopropyl alcohol that meets the requirements of 27 CFR 21.113 as a denaturant in the preparation of the finished hand sanitizer product is consistent with this policy.

- For more information regarding denatonium benzoate, we have posted on our website pro tips for using/handling the substance and FAQs prepared by one denatonium benzoate supplier.

- ***Minimum Proof:*** FDA requests that the alcohol be not less than 94.9% ethanol by volume prior to denaturing, which is consistent with the USP and FCC grade requirements for purity; however, they have provided that lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the finished hand sanitizer meets the ethanol volume to content concentration of 80%.

- ***Registration and Listing Required:*** FDA's guidance requires that companies register their facility and list these products in the FDA Drug Registration and Listing System (DRLS). Information regarding how to register your facility and hand sanitizer product can be found in the guidance document.

- ***Label:*** This guidance also provides the recommended label that should be included on the product.
  - **Note**: FDA has confirmed that manufacturers may include any denaturants on the label if they choose to do so.

- ***Aqueous Solution***: This guidance only applies to hand sanitizer that is an aqueous product and does not cover gel or foam hand sanitizer products because different or additional ingredients may impact the quality and potency of the product. This policy does not apply to aerosol sprays because aerosol sprays with propellent added to the formulation can result in altered potency of the finished hand sanitizer.

- ***Packaging***: FDA requests that the finished hand sanitizer product be packaged in packaging appropriate for liquid drug products that will seal sufficiently to prevent evaporation of the alcohol or IPA. Manual pump sprays that seal sufficiently to prevent evaporation are consistent with this policy.

- **Adverse Event Reporting**: Firms have a mechanism to accept adverse event reports for any products they manufacture under this enforcement policy, and submit such adverse event reports to FDA (for more information, please see FDA's guidance on adverse event reporting requirements, https://www.fda.gov/media/77193/download).42 This guidance on adverse event reporting advises that "for reporting purposes, an ICSR [individual case safety report] should

describe the known product attributes (e.g., dosage form, strength, color, SKU, NDC, lot number)." To facilitate reporting of adverse events and investigation of root causes, the immediate package also includes a lot/control number.

NOTE: This is not in the FDA policy, but a few additional items to consider:

- **Add overt warning:** Given FDA's concern related to children inadvertently ingesting this product, producers should consider adding a clear and overt warning that this product should be kept out of reach of children.
- **Avoid claims:** FDA has taken action against manufacturers making claims like "kills 99.99% of most common germs," arguing that they are insufficiently substantiated and thus violate federal law.
- **Make it clear that this is sanitizer:** The FDA has noted concerns that some bottles and labels may look too similar to beverage products and could be inadvertently consumed. Use packaging and labeling that make it clear that this is sanitizer and NOT a beverage alcohol product.

Regarding imported hand sanitizer, the FDA provided the following response:

Importing Hand Sanitizer

We understand that you have members who wish to import hand sanitizer from their facilities overseas. Hand sanitizers (and other drugs) imported into the United States must comply with all the applicable requirements under the Federal Food, Drug, and Cosmetic Act and the pertinent regulations found in Title 21 of the Code of Federal Regulations (21 CFR). However, FDA has described in the three recent guidances that FDA does not intend to take action on the manufacture of hand sanitizers, and ethanol used as an active pharmaceutical ingredient in hand sanitizers, that are introduced into U.S. commerce, provided certain circumstances are present.

For example, as described in the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), foreign manufacturers whose drugs, including over-the-counter drugs, are imported into the United States are required to register with FDA and submit a listing of drugs in commercial distribution, before the drugs are imported (as required by section 510 of the FD&C Act and 21 CFR Part 207). See Electronic Drug Registration and Listing Instructions for information and instructions on the electronic submission process.

The agency does not intend to take enforcement action against hand sanitizers made with imported ethanol, so long as it meets the specifications outlined in our guidance, Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19).

Manufacture of Alcohol to be Used in Hand Sanitizer

On February 10, 2021, FDA revised the *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry* for a fifth time (previous versions were published on June 1, April 15, March 27, March 24, and August 7*),* which provides further guidance on producing alcohol for the use in hand sanitizers and permits manufacturers to provide undenatured alcohol to firms that produce alcohol-based hand sanitizers, who will then denature the ethanol prior to their manufacturing process. *See* Appendix B-2.

- ***Denatured****:* This guidance requires the alcohol for hand sanitizer production to be denatured and requires the use of one of three TTB denaturing formulas: 40-A and 40-B (both of which can be used with or without the tert-butyl alcohol), and 3-C, which contains isopropyl alcohol.
    - The August 7 update includes an additional denaturant, triethyl citrate, though FDA notes that TTB has not approved this material as a denaturant under the Internal Revenue Code through its regulations at 27 CFR Part 21. When referring to this denaturant, FDA points to TTB's recognition that, through December 31, 2020, distilled spirits plants may withdraw distilled spirits tax-free for use in hand sanitizer that is produced and distributed consistent with this guidance.
    - FDA is continuing to evaluate other potential formulas. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.
    - For formula 3-C, using technical grade isopropyl alcohol that meets the requirements of 27 CFR 21.113 as a denaturant in the preparation of the finished hand sanitizer product is consistent with this policy.
    - For more information regarding denatonium benzoate, we have posted on our website pro tips for using/handling the substance and FAQs prepared by one denatonium benzoate supplier.
- ***Minimum Proof:*** FDA requests that the alcohol be not less than 94.9% ethanol by volume prior to denaturing, which is consistent with the USP and FCC grade requirements for purity; however, they have provided that lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the finished hand sanitizer meets the ethanol volume to content concentration of 80%.
    - **Ethanol:** Alcohol (ethanol) that is produced using fermentation and distillation processes typically used for consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer. Ethanol made using wet milling, fermentation, and distillation processes used for consumable goods (like alcoholic beverages made by distilleries) generally does not contain impurities above the limits listed in FDA's Attachment 1. However, all ethanol made for use in hand sanitizer should meet the limits in Attachment 1, if tested. Alcohol derived from synthetic processes may

be considered for use in hand sanitizer only if it meets USP or FCC grade. 17 FCC grade alcohol should be tested for impurities using the methods recommended in USP and confirmed to meet the limits in Attachment 1, Table 1.

- **Fuel or Technical Grade Ethanol**: Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) may be considered for use in hand sanitizer provided the following circumstances are present:

    i. the alcohol is produced using fermentation and distillation processes typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol;

    ii. the alcohol meets USP or FCC grade requirements or the conditions in Attachment 1 of this guidance; and

    iii. the alcohol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements but potentially present based on the specific manufacturing environment.

- Fuel grade ethanol that does not meet USP or FCC requirements may be considered for use in hand sanitizer under this temporary policy only if the following circumstances are present:

    1. Fuel or technical grade ethanol does not contain gasoline or any of its components (e.g., n-heptane).

    2. Impurities meet the interim limits listed in Table 1 below and no other potentially harmful impurities are present other than those addressed in Table 1. If a firm wishes to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should test the ethanol (or have a third party laboratory conduct testing) to identify the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment. These impurities and their interim limits in ethanol for use in hand sanitizer under this policy are provided in Table 1 below. These interim limits take into account the expected clinical usage and administration of hand sanitizers described under this temporary policy. We recommend using test methods described in USP.

Table 1

Impurity	Interim Limit under this policy
Methanol	NMT 630 ppm
Benzene	NMT 2 ppm
Acetaldehyde	NMT 50 ppm*
Acetal (1,1-diethoxyethane)	NMT 50 ppm
Sum of all other impurities	NMT 300 ppm

3. In cases where fuel or technical grade ethanol that does not meet the interim limits in Table 1 because the sum of all other impurities exceeds the interim limit of 300 ppm, all individual impurities are identified and meet the interim limits in Table 2 below. The interim impurity limits provided in Table 2 are generally based on ICH Q3C *Guideline on Impurities: Guideline for Residual Solvents*, considering the expected clinical usage and administration that has been defined for hand sanitizers under this policy.

Table 2

Impurity	Interim Limit under this policy
Acetone	NMT 4400 ppm
n-propanol (1-propanol)	NMT 1000 ppm
Ethyl acetate	NMT 2200 ppm
Sec-butanol (2-butanol)	NMT 6200 ppm
Iso-butanol (2-Methyl-1-propanol)	NMT 21700 ppm
n-butanol (1-butanol)	NMT 1000 ppm
iso-amyl alcohol (3-Methyl-1-butanol)	NMT 4100 ppm
Amyl alcohol	NMT 4100 ppm

4. For any impurity identified not listed in Table 1 or Table 2, the firm submits data with the level for each individual impurity with information regarding the safety of each impurity, if available, for FDA's assessment regarding whether the ethanol is suitable for use under this policy.

- **NOTE: Additional Considerations for Testing Stemming from Recent Methanol Substitution or Contamination in Hand Sanitizers:** Recent FDA sampling and test results demonstrating methanol substitution for ethanol in hand sanitizer products have raised serious safety concerns. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, adolescents and adults who drink these products as an alcohol (ethanol) substitute and young

children who accidentally ingest these products are most at risk for methanol poisoning.

Accordingly, methanol cannot safely be used as an ingredient, or as a denaturant, in hand sanitizer. FDA is continuing to investigate methanol substitution and/or contamination to help safeguard consumers from hand sanitizers that may cause harm.

- Use of alcohol (ethanol) or IPA procured from another source, rather than manufactured in-house by the firm, is consistent with this policy if the hand sanitizer manufacturer tests, or has tested, each lot of the active ingredient (either ethanol or IPA) for methanol content prior to use, regardless of the process used by the outside source in manufacturing the alcohol. For both alcohol (ethanol) and IPA, FDA recommends the test methods described in the USP monograph for alcohol (ethanol). Given the risks to consumers (including death) associated with methanol substitution, FDA strongly recommends the test for methanol be conducted in a laboratory that has been previously inspected by FDA and found in compliance with Current Good Manufacturing Practice (CGMP). As part of the Agency's evaluations of laboratory data, FDA may consider whether the laboratory has been previously inspected by FDA and found to be in compliance with CGMP.

- Any alcohol (ethanol) or IPA that contains more than 630 ppm methanol is not consistent with this temporary policy and may be considered evidence of substitution and/or contamination. Hand sanitizers containing methanol-contaminated alcohol (ethanol) or IPA are subject to adulteration charges under the FD&C Act. Such alcohol (ethanol) or IPA material should be destroyed, and the manufacturer should contact FDA regarding the material and its source. For more information, contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "METHANOL" in the subject line.

- **NOTE**: Submissions should be sent to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line for FDA's assessment regarding the use of the ethanol under this policy.

- **NOTE**: FDA notes that acetaldehyde appears to be genotoxic, and potentially carcinogenic, when in direct contact with tissues. Given the large number of applications of this product expected by consumers and health care personnel during the public health emergency, exposure to hand sanitizer with high levels of acetaldehyde poses a significant safety concern. FDA is aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers and that the CDC recommends consumers use hand sanitizer containing at least 60% alcohol when soap and water are unavailable. Therefore, FDA is temporarily willing to consider ethanol containing acetaldehyde above that permitted by USP at an interim level no higher

than 50 ppm, for use in hand sanitizer under this temporary policy. An interim upper limit of 50 ppm is based on available toxicity data for acetaldehyde considering the expected clinical usage and administration of hand sanitizers under this policy. FDA is continually assessing the needs and circumstances related to the COVID-19 temporary policies, including the use of ethanol containing acetaldehyde at an interim level no higher than 50 ppm, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw these policies as appropriate.

- ***Label:*** This guidance also provides the recommended labels that should be included on the product.

- ***American Chemical Society (ACS) Grade Ingredients***: Ingredients that are described as only meeting American Chemical Society (ACS) grade standards should generally not be used in hand sanitizers. Where an ingredient is described as meeting both ACS grade and USP or FCC grade, use of that ingredient is consistent with this policy.

    - **NOTE**: If a firm wants to use ethanol that is described only as ACS grade, submit relevant information on the ethanol's concentration and impurity profile to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line for FDA's assessment regarding the use of the ethanol under this policy.

- ***Record Keeping*****:** As a general matter, we recommend that all DSPs maintain clear and detailed records of any hand sanitizer produced and distributed.

- **FDA states that, beyond alcohol, water, and denaturants (if added at the point of production), the alcohol production firm should not add other ingredients. Different or additional ingredients in the API may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.**

- **Please review FDA's guidance documents in full and follow each requirement to ensure compliance**

Risk to Children: FDA has expressed concern about the risk to children consuming sanitizers and has pointed to increased calls to poison control centers during the COVID-19 pandemic. *See* FDA's recent press announcement.

We encourage all distillers to closely review and adhere to all FDA policies, and also consider taking a few additional steps to address concerns about children inadvertently consuming sanitizers, including: (1) add an overt warning to packaging that product be kept out of reach of children; (2) use packaging and labeling that makes it clear that the product is sanitizer and NOT a beverage; and (3) continue to spread awareness that these products be kept out of reach of children (see below).

Given the increase in use of this product in response to COVID-19, DISCUS recently launched a public education campaign to remind adults to keep hand sanitizer out of reach of children. The campaign features public education images created by DISCUS that will be shared on our website and highlighted across social media platforms. We encourage all distillers to visit the campaign webpage and help share this message.

DEPARTMENT OF TRANSPORTATION (DOT) TEMPORARY POLICY

On April 10, the Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) revised its guidance previously issued on April 2, "Temporary Policy for the Transportation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Notice of Enforcement Discretion." This revision provides the option to use labels that conform to FDA guidance (as a replacement for the DOT text markings required by the prior guidance) provided that the FDA labels are visible in transportation. Secondly, the DOT clarifies that registration with PHMSA is waived irrespective of the quantity of hand sanitizer transported.

Of note, this guidance provides temporary relief from certain HMR requirements while continuing to maintain an appropriate level of safety for companies that are producing products under the FDA guidance. The relief provided herein is for the highway mode only. Shipments by other modes of transportation must meet all requirements of the hazardous materials regulations unless relief has been provided elsewhere. This Notice of Enforcement Discretion expires 3 months from the date of issuance (April 10) or until the time when the public health emergency is over, whichever is sooner.

- **NOTE**: On December 8th, DOT granted an extension of their enforcement discretion for the transport of hand sanitizer to help assist those who produced sanitizer under the enforcement discretion who wish to deplete stock **until March 31, 2021.** More specifically, PHMSA states that it will not take enforcement action against any offeror or carrier who offers or transports hand sanitizers **manufactured and packaged prior to October 31, 2020**, and in accordance with the April 10, 2020 "*Temporary Policy for the Transportation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)"* and the June 24, 2020 notice, which extended the relief until October 31, 2020 and expanded it to include transportation by rail.

- It should be noted that the current notice provides relief to shippers offering stock that was packaged in accordance with the original notices PRIOR to October 31. PHMSA is NOT extending the original notice to anyone wishing to continue to manufacture and package the sanitizer, but only those who have stock manufactured and packaged prior to October 31, 2020. All hand sanitizers manufactured and packaged after October 31, 2020 must be in full compliance with the Hazardous Materials Regulations.

Background

Alcohol-based products, such as hand sanitizers, are typically classified according to the HMR as a Class 3, Flammable Liquid. The HMR defines Flammable Liquids as a liquid having a flash point of 60 °C (140 °F) or below (see 49 CFR 173.120). The provisions of the HMR include requirements applicable to classifying the material, selecting an appropriate packaging, and communicating the hazard through labeling, marking, placarding, and shipping papers. The requirements that apply vary depending on the concentrations of alcohol and the quantity and form of the product.

For instance, 49 CFR § 173.150(g), *Limited quantities of retail products containing ethyl alcohol*, establishes provisions applicable to beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol.

Specifically, these provisions apply to such products classed as a flammable liquid or flammable solid and containing not more than 70 percent ethyl alcohol by volume for liquids. Typically, hand sanitizers are transported in accordance with these provisions. If offered for transportation in the quantities and packagings that are specified in § 173.150(g), hand sanitizers are excepted from all other requirements of the HMR. During this public health emergency, PHMSA is providing relief for additional packaging configurations and sizes to facilitate transportation of these vital commodities from facilities operating under the FDA guidance.

Small Quantities of Hand Sanitizers Containing Ethyl Alcohol or Isopropyl Alcohol

PHMSA is providing this relief to companies that are producing hand sanitizer under the FDA guidance and will not take enforcement action for violations of the hazardous materials regulations if the procedures outlined below are followed. Specifically, the procedures below apply to transportation of hand sanitizers by private, common, or contract carriers by motor vehicle.

1. Packages contain hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.

2. Packagings are leak tight and securely closed, secured against shifting, and protected against damage.

3. The material is contained in a packaging having a capacity not over 8 gallons.

4. For inner packagings not exceeding 1 gallon:

    a. Packages are a combination package and the inner receptacle containing the liquid is placed inside an outer packaging where the inner packagings are secured and cushioned within the outer packaging to prevent breakage, leakage, and movement and inner packagings are packed with package closures in an upright orientation.

    b. The net contents of all inner packagings in any single outer packaging do not exceed 8 gallons (e.g., 8 x 1 gallon packages).

    c. The company name and the words "Sanitizer - Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" are marked on the outer package and, if applicable, the overpack. In addition, the FDA label is acceptable as an alternative marking provided it is visible in transportation. (See Appendix A through D of the FDA Guidance at: https://www.fda.gov/media/136289/download)

5. Packages exceeding a capacity of 1 gallon:

a. Are overpacked in crates, cages, carts, boxes, or similar overpacks.

b. Packages are secured in the transport vehicle in such a way as to prevent breakage, leakage, and movement. Packages are packed package closures in an upright orientation.

c. The company name and the words "Sanitizer - Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" is marked on the outside of the single package and the overpack. In addition, the FDA label is acceptable as an alternative marking provided it is visible in transportation. (See Appendix A through D of the FDA Guidance at: https://www.fda.gov/media/136289/download)

Transportation of Larger Quantities of Hand Sanitizers

PHMSA is aware that there may be a need to transport quantities greater than 8 gallons per package, for example, in drums or other packagings. To facilitate, PHMSA is providing relief from the existing provisions of the HMR. This relief applies for transportation by private or contract motor carrier, or common carrier in a vehicle under exclusive use for such service. This relief does not apply to shipments by air, vessel, or rail. PHMSA will not take enforcement action for failing to register with PHMSA irrespective of the quantity of hand sanitizer offered for transportation or transported. In addition, PHMSA will not take enforcement action for violations of the HMR for shipments of packagings containing more than 8 gallons but not more than 119 gallons of sanitizer, if the following procedures are followed:

1. The packaging contains hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.

2. Packagings is leak tight and securely closed, secured against shifting, and protected against damage.

3. The material is contained in a packaging having a capacity not over 119 gallons.

4. The packaging must be DOT or United Nations (UN) specification packaging (drums, jerricans, etc.) described in § 173.202 meeting the Packing Group (PG) II performance standard.

5. The packages are be secured to prevent breakage, leakage, and movement during the course of transportation.

6. The registration requirements found in Subpart G of Part 107 will not apply.

7. Offerers and transporters of this material provide their employees handling this material with the applicable training materials prepared by PHMSA, in lieu of the training required by 49 CFR Part 172, Subpart H (see LINK).

8. Each package is labeled with a flammable liquid label (see § 172.419).

9. The bill of lading or shipping paper includes the following basic description "UNl 987, Alcohols, n.o.s., Class 3, PG II" and indicate the number, type, and capacity of packages offered (for example, 25 drums - 119 gallons ea.).

10. A copy of the Emergency Response Guidebook Guide number 127 (attached) accompanies the shipment.

11. If the aggregate gross quantity in a transport vehicle or freight container exceeds 1,001 pounds, the vehicle is placarded as required by the HMR (see 49 CFR Part 172, Subpart F for Placarding requirements).

12. All motor carriers comply with § 177.804.

Questions for DOT?: DOT-PHMSA Hazardous Materials Information Center – one-on-one live assistance by phone; Available M-F 9am-5pm; Email: infocntr@dot.gov; 1-800-467-4922 or 202 366-4488

Regional team contact information:

Please review DOT's guidance document in full and follow each requirement to ensure compliance.

DEPARTMENT OF LABOR/OSHA GUIDELINES/MATERIALS

DISCUS met with Department of Labor/OSHA officials recently to explore helpful materials for distillers operating during COVID-19 and those who have shifted into making hand sanitizer. Included below are some DOL/OSHA resources, as well as a few other helpful protocols for safely operating during COVID-19.

Hand Sanitizer Production

OSHA wants to remind distillers making hand sanitizer that they should be receiving safety data sheets from ingredient suppliers and making them available to their employees, training employees on how to properly handle these new materials, and producing safety data sheets for any hand sanitizer products they make. Included here are links to some helpful information about complying with these requirements.

- OSHA Brief: Hazard Communication Standard – Labels and Pictograms
- Small Entity Compliance Guide for Employers That Use Hazardous Chemicals
- OSHA Brief Hazard Communication Standard/Safety Data Sheets
- OSHA Hazard Communication Main Page

We have included a sample safety data sheet in this document and will update that guidance soon with more information from OSHA. See Appendices D-1 and D-2.

- **NOTE**: The company UL has created an SDS for both the ethanol-based and isopropanol-based hand sanitizer formulas that comply with both WHO recommendations and FDA requirements. Their Safety Data Sheets are available in the relevant regional Globally Harmonized System (GHS) formats and UL is offering them **free of charge**. To obtain your free copy of an SDS, please complete the request form and email your completed request form to the email address provided. You will then receive your Safety Data Sheet in PDF format via email within two business days.

We will continue to stay in contact with DOL/OSHA and will pass along any other helpful information.

Operating During COVID-19

OSHA is providing a number of resources to help guide businesses operating during COVID-19 and encourages employers to regularly check their COVID-19 page for updates. We have set forth below links to a number of helpful documents released by the Agency.

In particular, we want to draw your attention to the Guidance on Preparing Workplaces for COVID-19 and the COVID-19 Guidance for the Manufacturing Industry Workforce to learn more about how to keep your employees and customers safe during this crisis.

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney for any specific guidance on legal or regulatory compliance.

- CDC Interim Guidance for Businesses and Employers to Plan and Respond to Coronavirus Disease 2019 (COVID-19)
- OSHA Guidance on Returning to Work
- CDC/OSHA COVID-19 Interim Guidance for Manufacturing Workers and Employers
- CDC COVID-19 Reopening Considerations for Restaurants and Bars
- CDC Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes
- Guidance on Preparing Workplaces for COVID-19
- Worker Exposure Risk to COVID-19
- COVID-19 Guidance for Restaurants & Beverage Vendors Offering Takeout or Curbside Pickup
- COVID-19 Guidance for the Manufacturing Industry Workforce
- COVID-19 Guidance for Retail Workers
- Prevent Worker Exposure to COVID-19
- COVID-19 Hazard Recognition Page
- COVID-19 Standards Page

OSHA Enforcement – COVID19: We also wanted to pass along the news release included below about OSHA's interim enforcement response plan for the coronavirus pandemic.

Other Helpful Materials: In addition, DISCUS is a member of the Food & Beverage Issue Alliance, which has developed the following protocols in collaboration with CDC and FDA. DISCUS is a signatory to each of these non-binding protocols and recommendations:

- Food Industry Recommended Protocols When Employee/Visitor/Customer Tests Positive for COVID-19
- Emergency Prevention Measures to Achieve Social Distancing in Food Manufacturing Facilities as related to COVID-19
- Screening Food Industry Employees for COVID-19 Symptoms or Exposure

These are all posted on the FBIA website at: https://www.feedingus.org/

APPENDIX A: MARCH 26, 2020 TTB PUBLIC GUIDANCE

TTB Public Guidance

Production of Hand Sanitizer to Address the COVID-19 Pandemic

March 26, 2020
TTB G 2020-1A

Summary

Tax-free ethanol may be used to produce hand sanitizer if it is denatured according to TTB regulations and Food and Drug Administration (FDA) guidance.

Alcohol, whether or not denatured, may be delivered tax-free to state and local governments for non-beverage purposes. The same is true for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale.

TTB is temporarily waiving certain formula approvals for the manufacture of hand sanitizer using and expediting certain permit requirements.

Purpose

On March 18, 2020, to facilitate the production of hand sanitizer, TTB temporarily relieved distilled spirits permittees of certain requirements related to the use of alcohol for this nonbeverage purpose (see TTB G 2020-1 "Production of Hand Sanitizer to Address the COVID-19 Pandemic"). TTB exempted permittees from obtaining formula approval from TTB before producing hand sanitizer if using a formula consistent with World Health Organization (WHO) guidance. Ethanol is one of the approved reagents in the WHO guidance. TTB's March 18 authorization referred to both denatured and undenatured ethanol. However, on March 23, 2020, the FDA issued guidance which specifies the use of denaturants when compounding ethanol-based hand sanitizers. *See* Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19). TTB is therefore providing this guidance to (1) supersede its prior guidance with regard to the authorized formula to be consistent with FDA guidance; (2) exempt distilled spirits plants (DSPs) from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits in bond from another DSP and to obtain additional bond coverage, through June 30, 2020; (3) provide guidance and certain exemptions from requirements for state and local governments wishing to obtain tax-free alcohol, and (4) offer hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions the same streamlined application process.

This guidance also restates the provisions of TTB G 2020-1 that remain unchanged.

Guidance

Due to the Coronavirus 2019 (COVID-19) pandemic, the Acting Administrator of the Alcohol and Tobacco Tax and Trade Bureau (TTB) has found it 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 first obtain authorization. Any existing DSP also may remove undenatured or denatured ethanol from bonded premises free of tax for use by any state or local government to produce hand sanitizer. In addition, any existing DSP may remove undenatured or denatured ethanol from bonded premises free of tax for use by hospitals, blood banks, sanitariums, certain pathological

laboratories, non-profit clinics, and qualifying educational institutions seeking to use it to manufacture hand sanitizer, and not for resale or use in the manufacture of any product for sale. *See* 26 U.S.C. 5214(a)(3). 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.

Although TTB is exempting industry members from certain tax requirements through this guidance, industry members must continue to comply with other federal and state law, and industry members should contact relevant federal or state agencies with questions about guidance issued by those agencies.

Permit guidance for alcohol fuel plants (AFPs) and beverage DSPs: 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 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: Nonbeverage products made with ethanol, including hand sanitizer, are not subject to federal excise tax. Please note that the FDA guidance referenced above specifies the use of denaturants when compounding hand sanitizer. For information regarding denaturants, please contact FDA.

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.

Guidance for industrial alcohol users: Industrial alcohol user permittees may also use denatured ethanol to manufacture hand sanitizer using a formulation in the FDA guidance cited above without first obtaining formula approval from TTB. During the period covered by 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), 20.56. TTB is authorizing these exemptions under its authority in 27 CFR 20.22(b) to approve emergency variations from regulatory requirements.

Guidance regarding transfers in bond. Under current TTB regulations, when DSPs want to receive either denatured or undenatured ethanol from another domestic DSP, the receiving DSP must submit an application to TTB for authorization prior to the first transfer and ensure appropriate bond coverage. *See* 27 CFR 19.403, 404. During the period covered by this guidance, for transfers of either denatured or undenatured distilled spirits between domestic DSPs, TTB is exempting DSPs from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits from another DSP and to obtain additional bond coverage. Rather than submit such requests to TTB for approval using TTB F 5100.16, DSPs must maintain records of such receipts, which would include records of the information currently required on TTB F 5100.16. TTB is authorizing these exemptions under its authority in 27 CFR 19.28 to approve emergency variations from regulatory requirements.

Guidance for state and local governments. Both denatured and undenatured alcohol may be removed free of tax for the use of a state, any political subdivision of a state, or the District of Columbia, for nonbeverage purposes, including making hand sanitizer. *See* 26 U.S.C. 5214(a)(2). An alcohol user permit is required to obtain alcohol from a distilled spirts plant. *See* 26 U.S.C. 5271(a); 27 CFR part 22. TTB provides state and local governments with a streamlined application, as authorized under 27 CFR 22.42 and 22.43(a)(1). TTB has dedicated personnel to process such applications seven days a week given the COVID-19 emergency. Please note that the recent FDA guidance cited above specifies using denaturants when compounding hand sanitizer. During the period of this guidance, TTB is authorizing state and local government permittees to make hand sanitizer for use anywhere, as needed to address the COVID-19 national emergency. *See* 27 CFR 22.22(b).

Guidance for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions. Hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions may obtain alcohol free of tax for their own nonbeverage

purpose use and not for resale or use in the manufacture of any product for sale, as described in 26 U.S.C. 5214(a)(3). Manufacturing hand sanitizer is one such nonbeverage use. As with state and local governments, such alcohol must be obtained from a distilled spirits plant and may only be obtained by those holding an alcohol user permit from TTB. *See* 26 U.S.C. 5271(a); 27 CFR part 22. TTB will offer these organizations the same streamlined application, as authorized under 27 CFR 22.42 and 22.43(a)(2). Again, please note that recent FDA guidance specifies using denaturants when making hand sanitizer.

Further Information

If you have questions regarding obtaining a TTB permit, please contact the National Revenue Center at 877-882-3277 / 877-TTB-FAQS (toll free) or online. For all other inquiries, please contact the Regulations and Rulings Division at 202-453-2265 or online. Please visit the homepage of TTB.gov for the most recent TTB news on COVID-19 related issues.

Page last reviewed: March 26, 2020
Page last updated: March 26, 2020
Maintained by: Regulations and Rulings Division

Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)

Guidance for Industry

March 2020
Updated February 10, 2021

U.S. Department of Health and Human Services Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1106 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA Webpage titled "Hand Sanitizers | COVID-19" *available at*: http://wcms-internet.fda.gov/drugs/coronavirus- covid-19-drugs/hand-sanitizers-covid-19. You may also send an e-mail request to druginfo@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1106 and complete title of the guidance in the request.

Questions

For questions regarding this document, contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov.

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Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from emerging infectious diseases, such as the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support continuity and response efforts to this pandemic.

This document updates the guidance of the same title issued in August 2020 (previous versions June, April, and March 2020). FDA is issuing this guidance in response to a number of queries from entities that are not currently licensed or registered drug manufacturers that would like to prepare alcohol-based hand sanitizers, either for public distribution or for their own internal use. The Agency is issuing this guidance to communicate its policy for the temporary preparation of certain alcohol-based[2] hand sanitizer products by firms that register their establishment with FDA as an over-the-counter (OTC) drug manufacturer, re-packager, or re-labeler[3] to prepare alcohol-based hand sanitizers under the circumstances described in this guidance ("firms") for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020,[4] including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdrawthis guidance. FDA is continually assessing the needs and circumstances related to this temporary policy, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research at the Food and Drug Administration. FDA has issued a separate guidance for industry entitled Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 2020, updated March 27, 2020, April 15, 2020, June 1, 2020, August 7, 2020 and February 10, 2021), that describes the Agency's policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in state or territory-licensed pharmacies or federal facilities and registered outsourcing facilities. The compounding guidance is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[2] Alcohol-based hand sanitizer for purposes of this guidance can be prepared using alcohol or isopropyl alcohol (IPA) consistent with FDA policies outlined in this guidance. *Alcohol* is defined as ethanol (ethyl alcohol) in the United States Pharmacopeia and National Formulary (USP-NF) and as ethyl alcohol in the Food Chemical Codex (FCC). The USP and FCC documents, known as "monographs," establish test methods and acceptance criteria for identity and purity. The USP and FCC definitions of *alcohol* do not include IPA. Unless otherwise specified, and consistent with the USP and FCC monographs, references in this guidance to "alcohol" refer to ethanol.

[3] This includes pharmacies that repackage or relabel finished hand sanitizer products prepared consistent with FDA policies outlined in this guidance.

[4] The HHS Public Health Emergency Declaration is available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020 (85 FR 16949), titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[5] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[6]

Hand hygiene is an important part of the response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol (also referred to as ethanol or ethyl alcohol).[7,8]

[5] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[6] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
[7] See https://www.cdc.gov/handwashing/hand-sanitizer-use.html.

[8] Isopropyl alcohol and ethyl alcohol are two of the active ingredients currently being evaluated by FDA as part of the OTC Drug Review of hand sanitizers, separate from the current public health emergency, for use in reducing bacteria on the skin that potentially can cause disease or decreasing presence of bacteria on the skin. See "Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 84 FR 14847 (April 12, 2019); "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-CounterHuman Use," Final Rule, 82 FR 60474 (December 20, 2017); "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17,1994) (1994 TFM). The temporary policies outlined in this guidance cover only alcohol-based (ethanol and

isopropyl alcohol) hand sanitizer produced during the public health emergency and do not cover the use of other active or inactive ingredients not otherwise mentioned in this guidance for use in hand sanitizer, including benzethonium chloride or benzalkonium chloride.

III. DISCUSSION

We understand that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers. We are also aware of reports that some consumers are producing hand sanitizers for personal use in their homes; the Agency lacks verifiable information on the methods being used to prepare such products and whether they are safe for use on human skin.

In response to the demand for alcohol-based sanitizers, certain entities that are not currently regulated by FDA as drug manufacturers have requested guidance on the preparation and distribution of hand sanitizer products for the public's use.

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against firms[9] that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs[10] for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

1. The hand sanitizer is manufactured using only the following ingredients in the preparation of the product
    a. *Select one of two options:*
    (i) Alcohol (ethanol) that is not less than 94.9% ethanol by volume[11]; **OR**

[9] Specifically, FDA does not intend to take action against firms, for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. 247d(a)(2)), for violations of sections 501(a)(2)(B), 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), 355, and 360eee-1), provided circumstances described in this guidance are present. These circumstances include (but are not limited to) preparation of hand sanitizer products using only the ingredients and formulas set forth in this guidance. FDA plans to continue to sample hand sanitizer products at the border and in distribution in the U.S. for quality issues, including potential contamination and impurity levels.

[10] Rubs are sometime referred to as "leave-on products," and are not rinsed off after use. Rub products include alcohol-based hand sanitizers for use by consumers and for use by health care professionals in hospitals or other health care settings. The health care antiseptic products include health care personnel hand rubs, surgical hand rubs, and patient antiseptic skin preparations. In the health care setting, this policy only applies to alcohol-based hand sanitizer for use as health care personnel hand rubs and does not apply to surgical hand rubs and patient antiseptic skin preparations. See "Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 84 FR 14847 (April 12, 2019); "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 82 FR 60474 (December 20, 2017); "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM).

[11] This is consistent with the USP and FCC grade requirements for purity. Lower ethanol content alcohol falls within this policy so long as it is labeled accordingly, and the finished hand sanitizer meets the ethanol concentration of 80%. (Also see below regarding the formula for finished hand sanitizer products.)

(ii) United States Pharmacopeia (USP grade) Isopropyl Alcohol (IPA)[12,13]

b. Glycerin (glycerol) USP or Food Chemical Codex (FCC) (also known as "food grade")
c. Hydrogen peroxide[14]
d. Sterile water (e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP). Water should be used as quickly as possible after it is rendered sterile or purified.

Additional Considerations for Ingredients in Preparation of the Product:

Alcohol (ethanol) [15] that is produced using fermentation and distillation processes typically used for consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer, provided the alcohol meets the interim impurity levels in Attachment 1, Table 1.[16]

Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if it meets USP or FCC[17] grade.

Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) may be considered for use in hand sanitizer provided the following circumstances are present:

(i) the alcohol is produced using fermentation and distillation processes typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol;
(ii) the alcohol meets USP or FCC[18] grade requirements or the conditions in Attachment 1; and,
(iii) the alcohol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements but potentially present based on the specific manufacturing environment.[19]

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[12] Isopropyl alcohol used as the active ingredient should be USP grade. If a firm wishes to use other grades of isopropyl alcohol as an active ingredient, provide analytical data for the isopropyl alcohol tested against all of the elements of the USP monograph, including listed impurities, to COVID-19-Hand-Sanitizers@fda.hhs.gov and include "ISOPROPYL ALCOHOL DATA" in the subject line, for FDA's assessment regarding the use of this ingredient under this policy.

[13] USP has made available to the public materials related to hand sanitizer ingredients, including monographs and test methods at https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-hand-sanitizer-ingredients.pdf.

[14] Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP, or technical grade hydrogen peroxide. The hand sanitizer formula should be adjusted based on the actual concentration of hydrogen peroxide used.

[15] The discussion concerning alcohol (ethanol) in this guidance is limited to ethanol used as an active pharmaceutical ingredient (API) for hand sanitizer manufactured as part of the temporary policies outlined in this guidance. FDA's intent to not take action with regard to alcohol meeting the circumstances described in this guidance does not reflect the risk-benefit calculus that FDA would find acceptable outside of this public health emergency and temporary policies.

[16] Ethanol made using wet milling, fermentation, and distillation processes used for consumable goods (like alcoholic beverages made by distilleries) generally does not contain impurities above the limits listed in Attachment 1. However, all ethanol made for use in hand sanitizer should meet the limits in Attachment 1, if tested.

[17] FCC grade alcohol should be tested for impurities using the methods recommended in USP and confirmed to meet the limits in Attachment 1, Table 1.

[18] See footnote 17.

[19] Special caution should be taken to ensure any other chemicals on site are not introduced into the ethanol either intentionally or via cross-contamination.

Ingredients that are described as only meeting American Chemical Society (ACS) grade standards should generally not be used in hand sanitizers.[20]

Additional Considerations for Testing Stemming from Recent Methanol Substitution or Contamination in Hand Sanitizers

Recent FDA sampling and test results demonstrating methanol substitution for ethanol in hand sanitizer products have raised serious safety concerns. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, adolescents and adults who drink these products as an alcohol (ethanol) substitute and young children who accidentally ingest these products are most at risk for methanol poisoning. Accordingly, methanol cannot safely be used as an ingredient, or as a denaturant, in hand sanitizer. FDA is continuing to investigate methanol substitution and/or contamination to help safeguard consumers from hand sanitizers that may cause harm.

Use of alcohol (ethanol) or IPA procured from another source, rather than manufactured in-house by the firm, is consistent with this policy if the hand sanitizer manufacturer tests, or has tested, each lot of the active ingredient (either ethanol or IPA) for methanol content prior to use, regardless of the process used by the outside source in manufacturing the alcohol. For both alcohol (ethanol) and IPA, FDA recommends the test methods described in the USP monograph for alcohol (ethanol).[21] Given the risks to consumers (including death) associated with methanol substitution, FDA strongly recommends the test for methanol be conducted in a laboratory that has been previously inspected by FDA and found in compliance with Current Good Manufacturing Practice (CGMP).[22] As part of the Agency's evaluations of laboratory data, FDA may consider whether the laboratory has been previously inspected by FDA and found to be in compliance with CGMP.

Any alcohol (ethanol) or IPA that contains more than 630 ppm methanol is not consistent with this temporary policy and may be considered evidence of substitution and/or contamination. Hand sanitizers containing methanol-contaminated alcohol (ethanol) or IPA are subject to

[20] The chemical standards that have been established by ACS for reagents are not designed to determine the suitability of a chemical for human use. For example, the ACS monographs for ethanol and glycerin do not include any impurity specifications. Where an ingredient is described as meeting both ACS grade and the other standard(s) cited in this section (e.g., USP or FCC grade), use of that ingredient is consistent with this policy. If a firm wishes to use an ingredient that is described only as ACS grade, the firm should submit relevant information on the ingredient's concentration and impurity profile to COVID-19-Hand-Sanitizers@fda.hhs.gov with "*name of ingredient* DATA" in the subject line for FDA's assessment regarding the use of the ingredient under this policy.

[21] See footnote 13. See also FDA guidance for industry *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19)*.

[22] FDA's public database on inspection classifications provides the final classification of the most recent inspection and can be found at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database.

adulteration charges under the FD&C Act.[23] Such alcohol (ethanol) or IPA material should be destroyed, and the manufacturer should contact FDA regarding the material and its source.[24]

2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.[25] Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21, respectively, describe requirements pertaining to, and provide a number of formulas for, denaturing alcohol. These formulas for use in hand sanitizers under FDA's temporary policies include:[26]

    a. Formula No. 40A or No. 40B with or without the tert-butyl alcohol[27]
    b. Formula No. 3C (isopropyl alcohol[28])

    The alcohol also may be denatured with a formula using 3% triethyl citrate (w/w).[29]

Denaturing is critical because there have been reports of adverse events, including deaths, from ingestion of hand sanitizer. Most reports are from unintentional ingestion by young children.[30] The alcohol should be denatured at either (1) the point of production by the alcohol production firm or (2) the point of manufacture or compounding of the hand sanitizer. Attachment 2 provides more information on the formulas used to denature alcohol before it is used in alcohol-based hand sanitizers. Attachment 2 reproduces Appendix C from FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19).*

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[23] See, e.g., Sections 501(a)(2)(A), 501(a)(2)(B) and 501(d) of the FD&C Act (21 U.S.C. 351(a)(2)(A), 351(a)(2)(B) and 351(d)).

[24] Contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "METHANOL" in the subject line. For more information see https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitzers-methanol.

[25] See FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19).*

[26] FDA is continuing to evaluate other potential formulas for denaturing. Firms that wish to use different denaturants (bitterants) should contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "DENATURANTS REQUEST" in the subject line.

[27] While Alcohol and Tobacco Tax and Trade Bureau (TTB) Formula Nos. 40A and No. 40B set forth in 27 CFR 21.75 and 21.76 require the use of tert-butyl alcohol, modified versions of these formulas that do not contain tert-butyl alcohol are consistent with this policy and are authorized by TTB through June 30, 2021 for use in manufacturing hand sanitizer products and denatured alcohol for use in hand sanitizer without first obtaining formula approval from TTB. See https://www.ttb.gov/public-guidance/ttb-pg-2020-1b.

[28] Using technical grade isopropyl alcohol that meets the requirements of 27 CFR 21.113 as a denaturant in the preparation of the finished hand sanitizer product is consistent with this policy.

[29] We note that the use of the triethyl citrate (TEC) denaturant formula in the preparation of alcohol-based hand sanitizer is consistent with this policy and is authorized by TTB through June 30, 2021 for use in manufacturing hand sanitizer products and denatured alcohol for use in hand sanitizer without first obtaining formula approval from TTB. See https://www.ttb.gov/public-guidance/ttb-pg-2020-1b.

[30] Every month, there are hundreds of calls to Poison Control centers for unintentional ingestion of hand sanitizer. As indicated from data provided by the American Association of Poison Control Centers (AAPCC) in March 2020 (during the COVID-19 pandemic), calls to Poison Control centers related to hand sanitizer increased by 79 percent compared to March 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger.

3. The finished hand sanitizer product is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations:[31]
    a. Alcohol (ethanol) (formulated to 80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (formulated to 75%, v/v) in an aqueous solution. [32, 33]
    b. Glycerin (glycerol) (1.45% v/v)
    c. Hydrogen peroxide (0.125% v/v).[34]
    d. Sterile distilled water or boiled cold water.[35]

4. **The firm does not add other active or inactive ingredients, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.**

5. The firm pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. If using ethanol or IPA from another source, the firm has tested the active ingredient to ensure that the methanol content does not exceed 630 ppm. A simple record should be used to document key steps and controls to ensure each batch matches the formula developed for the drug product.

6. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.[36]

7. The firm uses the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.

8. The hand sanitizer product is produced as an aqueous solution and not as a gel, foam, or aerosol spray.[37] The firm packages the finished hand sanitizer product in packaging appropriate for

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[31] WHO's recommendations, titled "Guide to Local Production: WHO-recommended Handrub Formulations," are available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf.

[32] These percentages are consistent with WHO's recommended formulation specifications of 80% alcohol and 75% isopropyl alcohol. In addition, they are consistent with the range of percentages for final products in the1994 TFM (see also FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*).

[33] One benefit of FDA's policy relying on use of this particular aspect of the WHO formula is that minor errors in production are still likely to result in a finished hand sanitizer product that exceeds the CDC recommendations of at least 60% ethanol or 70% IPA (isopropanol) content (see FDA's 1994 TFM and the CDC Statement for Healthcare Personnel on Hand Hygiene during the Response to the International Emergence of COVID-19).

[34] Formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP or technical grade hydrogen peroxide, ensuring that the alcohol (ethanol or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol.

[35] Water that is boiled should be cold when used to prepare the finished hand sanitizer product.

[36] Facilities must prevent insanitary conditions under section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)).

[37] This policy does not apply to hand sanitizer gel or foam products because different or additional ingredients may impact the quality and potency of the product. This policy does not apply to aerosol sprays because aerosol sprays with propellent added to the formulation can result in altered potency of the finished hand sanitizer. Aerosol sprays with propellent outside

of the formulation (bag on valve) may have safety and potency concerns due to the increased flammability risks of ethanol in

liquid drug products that will seal sufficiently to prevent evaporation of the alcohol or IPA.[38] Manual pump sprays that seal sufficiently to prevent evaporation are consistent with this policy.

9. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethanol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethanol Formulation Health Care Personnel Hand Rub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand Rub Use).[39,40]

10. Firms register their facility and list these products in the FDA Drug Registration and Listing System (DRLS, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls).[41] Upon completion of registration and listing, firms receive automatic confirmation from the FDA and do not need to wait for a further communication from FDA before the firm can begin to distribute these products. FDA relies on registration and listing information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manage product recalls, among other important FDA public safety activities. Our help desk is standing by to assist with facilitating this process and can be contacted by sending an email to: edrls@fda.hhs.gov.

11. Firms have a mechanism to accept adverse event reports for any products they manufacture under this enforcement policy, and submit such adverse event reports to FDA (for more information, please see FDA's guidance on adverse event reporting requirements, https://www.fda.gov/media/77193/download).[42] This guidance on adverse event reporting advises that "for reporting purposes, an ICSR [individual case safety report] should describe the known product attributes (e.g., dosage form, strength, color, SKU, NDC, lot number)." To facilitate reporting of adverse events and investigation of root causes, the immediate package also includes a lot/control number.

This policy does not extend to other types of products, such as products: (1) that use active ingredients other than ethanol or isopropyl alcohol; (2) whose potency falls above or below the formulation described above; (3) that are marketed with claims that do not conform to the "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (e.g., persistence claims, pathogen-specific disease claims); (4) that are marketed with superiority claims; (5) that are surgical

an aerosol, risk of overspraying, variability of delivery of the product, rapid evaporation of alcohol, and inhalational toxicities.

[38] We note that hand sanitizer offered for transportation or transported in commerce may be subject to the applicable requirements of the U.S. Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171-180). These regulations include classification, packaging, marking, labeling and other requirements relevant to transportation. More information is available on the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration website at: https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations.

[39] The label should include the name and contact information of the manufacturer.

[40] See footnote 38.

[41] Every person required to register with the FDA must, at the time of initial registration, list all drugs manufactured,

prepared, propagated, compounded, or processed for commercial distribution. See Section 510(j)(1) of the FD&C Act (21 U.S.C. 360(j)(1)); see also 21 CFR 207.17 and 207.41. Firms that are required to register their foreign establishment with FDA must list all known importers in the United States in their registration in accordance with Section 510(i)(1)(A) of the FD&C Act. See also 21 CFR 207.25(h)(2).

[42] See Section 760 of the FD&C Act (21 U.S.C. 379aa).

hand rubs or patient antiseptic skin preparations; (6) whose labeling is false or misleading in any particular; or (7) that are alcohol-based hand sanitizer for which FDA has identified a safety concern, including those that are subject to an FDA import alert due to safety concerns. (See the following website for a list of all FDA import alerts https://www.accessdata.fda.gov/cms_ia/ialist.html)

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178

Except as described in this guidance, hand sanitizers imported into the United States must comply with all applicable requirements under the FD&C Act and the pertinent regulations found in Title 21 of the Code of Federal Regulations (21 CFR). For general information on human drug imports, please see https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports.

Attachment 1

Use of Fuel or Technical Grade Alcohol (Ethanol)[43]

Quality standards and specifications for alcohol used in pharmaceuticals (including hand sanitizers) are set by the USP and enforced by FDA pursuant to section 501(b) of the FD&C Act. Alcohol (ethanol) used in pharmaceuticals that does not meet the USP monograph is considered adulterated under section 501(b) of the FD&C Act. The April 15, 2020 update to this guidance on fuel or technical grade ethanol reflected FDA's experience in which data submitted by fuel ethanol manufacturers producing ethanol via fermentation and distillation indicated that at least some fuel ethanol products included harmful chemicals, including gasoline and benzene, which is a known human carcinogen (cancer-causing agent).These impurities would not be expected from a typical fermentation and distillation process but may be present due to the manufacturing environment (e.g., equipment, containers). In addition, FDA has received data that indicate that certain fuel ethanol products contain excessive levels of acetaldehyde, which appears to be a genotoxic carcinogen when in direct contact with tissues.[44]

Consumer and health care personnel safety is a top priority for FDA, and an important part of FDA's mission is to protect the public from harm, including as we seek to increase supply of hand sanitizer. We are aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers, and that the CDC recommends consumers use hand sanitizer
containing at least 60% alcohol when soap and water are unavailable.[45] Therefore, FDA is working withindustry to ensure that harmful levels of impurities are not present in ethanol used in hand sanitizer.

Upon further review of the data, we are temporarily providing flexibility with respect to certain impurities at the levels established in Table 1 and Table 2 below. Based on our review of available data,we have determined these interim impurity levels can be tolerated for a relatively short period of time, given the emphasis on hand hygiene during the COVID-19 public health emergency and to avoid exacerbating access issues for alcohol-based hand sanitizer.

Accordingly, during this public health emergency, FDA does not intend to take action against firms thatmanufacture fuel or technical grade ethanol for hand sanitizer that does not meet the USP or FCC requirements or firms that use such ethanol to prepare hand sanitizer on an interim basis, provided all other circumstances in the guidance are present, including the interim limitations on the impurity levelslisted below. FDA is continually assessing the needs and circumstances related to these temporary policies, including the use of fuel and technical grade ethanol in hand sanitizer, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw these policies as appropriate.

Accordingly, we are clarifying that fuel or technical grade ethanol that does not meet USP or FCCrequirements may be considered for use in hand sanitizer under this temporary policy only if the following circumstances are present:

[43] Ethanol that contains carcinogens or other harmful impurities at unacceptable levels poses a safety risk to consumers and health care personnel using hand sanitizers. Ethanol that contains harmful levels of impurities and hand sanitizer products containing such ethanol would be considered adulterated under the FD&C Act; products are adulterated if they are prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health (see section 501(a)(2)(A)).[44] The toxicology for acetaldehyde differs when ingested as part of an alcoholic beverage (versus applied to the skin as with hand sanitizer), in part due to the liver's metabolism of acetaldehyde.

[45] See https://www.cdc.gov/handwashing/hand-sanitizer-use.html.

- Fuel or technical grade ethanol does not contain gasoline or any of its components (e.g., n-heptane).

- Impurities meet the interim limits listed in Table 1 below and no other potentially harmful impurities are present other than those addressed in Table 1. If a firm wishes to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should testthe ethanol (or have a third party laboratory conduct testing) to identify the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment. These impurities and their interim limits in ethanol for use in hand sanitizer under this policy are provided in Table 1 below. These interim limits take into account the expected clinical usage and administration of hand sanitizers described under this temporary policy. We recommend using test methods described in USP.

Table 1

Impurity	Interim Limit under this policy
Methanol	NMT 630 ppm
Benzene	NMT 2 ppm
Acetaldehyde	NMT 50 ppm*
Acetal (1,1-diethoxyethane)	NMT 50 ppm
Sum of all other impurities	NMT 300 ppm

* Acetaldehyde appears to be genotoxic, and potentially carcinogenic, when in direct contact with tissues. Given the large number of applications of this product expected by consumers and health care personnel during the public health emergency, exposure to hand sanitizer with high levels of acetaldehyde poses a significant safety concern. We are aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers and that the CDC recommends consumers use hand sanitizer containing at least 60% alcohol when soap and water are

unavailable.[46] CDC recommends consumers use hand sanitizer containing at least 60% ethanol when soap and water are unavailable. Therefore, FDA is temporarily willing to consider ethanol containing acetaldehyde above that permitted by USP at an interim level no higher than 50 ppm, for use in hand sanitizer under this temporary policy. An interim upper limit of 50 ppm is based on available toxicity data for acetaldehyde consideringthe expected clinical usage and administration of hand sanitizers under this policy. FDA is continually assessing the needs and circumstances related to the COVID-19 temporary policies, including the use of ethanol containing acetaldehyde at an interim level no higher than 50 ppm, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw these policies as appropriate.

- In cases where fuel or technical grade ethanol that does not meet the interim limits in Table 1because the sum of all other impurities exceeds the interim limit of 300 ppm, all individual impurities are identified and meet the interim limits in Table 2 below.

[46] See https://www.cdc.gov/handwashing/hand-sanitizer-use.html.

The interim impurity limits provided in Table 2 are generally based on ICH Q3C *Guideline onImpurities: Guideline for Residual Solvents*, considering the expected clinical usage and administration that has been defined for hand sanitizers under this policy.

Table 2

Impurity	Interim Limit under this policy
Acetone	NMT 4400 ppm
n-propanol (1-propanol)	NMT 1000 ppm
Ethyl acetate	NMT 2200 ppm
Sec-butanol (2-butanol)	NMT 6200 ppm
Iso-butanol (2-Methyl-1-propanol)	NMT 21700 ppm
n-butanol (1-butanol)	NMT 1000 ppm
iso-amyl alcohol (3-Methyl-1-butanol)	NMT 4100 ppm
Amyl alcohol	NMT 4100 ppm

- For any impurity identified not listed in Table 1 or Table 2, the firm submits data with the level for each individual impurity with information regarding the safety of each impurity, if available,for FDA's assessment regarding whether the ethanol is suitable for use under this policy.[47]

[47] Submissions should be sent to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line forFDA's assessment regarding the use of the ethanol under this policy.

Attachment 2

From FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation IntoAlcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*: Appendix
C. Formulas That May Be Used To Denature Alcohol Before It Is Used in Alcohol-Based HandSanitizers (Antiseptic Hand Rubs)

Preferred Formulas

1. **27 CFR 21.76 Formula No. 40-B**

   To every 100 gallons of alcohol add:
   One-sixteenth avoirdupois ounce of denatonium benzoate,[48] N.F., and 1⁄8 gallon of tert-butylalcohol

OR

   To every 100 gallons of alcohol add:
   One-sixteenth avoirdupois ounce of denatonium benzoate,[49] N.F.[50]

Alternative Formulas

2. **27 CFR 21.75 Formula No. 40-A**

   To every 100 gallons of alcohol add:
   One pound of sucrose octaacetate and 1⁄8 gallon of tert-butyl alcohol

OR

   To every 100 gallons of
   alcohol add:One pound of
   sucrose octaacetate[51]

3. **27 CFR 21.37 Formula No. 3-C**

   To every 100 gallons of alcohol add:
   Five gallons of isopropyl alcohol[52]

4. **Formula using 3% triethyl citrate (w/w)**[53]

   To every 100 gallons of alcohol add:
   9239.5 g (20.4 pounds) triethyl citrate (USP or FCC grade)

[48] Denatonium benzoate can be added as either a solid or in liquid form, provided the added amount is calculated on a dry basis.

[49] See footnote 48.
[50] See footnote 27.
[51] See footnote 27.
[52] See footnote 28.
[53] See footnote 29.

Appendix A. Labeling for Ethanol Formulation Consumer Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic
80% Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s]	***Purpose***
Alcohol 80% v/v	Antiseptic

Use[s]
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.
Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Appendix B. Labeling for Isopropyl Alcohol Formulation Consumer Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75% Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] ***Purpose***
Isopropyl alcohol 75% v/v .....Antiseptic

Use[s]
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame
Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney and other subject matter advisors for any specific guidance on legal or regulatory compliance.

Appendix C. Labeling for Ethanol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s]	***Purpose***
Alcohol 80% v/v	Antiseptic

Use[s]
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings
For external use only. Flammable. Keep away from heat or flame
Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney and other subject matter advisors for any specific guidance on legal or regulatory compliance.

Appendix D. Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] ***Purpose***
Isopropyl alcohol 75% v/v..... Antiseptic

Use[s]
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings
For external use only. Flammable. Keep away from heat or flame
Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney and other subject matter advisors for any specific guidance on legal or regulatory compliance.

Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2020
Updated February 10, 2020
Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1106 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA web page titled " COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19, and from the FDA web page "Hand Sanitizers | COVID-19" *available at*: http://wcms-internet.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19. You may also send an e-mail request to druginfo@fda.hhs.gov to receive a copy of the guidance. Please include the document number FDA-2020-D-1106 and complete title of the guidance in the request.

Questions

For questions regarding this document, contact FDA at: COVID-19-Hand-Sanitizers@fda.hhs.gov.

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Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United Statesfrom emerging infectious diseases, such as the Coronavirus Disease 2019 (COVID-19) pandemic. FDAis committed to providing timely guidance to support continuity and response efforts to this pandemic.

FDA is issuing this guidance in response to a number of queries from entities that are not currentlyregistered drug manufacturers that would like to produce alcohol (ethanol)[2] for incorporation into alcohol-based hand sanitizers. This policy does not extend to other types of active ingredients for incorporation into alcohol-based hand sanitizers, such as isopropyl alcohol.[3]

This document updates the guidance of the same title issued in August 2020 (previous versions June, April and March 2020). The Agency is issuing this guidance to communicate its policy for the temporary manufacture of ethanol products by firms that manufacture alcohol for incorporation into alcohol-based hand sanitizer products under the circumstances described in this guidance (alcohol production firms)[4] for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020,[5] including any renewals made by the HHS Secretaryin accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). At such time when the public health emergency is over, as declared by the Secretary, FDAintends to discontinue this enforcement discretion policy and withdraw this guidance. FDA is

[1] This guidance has been prepared by the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] *Alcohol* is defined as ethanol (ethyl alcohol) in the United States Pharmacopeia and National Formulary (USP-NF) and as ethyl alcohol in the Food Chemical Codex (FCC). The USP and FCC documents, known as "monographs," establish test methods and acceptance criteria for identity and purity. The USP and FCC definitions of *alcohol* does not include isopropyl alcohol. Unless otherwise specified, and consistent with USP and FCC monographs, references in this guidance to "alcohol" refer to ethanol.

[3] Isopropyl alcohol is manufactured by different chemical processes and is therefore not discussed in this guidance.

[4] This includes firms that repackage or relabel ethanol manufactured consistent with FDA policies outlined in this guidance.[5] The HHS Public Health Emergency Declaration is available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

continually assessing the needs and circumstances related to this temporary policy, and as relevant needsand circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25,2020 (85 FR 16949), titled "Process for Making Available Guidance Documents Related to CoronavirusDisease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something issuggested or recommended, but not required.

II. BACKGROUND

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Secretary of HHS declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[6] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[7]

We understand that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers. We are also aware of reports that some consumers are producing hand sanitizers for personal use in their homes; the Agency lacks verifiable information on the methods being used to prepare such products and whether they are safe for use on human skin. To enhance the availability of hand sanitizer products, FDA has issued a guidance for industry entitled *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency* (March 2020, updated March 27, 2020, April 15, 2020, June 1, 2020, August7, 2020, and February 10, 2021) (compounding guidance) that describes the Agency's policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State or territory-licensed pharmacies or Federal facilities and registered outsourcing facilities.[8] FDA has also

[6] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. [7] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar.13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national- emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
[8] The compounding guidance is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

issued a guidance for industry entitled *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* (March 2020, updated March 27, 2020, April 15, 2020, June 1, 2020, August 7, 2020, and February 10, 2021) that describes the Agency's temporary policy for preparation of certain alcohol-based hand sanitizer products by firmsthat register as an over-the-counter (OTC) drug manufacturer, re-packager, or re-labeler to prepare alcohol-based hand sanitizers.[9]

I. DISCUSSION

In response to the demand for alcohol-based hand sanitizers and their active ingredient, alcohol, certain entities that are not currently regulated by FDA as drug manufacturers have requested guidance on the preparation and distribution of alcohol for incorporation into hand sanitizer products for the public's use.

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against alcohol production firms[10] that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as theactive pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use ashealth care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

1. To meet component quality requirements for hand sanitizer production, the alcohol manufacturedas an API is not less than 94.9% ethanol by volume.[11,12]

2. Any water used to adjust the finished ethanol content in the alcohol API is sterile (e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP). Water is used as quickly as possible after it is rendered sterile or purified.

Additional Considerations for Alcohol (Ethanol):

[9] This guidance is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during.

[10] Specifically, FDA does not intend to take action against alcohol production firms for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. 247d(a)(2)), for violations of sections 501(a)(2)(B), 501(b), 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 351(b), 352(f)(1), 355, or 360eee-1))), provided circumstances described in this guidance are present. These circumstances include (but are not limited to) preparation of ethanol using only the ingredients and formulas set forth in this guidance. FDA plans to continue to sample hand sanitizerproducts at the border and in distribution in the U.S. for quality issues, including potential contamination and impurity levels.

[11] This is consistent with the United States Pharmacopoeia (USP) and Food Chemical Codex (FCC) grade requirements for purity. Lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the content is sufficient to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v, as described in the FDA guidance *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*.

[12] Alcohol (ethanol) used for this purpose is derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes is used only if it meets USP or FCC grade.

Alcohol (ethanol) [13] that is produced using fermentation and distillation processes typically usedfor consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer, provided the alcohol meets the interim impurity levels inAttachment 1, Table 1.[14]

Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if itmeets USP or FCC[15] grade.

Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) maybe considered for use in hand sanitizer provided the following circumstances are present:

(i) the alcohol is produced using fermentation and distillation processes typically used forconsumable goods, and no other additives or other chemicals have been added to the ethanol;

(ii) the alcohol meets USP or FCC[16,17] grade requirements or the conditions in Attachment1; and,

(iii)the alcohol has been screened for any other potentially harmful impurities not specifiedin the USP or FCC requirements but potentially present based on the specific manufacturing environment.[18]

Ingredients that are described as only meeting American Chemical Society (ACS) gradestandards should generally not be used in hand sanitizers.[19]

Additional Considerations for Testing Stemming from Recent Methanol Substitution orContamination in Hand Sanitizers

Recent FDA sampling and test results demonstrating methanol substitution for ethanol in

hand sanitizer products have raised serious safety concerns. Substantial methanol exposure can result

[13] The discussion concerning alcohol (ethanol) in this guidance is limited to ethanol used as an active pharmaceutical ingredient (API) for hand sanitizer manufactured as part of the temporary policies outlined in this guidance. FDA's intent to not take action with regard to alcohol meeting the circumstances described in this guidance does not reflect the risk-benefit calculus that FDA would find acceptable outside of this public health emergency and temporary policies.
[14] Ethanol made using wet milling, fermentation, and distillation processes used for consumable goods (like alcoholic beverages made by distilleries), generally does not contain impurities above the limits listed in Attachment 1. However, all ethanol made for use in hand sanitizer should meet the limits in Attachment 1, if tested.
[15] FCC grade alcohol should be tested for impurities using the methods recommended in USP and confirmed to meet thelimits in Attachment 1, Table 1.
[16] See note 15.
[17] USP has made available to the public materials related to hand sanitizer ingredients, including monographs and test methods at https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-hand-sanitizer-ingredients.pdf.[18] Special caution should be taken to ensure any other chemicals on site are not introduced into the ethanol either intentionally or via cross-contamination.
[19] The chemical standards that have been established by ACS for reagents are not designed to determine the suitability of achemical for human use. For example, the ACS monographs for ethanol and glycerin do not include any impurity specifications. Where an ingredient is described as meeting both ACS grade and the other standard(s) cited in this section (e.g., USP or FCC grade), use of that ingredient is consistent with this policy. If a firm wishes to use an ingredient that is described only as ACS grade, the firm should submit relevant information on the ingredient's concentration and impurity profile to COVID-19-Hand-Sanitizers@fda.hhs.gov with "*name of ingredient* DATA" in the subject line for FDA's assessment regarding the use of the ingredient under this policy.

in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system, or death. Although all persons using these products on their handsare at risk, adolescents and adults who drink these products as an alcohol (ethanol) substitute andyoung children who accidentally ingest these products are most at risk for methanol poisoning.
Accordingly, methanol cannot safely be used as an ingredient, or as a denaturant, in hand sanitizer. Any alcohol (ethanol) found to contain more than 630 ppm methanol is not consistent with this temporary policy and may be considered evidence of substitution and/or contamination.Hand sanitizers containing methanol-contaminated alcohol (ethanol) are subject to adulteration charges under the FD&C Act.[20] Such alcohol (ethanol) material should be destroyed, and the manufacturer should contact FDA regarding the material and its source.[21]

2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production ofthe finished hand sanitizer product. Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21, respectively, describe requirements pertaining to, and provide a numberof formulas for, denaturing alcohol. These formulas for use in hand sanitizers under FDA's temporary policies are included in Appendix C of this document and include:[22]

    a. Formula No. 40A or No. 40B with or without the tert-butyl alcohol[23]

b. Formula No. 3C (isopropyl alcohol).[24]

The alcohol also may be denatured with a formula using 3% triethyl citrate (w/w).[25]

Denaturing is critical because there have been reports of adverse events, including deaths, from ingestion of hand sanitizer. Most reports are for unintentional ingestion in young children.[26] The

[20] See, e.g., Sections 501(a)(2)(A), 501(a)(2)(B) and 501(d) of the FD&C Act (21 U.S.C. 351(a)(2)(A), 351(a)(2)(B) and 351(d)). See also FDA guidance for industry *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19)*.

[21] Contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov with "METHANOL" in the subject line. For more informationsee https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitzers-methanol.

[22] FDA is continuing to evaluate other potential formulas for denaturing and will update Appendix C as we conduct thatanalysis. Firms that wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand- sanitizers@fda.hhs.gov.

[23] While Alcohol and Tobacco Tax and Trade Bureau (TTB) Formula Nos. 40A and No. 40B set forth in 27 CFR 21.75 and 21.76 require the use of tert-butyl alcohol, modified versions of these formulas that do not contain tert-butyl alcohol are consistent with this policy and are authorized by TTB through June 30, 2021 for use in manufacturing hand sanitizer products and denatured alcohol for use in hand sanitizer without first obtaining formula approval from TTB. See https://www.ttb.gov/public-guidance/ttb-pg-2020-1b.

[24] Using technical grade isopropyl alcohol that meets the requirements of 27 CFR 21.113 as a denaturant is consistent with this policy.

[25] We note that the use of the triethyl citrate (TEC) denaturant formula in the preparation of ethanol for use in alcohol-based hand sanitizer is consistent with this policy and is authorized by TTB through June 30, 2021 for use in manufacturing hand sanitizer products and denatured alcohol for use in hand sanitizer without first obtaining formula approval from TTB. See https://www.ttb.gov/public-guidance/ttb-pg-2020-1b.

[26] Every month, there are hundreds of calls to Poison Control centers for unintentional ingestion of hand sanitizer. As indicated from data provided by the American Association of Poison Control Centers (AAPCC), in March 2020 (during theCOVID-19 pandemic), calls to Poison Control centers related to hand sanitizer increased by 79 percent compared to Marchof 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger.

alcohol should be denatured at either (1) the point of production by the alcohol production firmor (2) the point of manufacture or compounding of the hand sanitizer, with the alcohol intendedfor incorporation into a finished product labeled accurately as "denatured" or "undenatured" accordingly.

Beyond alcohol, water, and denaturants (if added at the point of production), the alcohol production firm does not add other ingredients. Different or additional ingredients in theAPI may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.

3. The alcohol production firm ensures the ethanol content in the finished API before being denatured is at least 94.9% by volume[27] (see United States Pharmacopeia National Formulary [USP-NF] or Food Chemical Codex [FCC])). If the alcohol is to be distributed to another firmfor producing the hand sanitizer, it is labeled with the ethanol content determined by an appropriate test so that the hand sanitizer can be

reliably produced at the intended labeled strength. A simple record should be used to document key steps and controls.

4. The alcohol is prepared under sanitary conditions and equipment used is well maintained and fitfor this purpose.[28]

5. The alcohol production firm uses the most accurate method of analysis available at the site for verification of ethanol content in a sample before each batch is released for distribution or for usein producing the hand sanitizer. Methods can include gas chromatography (GC), specific gravity(e.g., alcoholmeter, hydrometer, pycnometer, or gravity density meter), or another test that is at least as accurate. The sample tested can be from the final API before packaging (if distributed asan API) or before actual use in producing the hand sanitizer.

6. The alcohol API, if distributed to other producers, is labeled consistent with the attached labelingin Appendices A and B (Labeling for Undenatured/Denatured Alcohol to be used for incorporation into hand sanitizers).

7. Alcohol production firms register their facility and list these products in the FDA Drug Registration and Listing System (DRLS, https://www.fda.gov/drugs/guidance-compliance- regulatory-information/drug-registration-and-listing-system-drls-and-edrls).[29] Upon completion of registration and listing, firms receive automatic confirmation from FDA and do not need to wait for further communication from FDA before the firm can begin to distribute these products. FDA relies on registration and listing information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manageproduct recalls, among other important FDA public safety activities. Our help desk is standing by to assist with facilitating this process and can be contacted by sending an emailto: edrls@fda.hhs.gov.

[27] Or of sufficient content to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v.

[28] Facilities must prevent insanitary conditions under section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)).

[29] Every person required to register with the FDA must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. See Section 510(j)(1) of the FD&C Act (21 U.S.C. 360(j)(1)); see also 21 CFR 207.17 and 207.41). Firms that are required to register their foreign establishment with FDA must list all known importers in the United States in their registration in accordance with Section 510 (i)(1)(A) of theFD&C Act. See also 21 CFR 207.25(h)(2).

If alcohol production firms receive adverse event reports, they are encouraged to submit them toFDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

This policy does not extend to alcohol-based hand sanitizer for which FDA has identified a safety concern, including those that are subject to an FDA import alert due to safety concerns. (See the following website for a list of all FDA import alerts https://www.accessdata.fda.gov/cms_ia/ialist.html).Except as described in this guidance, alcohol imported into the United States must comply with all applicable requirements under the FD&C Act and the pertinent regulations found in Title 21 of the Codeof Federal Regulations (21 CFR). For general information on human drug imports, please see https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports

Attachment 1

Use of Fuel or Technical Grade Alcohol (Ethanol)[30]

Quality standards and specifications for alcohol used in pharmaceuticals (including hand sanitizers) are set by the USP and enforced by FDA pursuant to section 501(b) of the FD&C Act. Alcohol (ethanol) used in pharmaceuticals that does not meet the USP monograph is considered adulterated under section 501(b) of the FD&C Act. The April 15, 2020 update to this guidance on fuel or technical grade ethanol reflected FDA's experience in which data submitted by fuel ethanol manufacturers producing ethanol via fermentation and distillation indicated that at least some fuel ethanol products included harmful chemicals, including gasoline and benzene, which is a known human carcinogen (cancer-causing agent).These impurities would not be expected from a typical fermentation and distillation process but may be present due to the manufacturing environment (e.g., equipment, containers). In addition, FDA has received data that indicate that certain fuel ethanol products contain excessive levels of acetaldehyde, which appears to be a genotoxic carcinogen when in direct contact with tissues.[31]

Consumer and health care personnel safety is a top priority for FDA, and an important part of FDA's mission is to protect the public from harm, including as we seek to increase supply of hand sanitizer. We are aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers, and that the CDC recommends consumers use hand sanitizer containing at least 60% alcohol when soap and water are unavailable.[32] Therefore, FDA is working withindustry to ensure that harmful levels of impurities are not present in ethanol used in hand sanitizer.

Upon further review of the data, we are temporarily providing flexibility with respect to certain impurities at the levels established in Table 1 and Table 2 below. Based on our review of available data,we have determined these interim impurity levels can be tolerated for a relatively short period of time given the emphasis on hand hygiene during the COVID-19 public health emergency and to avoid exacerbating access issues for alcohol-based hand sanitizer.

Accordingly, during this public health emergency, FDA does not intend to take action against firms thatmanufacture fuel or technical grade ethanol for hand sanitizer that does not meet the USP or FCC requirements or that use such ethanol to prepare hand sanitizer, provided all other circumstances in the guidance are present, including the interim limitations on the impurity levels listed below. FDA is continually assessing the needs and circumstances related to these temporary policies, including the useof fuel and technical grade ethanol in hand sanitizer, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw these policies as appropriate.

[30] Ethanol that contains carcinogens or other harmful impurities at unacceptable levels poses a safety risk to consumers and health care personnel using hand sanitizers. Ethanol that contains harmful levels of impurities and hand sanitizer products containing such ethanol would be considered adulterated under the FD&C Act; products are adulterated if they are prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health (see section 501(a)(2)(A)).[31] The toxicology for acetaldehyde differs when ingested as part of an alcoholic beverage (versus applied to the skin as with hand sanitizer), in part due to the liver's metabolism of acetaldehyde.

[32] See https://www.cdc.gov/handwashing/hand-sanitizer-use.html.

Accordingly, we are clarifying that fuel or technical grade ethanol that does not meet USP or FCCrequirements may be considered for use in hand sanitizer under this temporary policy only if the following circumstances are present:

- Fuel or technical grade ethanol does not contain gasoline or any of its components (e.g., n-heptane).

- Impurities meet the interim limits listed in Table 1 below and no other potentially harmful impurities are present other than those addressed in Table 1. If a firm wishes to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should testthe ethanol (or have a third party laboratory conduct testing) to identify the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment. These impurities and their interim limits in ethanol for use in hand sanitizer under this policy are provided in Table 1 below. These interim limits take into account the expected clinical usage and administration of hand sanitizers described under this temporary policy. We recommend using test methods described in USP.

Table 1

Impurity	Interim Limit under this policy
Methanol	NMT 630 ppm
Benzene	NMT 2 ppm
Acetaldehyde	NMT 50 ppm*
Acetal (1,1-diethoxyethane)	NMT 50 ppm
Sum of all other impurities	NMT 300 ppm

*Acetaldehyde appears to be genotoxic, and potentially carcinogenic, when in direct contact with tissues. Given the large number of applications of this product expected by consumers and health care personnel during the public health emergency, exposure to hand sanitizer with high levels of acetaldehyde poses a significant safety concern. We are aware that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers and that the CDC recommends consumers use hand sanitizer containing at least 60% alcohol when soap and water are unavailable.[33] CDC recommends consumers use hand sanitizer containing at least 60% ethanol when soap and water are unavailable. Therefore, FDA is temporarily willing to consider ethanol containing acetaldehyde above that permitted by USP at an interim level no higher than 50 ppm, for use in hand sanitizer under this temporary policy. An interim upper limit of 50 ppm is based on available toxicity data for acetaldehyde considering

the expected clinical usage and administration of hand sanitizers under this policy. FDA is continually assessing the needs and circumstances related to the COVID-19 temporary policies, including the use of ethanol containing acetaldehyde at an interim level no higher than 50 ppm, and as relevant needs and circumstances evolve, FDA intends to update, modify,or withdraw these policies as appropriate.

[33] See https://www.cdc.gov/handwashing/hand-sanitizer-use.html.

- In cases where fuel or technical grade ethanol that does not meet the interim limits in Table 1because the sum of all other impurities exceeds the interim limit of 300 ppm, all individual impurities are identified and meet the interim limits in Table 2 below.

  The interim impurity limits provided in Table 2 are generally based on ICH Q3C *Guideline onImpurities: Guideline for Residual Solvents*, considering the expected clinical usage and administration that has been defined for hand sanitizers under this policy.

Table 2

Impurity	Interim Limit under this policy
Acetone	NMT 4400 ppm
n-propanol (1-propanol)	NMT 1000 ppm
Ethyl acetate	NMT 2200 ppm
Sec-butanol (2-butanol)	NMT 6200 ppm
Iso-butanol (2-Methyl-1-propanol)	NMT 21700 ppm
n-butanol (1-butanol)	NMT 1000 ppm
iso-amyl alcohol (3-Methyl-1-butanol)	NMT 4100 ppm
Amyl alcohol	NMT 4100 ppm

- For any impurity identified not listed in Table 1 or Table 2, the firm submits data with the level for each individual impurity with information regarding the safety of each impurity, if available,for FDA's assessment regarding whether the ethanol is suitable for use under this policy.[34]

[34] Submissions should be sent to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line for FDA's assessment regarding the use of the ethanol under this policy.

Appendix A. Labeling for Undenatured Alcohol for Incorporation Into Alcohol-Based Hand Sanitizers (Antiseptic Hand Rubs) [29]

PRINCIPAL DISPLAY PANEL ADHERED TO EACH CONTAINER DISTRIBUTED

UNDENATURED Alcohol

Ethanol (ethyl alcohol) XX%,
as determined by <Insert test method>

[Insert Volume of Product in Milliters (mL) or Liters]

For use in production of hand sanitizers (antiseptic hand rubs) only. Denaturing required during hand sanitizer production.

Non-potable.

Manufactured by:
<Name of Manufacturer>
<Physical Address of Manufacturing site>
<Contact phone and email address>

Manufacturer FDA registration number (DUNS):

Manufactured on <Insert Date>

35 Entities regulated by the U.S. Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB) should check with TTB for additional labeling requirements.

Appendix B. Labeling for Denatured Alcohol for Incorporation Into Alcohol-Based Hand Sanitizers (Antiseptic Hand Rubs) [30]

PRINCIPAL DISPLAY PANEL ADHERED TO EACH CONTAINER DISTRIBUTED

DENATURED Alcohol [insert process/denaturing compound]

Ethanol (ethyl alcohol) XX%,
as determined by <Insert test method>

[Insert Volume of Product in mL or Liters]

For use in production of hand sanitizers (antiseptic hand rubs) only.

Non-potable.

Manufactured by:
<Name of Manufacturer>
<Physical Address of Manufacturing site>
<Contact phone and email address>

Manufacturer FDA registration number (DUNS):

Manufactured on <Insert Date>
Released on <Insert Date>
Batch Number

36 Entities regulated by the U.S. Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB) should check with TTB for additional labeling requirements.

Appendix C. Formulas That May Be Used To Denature Alcohol Before It Is Used in Alcohol Based Hand Sanitizers (Antiseptic Hand Rubs)

Preferred Formula

1. **27 CFR 21.76 Formula No. 40-B**

   To every 100 gallons of alcohol add:

   One-sixteenth avoirdupois ounce of denatonium benzoate,[37] N.F., and 1⁄8 gallon of tert-butyl alcohol

OR

   To every 100 gallons of alcohol add:

   One-sixteenth avoirdupois ounce of denatonium benzoate,[38] N.F. [39]

Alternative Formulas

2. **27 CFR 21.75 Formula No. 40-A**

   To every 100 gallons of alcohol add:
   One pound of sucrose octaacetate and 1⁄8 gallon of tert-butyl alcohol

OR

   To every 100 gallons of
   alcohol add: One pound of
   sucrose octaacetate[40]

3. **27 CFR 21.37 Formula No. 3-C**

   To every 100 gallons of alcohol add:
   Five gallons of isopropyl alcohol[41]

4. **Formula using 3% triethyl citrate (w/w)[42]**

   To every 100 gallons of alcohol add:
   9239.5 g (20.4 pounds) triethyl citrate (USP or FCC grade)

[37] Denatonium benzoate can be added as either a solid or in liquid form, provided the added amount is calculated on a dry basis.
[38] See footnote 37.
[39] See footnote 23.
[40] See footnote 23.
[41] See footnote 24.
[42] See footnote 25.

APPENDIX B-3: FDA DRUG REGISTRATION & LISTING SYSTEM GUIDE

Helpful Hints for the FDA Registration Process for US-based Craft Distilleries Making Alcohol-Based

Hand Sanitizer

Make sure you have thoroughly reviewed the FDA's guidance at: https://www.fda.gov/media/136289/download before you start

1. You must have a Dun & Bradstreet number in order to use the FDA's system. If you don't have one, you will need one before you can proceed. Go to the D&B website and go from there.

2. Request an access code on the FDA's CDER website, (link is in the FDA guidance) then go in and register your establishment.
    a. The BUSINESS OPERATION type will probably be: MANUFACTURE MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NOT PRODUCED UNDER AN APPROVED DRUG APPLICATION OR UNDER A MONOGRAPH

3. After that submission is accepted (which means you are done with that step), go back to the Home

Screen into "Edit User Profile" on the bottom left side, and ADD the selections for:

a. FORM ACCESS
    i. Labeler Code Request/Activation
b. PRODUCT LISTINGS
    i. HUMAN OTC DRUG LABEL

4. Then go back to the Home screen, and complete a Labeler Code Request submission - it should be pretty straightforward.

5. Once you receive confirmation of the fact that you have been given a Labeler Code (which will come by email to you, clearly marked), then:

6. Create a new Labeler Code Request (select "Complete New Version" from the top of the screen once you open the one you have already submitted) - add your labeler code to the box where is goes. Submit that one too.

7. Once that one is accepted, then you can do your Product Listing Request.
    a. You need to link in the establish you already created, then

b. Add a product
    i. The NDC Code here will be 8 digits: 5 digits - 3 digits
        - The 5 digits is your Labeler Code from the FDA
        - The 3 digit number is one you assign, e.g., 001 or 101 – it is used for tracking purposes and does not have a specific meaning
    ii. Non-Proprietary Name: Hand Sanitizer
    iii. Dosage Form: Liquid
    iv. Route of Administration: Cutaneous or something else that indicates rub on skin
    v. Marketing Category: unapproved drug other
c. List all the ingredients

i. Only use the WHO approved recipe and ingredients, and be specific

ii. For active ingredient, list % - so if 80% ABV ethanol in finished product, choose "ALCOHOL" as the ingredient and put 100 mL for the Denominator and 80 mL for the Strength

d. In the packaging section, add a line for each size you are offering, e.g.,
    i. NDC is 5 digits + 3 digits + 01 for the first size
    ii. NDC is 5 digits + 3 digits + 02 for the second size
    iii. Quantity and Unit of Measure here is for the individual package size, expressed in mL – so 59 ml, 1000 ml, etc.

e. Then fill out the CONTENT OF LABELING Tab. One recently approved submission of this type included the following items from the list. Each was completed with the information stipulated in the language provided by the FDA in the guidance they published for this with the required label information:
    i. Warnings: [WARNINGS SECTION]
    ii. Active Ingredient(s) [OTC - ACTIVE INGREDIENT SECTION]
    iii. Do not use [OTC - DO NOT USE SECTION]
    iv. [OTC - WHEN USING SECTION]
    v. [OTC - STOP USE SECTION]
    vi. [OTC - KEEP OUT OF REACH OF CHILDREN SECTION]
    vii. Inactive Ingredients [INACTIVE INGREDIENT SECTION]
    viii. Other Information [OTHER SAFETY INFORMATION]
    ix. Use(s) [INDICATIONS & USAGE SECTION]
    x. Directions [DOSAGE & ADMINISTRATION SECTION]
    xi. NSD Hand Sanitizer [PACKAGE LABEL.PRINCIPAL DISPLAY PANEL]
    xii. Use(s) [OTC - PURPOSE SECTION]

Once you have completed this, use the Submission Validation process, and read the errors carefully. Usually there is some hint in there about what is wrong.
Hopefully you get to where you can hit "Ready for Submission" on that last one, and then send it in!

APPENDIX C-1: DOT PHMSA HAND SANITIZER TEMPORARY POLICY

Temporary Policy for the Transportation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)
Notice of Enforcement Discretion
U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration Office of Hazardous Materials Safety

April 10, 2020

I. INTRODUCTION

The U.S. Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) plays a leading role in ensuring the safe transportation of hazardous materials throughout the United States by all modes. Because of the ongoing Coronavirus Disease 2019 (COVID-19) public health emergency, there has been a notable increase in the demand for products used for sanitization purposes - many of which contain alcohol and may be considered a hazardous material for transportation as defined by the Hazardous Materials Regulations (HMR, 49 CFR Parts 171-180). PHMSA is aware of multiple companies throughout the country that will be producing products such as hand sanitizer and other alcohol- based products to help respond to the COVID-19 public health emergency under specific FDA guidance. To facilitate the increased availability of products during this public health emergency, PHMSA intends to provide temporary relief from certain HMR requirements while continuing to maintain an appropriate level of safety for companies that are producing products under the FDA guidance. The relief provided herein is for the highway mode only. Shipments by other modes of transportation must meet all requirements of the hazardous materials regulations unless relief has been provided elsewhere.

II. BACKGROUND

As specified in the Food and Drug Administration's (FDA) guidance document "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry"1, there is currently a public health emergency of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID- 19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.

Hand hygiene is an important part of the U.S. response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent ethanol or 70 percent isopropanol.

III. DISCUSSION

Alcohol-based products, such as hand sanitizers, are typically classified according to the HMR as a Class 3, Flammable Liquid. The HMR defines Flammable Liquids as a liquid having a flash point of 60 °C (140 °F) or below (see 49 CFR 173.120). The provisions of the HMR include requirements applicable to classifying the material, selecting an appropriate packaging, and communicating the hazard through labeling, marking, placarding, and shipping papers. The requirements that apply vary depending on the concentrations of alcohol and the quantity and form of the product. For instance, 49 CFR § 173.150(g), *Limited quantities of retail products containing ethyl alcohol*, establishes provisions applicable to beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol. Specifically, these provisions apply to such products classed as a flammable liquid or flammable solid and containing not more than 70 percent ethyl alcohol by volume for liquids. Typically, hand sanitizers are transported in accordance with these provisions. If offered for transportation in the quantities and packagings that are specified in§ l 73.150(g), hand sanitizers are excepted from all other requirements of the HMR. During this public health emergency, PHMSA is providing relief for additional packaging configurations and sizes to facilitate transportation of these vital commodities from facilities operating under the FDA guidance.

(1 FDA "Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)". https://www.fda.gov/regulatory-information/search-fda- guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer- products-during
Docket#: FDA-2020-D-1106)

IV. RELIEF PROVIDED FOR THE TRANSPORTATION OF HAND SANITIZERS PRODUCED IN ACCORDANCE WITH FDA GUIDANCE

PHMSA is providing the relief outlined below to companies that are producing hand sanitizer under the FDA guidance document referenced above to address the current COVID-19 public health emergency and companies that subsequently transport the hand sanitizer. PHMSA will not take enforcement action for violations of the hazardous materials regulations if the procedures below are followed.

A. SMALL QUANTITIES OF HAND SANITIZERS CONTAINING ETHYL ALCOHOL OR ISOPROPYL ALCOHOL

This relief applies only to transportation by highway, and does not apply to shipments by air, vessel, or rail. Specifically, the procedures below apply to transportation of hand sanitizers by private, common, or contract carriers by motor vehicle. PHMSA will not take enforcement action for violations of the HMR when the following procedures are followed:

1. Packages contain hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.

2. Packagings are leak tight and securely closed, secured against shifting, and protected

against damage.

3. The material is contained in a packaging having a capacity not over 8 gallons.

4. For inner packagings not exceeding 1 gallon:

   a. Packages are a combination package and the inner receptacle containing the liquid is placed inside an outer packaging where the inner packagings are secured and cushioned within the outer packaging to prevent breakage, leakage, and movement and inner packagings are packed with package closures in an upright orientation.

   b. The net contents of all inner packagings in any single outer packaging do not exceed 8 gallons (e.g., 8 x 1 gallon packages).

   c. The company name and the words "Sanitizer - Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" are marked on the outer package and, if applicable, the overpack. In addition, the FDA label is acceptable as an alternative marking provided it is visible in transportation. (See Appendix A through D of the FDA Guidance at: https://www.fda.gov/media/136289/download)

5. Packages exceeding a capacity of 1 gallon:

   a. Are overpacked in crates, cages, carts, boxes, or similar overpacks.

   b. Packages are secured in the transport vehicle in such a way as to prevent breakage, leakage, and movement. Packages are packed package closures in an upright orientation.

   c. The company name and the words "Sanitizer - Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" is marked on the outside of the single package and the overpack. In addition, the FDA label is acceptable as an alternative marking provided it is visible in transportation. (See Appendix A through D of the FDA Guidance at: https://www.fda.gov/media/136289/download)

B. TRANSPORTATION OF LARGER QUANTITIES OF HAND SANITIZERS

PHMSA is aware that there may be a need to transport quantities greater than 8 gallons per package, for example, in drums or other packagings. To facilitate, PHMSA is providing relief from the existing provisions of the HMR. This relief applies for transportation by private or contract motor carrier, or common carrier in a vehicle under exclusive use for such service. This relief does not apply to shipments by air, vessel, or rail. PHMSA will not take enforcement action for failing to register with PHMSA irrespective of the quantity of hand sanitizer offered for transportation or transported. In addition, PHMSA will not take enforcement action for violations of the HMR for shipments of packagings containing more than 8 gallons but not more than 119 gallons of sanitizer, if the following procedures are followed:

1. The packaging contains hand sanitizer containing either ethyl alcohol or isopropyl alcohol at a concentration not to exceed 80 percent.

2. Packagings is leak tight and securely closed, secured against shifting, and protected against damage.

3. The material is be contained in a packaging having a capacity not over 119 gallons.

4. The packaging must be DOT or United Nations (UN) specification packaging (drums, jerricans, etc.) described in § 173.202 meeting the Packing Group (PG) II performance standard.

5. The packages are be secured to prevent breakage, leakage, and movement during the course of transportation.

6. The registration requirements found in Subpart G of Part 107 will not apply.

7. Offerers and transporters of this material provide their employees handling this material with the applicable training materials prepared by PHMSA, in lieu of the training required by 49 CFR Part 172, Subpart H (see LINK).

8. Each package is labeled with a flammable liquid label (see§ 172.419).

9. The bill of lading or shipping paper includes the following basic description "UNl 987, Alcohols, n.o.s., Class 3, PG II" and indicate the number, type, and capacity of packages offered (for example, 25 drums - 119 gallons ea.).

10. A copy of the Emergency Response Guidebook Guide number 127 (attached) accompanies the shipment.

11. If the aggregate gross quantity in a transport vehicle or freight container exceeds 1,001 pounds, the vehicle is placarded as required by the HMR (see 49 CFR Part 172, Subpart F for Placarding requirements).

12. All motor carriers comply with§ 177.804.

V. WITHDRAWAL OF RELIEF

This Notice of Enforcement Discretion expires 3 months from its date of issuance or until the time when the public health emergency is over, whichever is sooner.

Issued April 10, 2020, in Washington, D.C.

William S. Schoonover Associate Administrator
for Hazardous Materials Safety

GUIDE 127
FLAMMABLE LIQUIDS (Polar/ Water-Miscible)

POTENTIAL HAZARDS

FIRE OR EXPLOSION

- HIGHLY FLAMMABLE: Will be easily ignited by heat, sparks or flames.
- Vapors may form explosive mixtures with air.
- Vapors may travel to source of ignition and flash back.
- Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks).
- Vapor explosion hazard indoors, outdoors or in sewers.
- Those substances designated with a P may polymerize explosively when heated or involved in a fire.
- Runoff to sewer may create fire or explosion hazard.
- Containers may explode when heated.
- Many liquids are lighter than water.

HEALTH

- Inhalation or contact with material may irritate or burn skin and eyes.
- Fire may produce irritating, corrosive and/or toxic gases.
- Vapors may cause dizziness or suffocation.
- Runoff from fire control may cause pollution.

PUBLIC SAFETY

- CALL Emergency Response Telephone Number on Shipping Paper.
- As an immediate precautionary measure, isolate spill or leak area for at least SO meters (150 feet) in all directions.
- Keep unauthorized personnel away.
- Stay upwind.
- Keep out of low areas.
- Ventilate closed spaces before entering.

PROTECTIVE CLOTHING

- Wear positive pressure self-contained breathing apparatus (SCBA).
- Structural firefighters' protective clothing will only provide limited protection.

EVACUATION

Large Spill

- Consider initial downwind evacuation for at least 300 meters (1000 feet).

Fire

- If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile} in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions.

EMERGENCY RESPONSE

FIRE

CAUTION: All these products have a very low flash point: Use of water spray when fighting fire may be inefficient.

Small Fire

- Dry chemical, CO2, water spray or alcohol-resistant foam.

Large Fire

- Water spray, fog or alcohol-resistant foam.
- Use water spray or fog; do not use straight streams.
- Move containers from fire area if you can do it without risk.

Fire involving Tanks or Car/Trailer Loads

- Fight fire from maximum distance or use unmanned hose holders or monitor nozzles.
- Cool containers with flooding quantities of water until well after fire is out.
- Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.
- ALWAYS stay away from tanks engulfed in fire.
- For massive fire, use unmanned hose holders or monitor nozzles; if this is impossible, withdraw from area and let fire burn.

SPILL OR LEAK

- ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area).
- All equipment used when handling the product must be grounded.
- Do not touch or walk through spilled material.
- Stop leak if you can do it without risk.
- Prevent entry into waterways, sewers, basements or confined areas.
- A vapor suppressing foam may be used to reduce vapors.
- Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.
- Use clean non-sparking tools to collect absorbed material.

Large Spill

- Dike far ahead of liquid spill for later disposal.
- Water spray may reduce vapor; but may not prevent ignition in closed spaces.

FIRST AID

- Move victim to fresh air.
- Call 911 or emergency medical service.
- Give artificial respiration if victim is not breathing.
- Administer oxygen if breathing is difficult.
- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
- Wash skin with soap and water.
- In case of burns, immediately cool affected skin for as long as possible with cold water. Do not remove clothing if adhering to skin.
- Keep victim warm and quiet.
- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Related Resources

- Guide for Handling Household Chemicals
  Things you can do to make your home safer.

- USDOT Hazardous Materials Table 49 CFR 172.101
  An online version of the USDOT's listing of hazardous materials from 49CFR 172.101. This table can be sorted by proper shipping name, UN/NA ID and/or by primary hazard class/division.

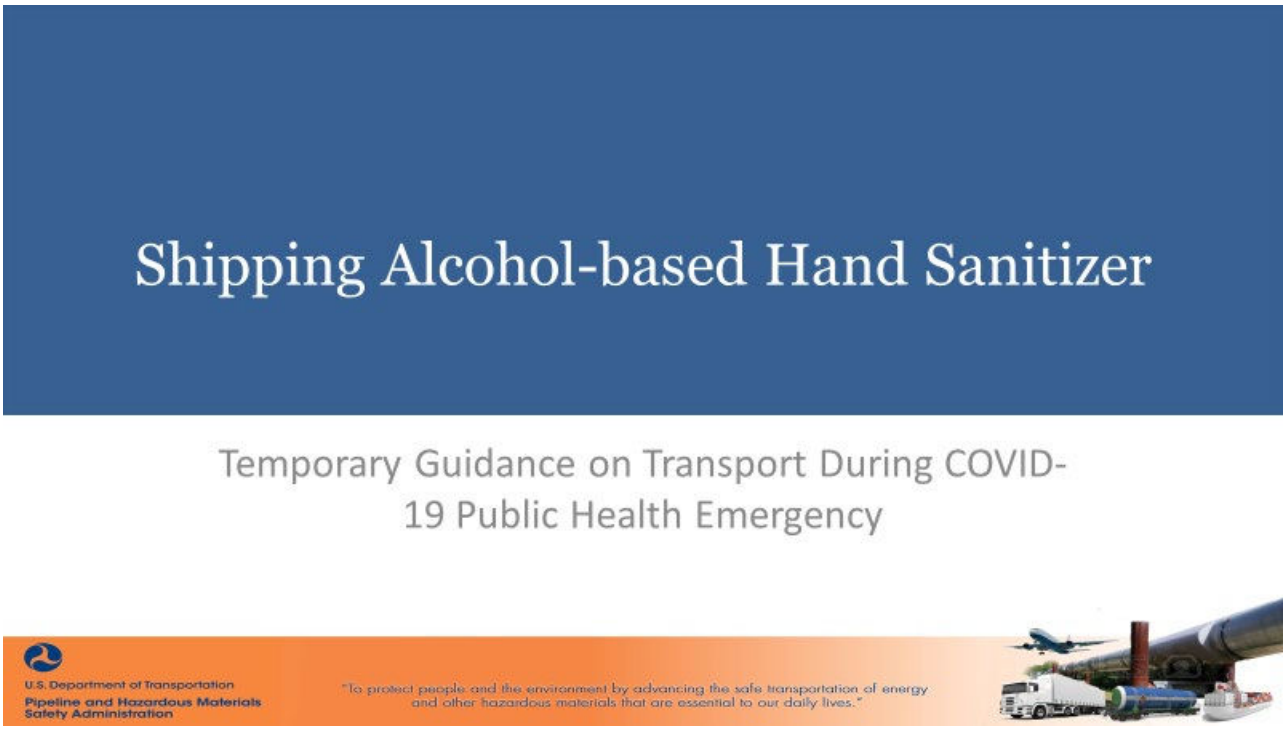
- US DOT Hazardous Materials Transportation Placards
  Hazardous materials placards (DOT placards) are required when shipping hazardous materials in the United States, Canada and Mexico. These pages provide US DOT definitions for each hazmat placard.

- Chemical Database
  This database focuses on the most common chemical compounds used in the home and industry.

- PHMSA Hazardous Materials Information Center
  Need clarification on an entry in the Hazardous Materials Regulations? PHMSA's Hazmat Information Center provides live, one-on-one assistance Monday through Friday from 9 a.m. - 5 p.m.
  Call: 1-800-467-4922
  Email: infocntr@dot.gov

APPENDIX C-2: DOT PRESENTATION ON SHIPPING ALCOHOL-BASED HAND SANITIZER, TEMPORARY GUIDANCE ON TRANSPORT DURING COVID-19 PUBLIC HEALTH EMERGENCY

(Based on the April 2 Guidance)



Agenda

- Applicability/Exceptions
- Small Quantities
  - Packaging
  - Hazard Communication
- Non-Bulk Quantities
  - Classification
  - Packaging
  - Hazard Communication
  - Other Considerations
- Bulk Quantities
- Questions Moving Forward

Applicability

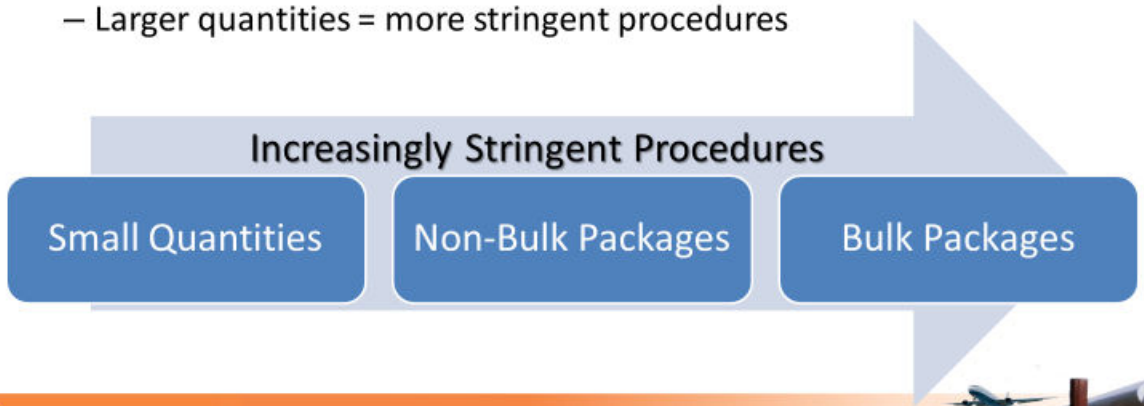
- Transportation in commerce of hand sanitizer covered under FDA's temporary guidance
- Two distinctions:

Transportation By Contract Carrier or Common Carrier (e.g., UPS, FedEx)	Transportation as Private Carrier

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
"To protect people and the environment by advancing the safe transportation of energy and other hazardous materials that are essential to our daily lives."

Applicability—Quantities

- As quantity increases, safety procedures increase
  - Larger quantities = more stringent procedures



Applicability—Modes of Transport

- Each mode of transport (Rail, Highway, Vessel, Air) presents unique risks
- This guidance is limited to ground transportation by motor vehicle only
- Transportation by rail, vessel, or air is not authorized – such transportation is subject to all applicable requirements of hazmat regulation

Small Quantities – Packaging

- Basic Guideline: leak tight and securely closed, secured against shifting, and protected against damage

Inner Packagings Not Exceeding 1 Gallon

- Place inner packaging inside outer package; closures upward
- Secure and cushion within the outer package to prevent breakage, leakage, and movement in transport
- Net contents of all inner packagings in any single outer packaging not exceeding 8 gallons (e.g., 8 x 1 gallon receptacles)

Small Quantities – Overview

- Applies to transport by a common or contract carrier and transport as a private carrier (motor vehicle transport only)
- Exception from all DOT hazmat regulations provided all packaging and hazard communication procedures are met
- Two distinctions between packaging sizes:

Not Exceeding 1 Gallon

Exceeding 1 Gallon, but Not Exceeding 8 Gallons

Small Quantities – Packaging

- Basic Guideline: leak tight and securely closed, secured against shifting, and protected against damage

Packagings exceeding 1 Gallon, but not exceeding 8 Gallons

- Overpacked in crates, cages, carts, boxes or similar overpacks; closures upward
- Secure in such a way as to prevent breakage, leakage, and movement in transport

Small Quantities – Hazard Communication

- Mark the company name and the words "Sanitizer - Contains Ethyl Alcohol" or "Sanitizer - Contains Isopropyl Alcohol" on each package and overpack (if applicable)
- Work with your carrier of choice (e.g., UPS, FedEx, contract carriers) on any other carrier-imposed requirements
- Contact DOT-PHMSA to work though any sticking points in the supply chain

Non-Bulk Quantities – Overview

- Applies to transportation as a private carrier, contract carrier, or common carrier in a vehicle under exclusive use for such service (motor vehicle only)
- Exception from most DOT hazmat regulations provided all outlined packaging and hazard communication guidelines are met:
  - –Classification
  - –Packaging
  - –Hazard Communication

Non-Bulk Quantities – Classification

- FDA has approved four formulations
  - – Ethyl Alcohol-based (Consumer Use and Healthcare Use)
  - – Isopropyl Alcohol-based (Consumer Use and Healthcare Use)
- DOT-PHMSA recommends the following classification for these FDA formulations:

UN 1987, Alcohols, n.o.s., 3, PGII

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
To Protect People and the Environment From the Risks of Hazardous Materials Transportation

Non-Bulk Quantities – Classification Detail

UN 1987, Alcohols, n.o.s., 3, PGII

- *UN ID Number*: 1987
- *Proper Shipping Name (PSN)*: Alcohols, n.o.s.
- *Hazard Class*: 3 (Flammable Liquids)
- *Packing Group (PG)*: PGII

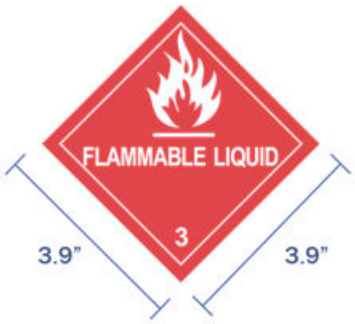
Non-Bulk Quantities – Packaging

- DOT or UN-specification packaging meeting PGII performance standards
- Not exceeding a net capacity of 119 gallons
- DOT or UN-specification packaging must be prepared and closed according to manufacturer's instructions
- Secure closures/leak tight
- Secure against movement or damage in vehicle

Non-Bulk Quantities – Hazard Communication

Packages Display:

- Class 3 Flammable Liquid Label

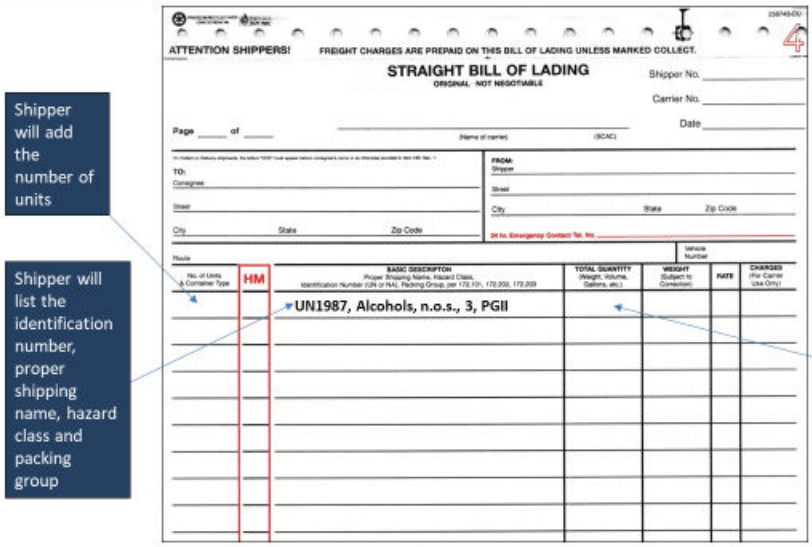


Non-Bulk Quantities – Hazard Communication

- Shipping paper with driver that communicates:
  - UN 1987, Alcohols, n.o.s., 3, PGII
  - Number and type of packages and total quantity (include a unit of measure – e.g., lbs, kgs, gallons, liters)
- Emergency response information with shipping paper:
  - ERG Guidebook Pages: Guide No. 127 (Flammable Liquids, Water-Miscible)

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
To Protect People and the Environment From the Risks of Hazardous Materials Transportation

SAMPLE – Shipping Paper



Shipper will add the number of units

Shipper will list the identification number, proper shipping name, hazard class and packing group

Shipper will add the quantity here, once know

Non-Bulk Quantities – Other Considerations

- DOT-PHMSA registration requirements are waived
- Vehicle placarding is required if quantities exceed an aggregate gross quantity of 1,001 lbs on a transport vehicle
- All applicable motor carrier requirements apply (§177.804)
- Familiarity with these guidelines and accompanying guidance document as a substitute for training requirements

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

To Protect People and the Environment From the Risks of Hazardous Materials Transportation

Non-Bulk Quantities – Training Considerations

- General Awareness/Familiarization Training
- Function-Specific Training
- Safety Training
- Security Awareness Training

Bulk Quantities – Overview

- Containers with capacity of greater than 119 gallons
- Subject to all requirements of the DOT hazmat regulations
- If you are not already a fully trained shipper of hazardous materials, contact DOT-PHMSA to get started

Questions Moving Forward

- DOT is here to support safe operations and serve as a resource to you to keep supplies moving

- DOT-PHMSA Hazardous Materials Information Center – one-on-one live assistance by phone
  - Available M-F 9am-5pm; Email: infocntr@dot.gov; 1-800-467-4922 or 202 366-4488

Questions Moving Forward

- Regional Hazardous Materials Safety Assistance Team (HMSAT)

Neal Suchak (Central Region)
- Neal.Suchak@dot.gov
- OH, IN, IL, MI, MN, WI, IA, NE, KS, MO, ND, SD

Dan Richards (Central Region)
- Daniel.Richards@dot.gov
- OH, IN, IL, MI, MN, WI, IA, NE, KS, MO, ND, SD

Liz LaDow (Southern Region)
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- NC, SC, GA, FL, AL, MS, TN, KY, PR

Mike Roberts (Southwest Region)
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- LA, AR, OK, TX, NM

Jack Whitley (Western Region)
- Earl.Whitley@dot.gov
- AK, AZ, CA, CO, HI, ID, MT, NV, OR, UT, WA, WY

Dave Williamson (Eastern Region)
- David.Williamson@dot.gov
- CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT, VA, WV

APPENDIX D-1: SAMPLE MATERIAL SAFETY DATA SHEET FOR THE WHO HAND SANITIZER FORMULA

Thank you to Ed Croom for supplying this example document!

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution

Product Use : Sanitizer

Manufacturer or supplier's details

Company : Company name
Company address

Address

Emergency telephone number:

Health North America: Company phone number

Transport North America: Company phone number

Additional Information: : Responsible Party: Company name
E-Mail: company email
SDS Requests: company email
Website: company website

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 2

Eye irritation : Category 2A

Specific target organ toxicity - single exposure : Category 3 (Respiratory system, Central nervous system)

GHS Label element

Hazard pictograms

Signal word: Danger

Hazard statements: H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.

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H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

Precautionary Statements:

Prevention:
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
Storage:
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Potential Health Effects

Carcinogenicity:

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Emergency Overview

Appearance	liquid
Color	colourless
Odor	alcohol-like, sweet
Hazard Summary	No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

CAS-No.	Chemical Name	Concentration (%)	Hazard
64-17-5	Ethanol	80-90%	Flam. Liq. 2, Eye irrit.2A STOTSE 3 (Respiratory, CNS)
7722-84-1	Hydrogen peroxide	0.125%	Ox. Liq. 1, H271 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1A, H314

All concentrations are in percent by weight unless otherwise indicated. Components not listed are either non-hazardous or are below reportable limits. Note this product lacks tert-butanol and has been denatured with denatonium benzoate only per FDA guidance in response to the COVID-19 pandemic and the current lack of tert-butanol.

SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Show this safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	If unconscious place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.

		If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

Most important symptoms/effects acute and delayed: Headache. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Coughing.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	No hazardous combustion products are known
Specific extinguishing methods	:	Use a water spray to cool fully closed containers.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. For safety reasons in case of fire, cans should be stored separately in closed containments.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

NFPA Flammable and Combustible Liquids Classification:
Flammable Liquid Class IB

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up	:	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

SECTION 7. HANDLING AND STORAGE

Advice on safe handling:	Avoid formation of aerosol. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Take precautionary measures against static discharges. Provide sufficient air exchange and/or exhaust in work rooms. Container may be opened only under exhaust ventilation hood. Open drum carefully as content may be under pressure. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage:	No smoking. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Observe label precautions. Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

CAS-No.	Components	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
64-17-5	Ethanol	TWA	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m3	OSHA P0
		STEL	1,000 ppm	ACGIH
7722-84-1	Hydrogen peroxide	TWA	1 ppm 1.4 mg/m³	ACGIH
		TWA	1 ppm	OSHA

			1.4 mg/m³	
		IDLH	75 ppm	IDLH US
		TWA	1 ppm 1.4 mg/m³	NIOSH

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection		
Remarks	:	The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	:	impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	:	Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colourless
Odor	:	alcohol-like, sweet
Odor Threshold	:	No data available
pH	:	No data available
Freezing Point (Melting point/range)	:	-114.1 °C (-173.4 °F)
Boiling Point (Boiling point/boiling range)		79 °C (174 °F) (1013 hPa)
Flash point	:	12 °C (54 °F)
Evaporation rate	:	Expected to be rapid
Flammability (solid, gas)	:	Not applicable
Burning rate	:	No data available
Upper explosion limit	:	19 % (by volume 100% ethanol)
Lower explosion limit	:	3.3 %(by volume 100% ethanol)
Vapor pressure	:	60 hPa @ 20 °C (68 °F)
Relative vapor density	:	1.6
Relative density	:	0.789 @ 20 °C (68 °F)
Density	:	0.816 g/cm3 @ 20 °C (68 °F)
Bulk density	:	No data available
Solubility(ies)		
Water solubility	:	completely soluble
Other solubilities	:	Miscible in many other organic solvents
Partition coefficient: n-	:	No data available

octanol/water		
Auto-ignition temperature	:	No data available
Thermal decomposition	:	No data available
Viscosity	:	Water thin

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No hazards to be specially mentioned.
Conditions to avoid	:	Extremes of temperature and direct sunlight. Heat, flames and sparks.
Incompatible materials	:	Alkali metals Ammonia Oxidizing agents peroxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Information on likely routes of exposure

Inhalation: Prolonged inhalation may be harmful.

Skin contact: Prolonged skin contact may cause temporary irritation.

Eye contact: Causes serious eye irritation.

Ingestion: Expected to be a low ingestion hazard due to denaturant.

Product:

Acute oral toxicity	:	Not expected to be acutely toxic.

Components:

64-17-5: Ethanol

Aspiration toxicity

Components:

64-17-5:

No aspiration toxicity classification

Further information

Product:

Remarks: Solvents may degrease the skin.

Skin corrosion/irritation: Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye: Causes serious eye irritation.
Respiratory or skin sensitization:
Not a respiratory sensitizer.
This product is not expected to cause skin sensitization.

Germ cell mutagenicity: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity Not classifiable as to carcinogenicity to humans.
IARC Monographs. Overall Evaluation of Carcinogenicity: Not listed. Only drinking of alcoholic beverages is listed. Denaturing removes that risk.
NTP Report on Carcinogens: Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053): Not regulated.
Reproductive toxicity This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure: Not classified.
Specific target organ toxicity - repeated exposure: Not classified.
Aspiration hazard: Not an aspiration hazard.
Chronic effects: Prolonged inhalation may be harmful.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

64-17-5:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 15,300 mg/l Exposure time: 96 h Test Type: flow-through test
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia): 5,012 mg/l Exposure time: 48 h Test Type: static test
Toxicity to algae	:	EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Method: OECD Test Guideline 201 GLP: No data available

Persistence and degradability

Components:

64-17-5:

Biodegradability	:	Result: Readily biodegradable.

Bioaccumulative potential

Components:

64-17-5:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation	40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks	This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Dispose of in accordance with all applicable local, state and federal regulations. For assistance with your waste management needs - including disposal, recycling and waste stream reduction, contact NEXEO's Environmental Services Group at 800-637-7922.
Contaminated packaging	: Empty remaining contents. Dispose of as unused product. Do not re-use empty containers. Do not burn, or use a cutting torch on, the empty drum.

SECTION 14. TRANSPORT INFORMATION

IATA (International Air Transport Association): UN1170, ETHANOL, 3, II, Flash Point:12 °C(54 °F)

IMDG (International Maritime Dangerous Goods): UN1170, ETHANOL, 3, II

DOT (Department of Transportation): UN1170, ETHANOL, 3, II

SECTION 15. REGULATORY INFORMATION

OSHA Hazards	: Flammable liquid, Moderate eye irritant, Moderate respiratory irritant
WHMIS Classification	: B2: Flammable liquid D2B: Toxic Material Causing Other Toxic Effects

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards	:	Fire Hazard Acute Health Hazard
SARA 302	:	SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313	:	SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

64-17-5	Ethanol	≥ 80 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

64-17-5	Ethanol	80 - 95 %

Pennsylvania Right To Know

64-17-5	Ethanol	80 - 95 %

New Jersey Right To Know

64-17-5	Ethanol	80 - 95 %

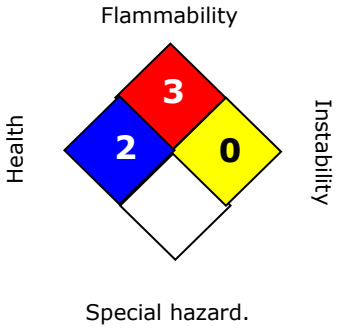
California Prop 65		WARNING! This product contains a chemical known to the State of California to cause cancer.
75-07-0	Acetaldehyde	

The components of this product are reported in the United States TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	**2**
FLAMMABILITY	**3**
PHYSICAL HAZARD	**0**

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 =Extreme, * = Chronic

The information provided is based on the data we are aware of and is believed to be correct as of the date of creation. Since this information may be applied under conditions beyond our control and with which we may be unfamiliar and since data made become available subsequently to the date of creation, we do not assume any responsibility for the results of its use. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This SDS has been prepared by Company Name company email.

Revision Date Add date.

APPENDIX D-2: SAMPLE MATERIAL SAFETY DATA SHEET FOR SDA FORMULA 40-B

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ethanol SDA 40B 160 Proof
Product Use : Sanitizer

Manufacturer or supplier's details

Company : Company name
Company address

Address
Emergency telephone number:
Health North America: Company phone number
Transport North America: Company phone number
Additional Information: : Responsible Party: Company name
E-Mail: company email
SDS Requests: company email
Website: company website

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 2

Eye irritation : Category 2A

Specific target organ toxicity - single exposure : Category 3 (Respiratory system, Central nervous system)

GHS Label element

Hazard pictograms

Signal word: Danger

Hazard statements:
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

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Precautionary Statements:	**Prevention:** P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/ eye protection/ face protection. **Response:** P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/ attention. P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction. **Storage:** P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. **Disposal:** P501 Dispose of contents/ container to an approved waste disposal plant.

Potential Health Effects

Carcinogenicity:

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Emergency Overview

Appearance	liquid
Color	colourless
Odor	alcohol-like, sweet
Hazard Summary	No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

CAS-No.	Chemical Name	Concentration (%)
64-17-5	Ethanol	80 - 90

All concentrations are in percent by weight unless otherwise indicated. Components not listed are either non-hazardous or are below reportable limits. Note this product lacks tert-butanol and has been denatured with denatonium benzoate only per FDA guidance in response to the COVID-19 pandemic and the current lack of tert-butanol.

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.
If on clothes, remove clothes.

In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

Most important symptoms/effects acute and delayed: Headache. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Coughing.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	No hazardous combustion products are known
Specific extinguishing methods	:	Use a water spray to cool fully closed containers.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. For safety reasons in case of fire, cans should be stored separately in closed containments.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

NFPA Flammable and Combustible Liquids Classification:
Flammable Liquid Class IB

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.
Methods and materials for containment and cleaning up	:	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

SECTION 7. HANDLING AND STORAGE

Advice on safe handling:	Avoid formation of aerosol. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Take precautionary measures against static discharges. Provide sufficient air exchange and/or exhaust in work rooms. Container may be opened only under exhaust ventilation hood. Open drum carefully as content may be under pressure. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage:	No smoking. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Observe label precautions. Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

CAS-No.	Components	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
64-17-5	Ethanol	TWA	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m3	OSHA P0
		STEL	1,000 ppm	ACGIH

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection		
Remarks	:	The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	:	impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures	:	Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colourless
Odor	:	alcohol-like, sweet
Odor Threshold	:	No data available
pH	:	No data available
Freezing Point (Melting point/range)	:	-114.1 °C (-173.4 °F)
Boiling Point (Boiling point/boiling range)		79 °C (174 °F) (1013 hPa)
Flash point	:	12 °C (54 °F)
Evaporation rate	:	Expected to be rapid
Flammability (solid, gas)	:	Not applicable
Burning rate	:	No data available
Upper explosion limit	:	19 % (by volume 100% ethanol)
Lower explosion limit	:	3.3 %(by volume 100% ethanol)
Vapor pressure	:	60 hPa @ 20 °C (68 °F)
Relative vapor density	:	1.6
Relative density	:	0.789 @ 20 °C (68 °F)
Density	:	0.816 g/cm3 @ 20 °C (68 °F)
Bulk density	:	No data available
Solubility(ies)		
Water solubility	:	completely soluble
Other solubilities	:	Miscible in many other organic solvents
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Thermal decomposition	:	No data available
Viscosity	:	Water thin

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No hazards to be specially mentioned.
Conditions to avoid	:	Extremes of temperature and direct sunlight. Heat, flames and sparks.
Incompatible materials	:	Alkali metals Ammonia Oxidizing agents peroxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Information on likely routes of exposure

Inhalation: Prolonged inhalation may be harmful.

Skin contact: Prolonged skin contact may cause temporary irritation.

Eye contact: Causes serious eye irritation.

Ingestion: Expected to be a low ingestion hazard due to denaturant.

Product:

Acute oral toxicity : Not expected to be acutely toxic.

Components:

64-17-5: Ethanol

Aspiration toxicity

Components:

64-17-5:

No aspiration toxicity classification

Further information

Product:

Remarks: Solvents may degrease the skin.

Skin corrosion/irritation: Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye: Causes serious eye irritation.
Respiratory or skin sensitization:
Not a respiratory sensitizer.
This product is not expected to cause skin sensitization.
Germ cell mutagenicity: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity Not classifiable as to carcinogenicity to humans.
IARC Monographs. Overall Evaluation of Carcinogenicity: Not listed. Only drinking of alcoholic beverages is listed. Denaturing removes that risk.
NTP Report on Carcinogens: Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053): Not regulated.
Reproductive toxicity This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure: Not classified.
Specific target organ toxicity - repeated exposure: Not classified.
Aspiration hazard: Not an aspiration hazard.
Chronic effects: Prolonged inhalation may be harmful.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

64-17-5:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 15,300 mg/l Exposure time: 96 h Test Type: flow-through test
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia): 5,012 mg/l Exposure time: 48 h Test Type: static test
Toxicity to algae	:	EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Method: OECD Test Guideline 201 GLP: No data available

Persistence and degradability

Components:

64-17-5:

Biodegradability	:	Result: Readily biodegradable.

Bioaccumulative potential

Components:

64-17-5:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation	40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks	This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information	:	No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with all applicable local, state and federal regulations. For assistance with your waste management needs - including disposal, recycling and waste stream reduction, contact NEXEO's Environmental Services Group at 800-637-7922.
Contaminated packaging	:	Empty remaining contents. Dispose of as unused product. Do not re-use empty containers. Do not burn, or use a cutting torch on, the empty drum.

SECTION 14. TRANSPORT INFORMATION

IATA (International Air Transport Association): UN1170, ETHANOL, 3, II, Flash Point:12 °C(54 °F)

IMDG (International Maritime Dangerous Goods): UN1170, ETHANOL, 3, II

DOT (Department of Transportation): UN1170, ETHANOL, 3, II

SECTION 15. REGULATORY INFORMATION

OSHA Hazards	:	Flammable liquid, Moderate eye irritant, Moderate respiratory irritant
WHMIS Classification	:	B2: Flammable liquid D2B: Toxic Material Causing Other Toxic Effects

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards	:	Fire Hazard Acute Health Hazard
SARA 302	:	SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313	:	SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

64-17-5	Ethanol	≥ 80 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

64-17-5	Ethanol	80 - 95 %

Pennsylvania Right To Know

64-17-5	Ethanol	80 - 95 %

New Jersey Right To Know

64-17-5	Ethanol	80 - 95 %

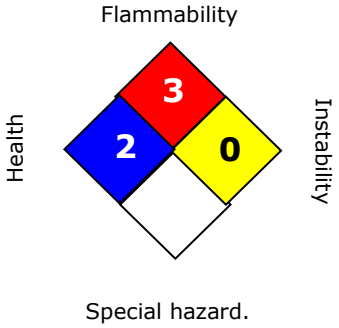
California Prop 65	WARNING! This product contains a chemical known to the State of California to cause cancer.
75-07-0	Acetaldehyde

The components of this product are reported in the United States TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	**2**
FLAMMABILITY	**3**
PHYSICAL HAZARD	**0**

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 =Extreme, * = Chronic

The information provided is based on the data we are aware of and is believed to be correct as of the date of creation. Since this information may be applied under conditions beyond our control and with which we may be unfamiliar and since data made become available subsequently to the date of creation, we do not assume any responsibility for the results of its use. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This SDS has been prepared by Company Name company email.

Revision Date Add date.

APPENDIX D-3: SAMPLE CERTIFICATE OF ANALYSIS FOR ETHANOL SDA FORMULA 40-B

Thank you to Ed Croom for supplying this example document!

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney and other subject matter advisors for any specific guidance on legal or regulatory compliance.

Certificate of Analysis

Product Description: Product Name. Ethanol SDA-40B 160+ proof
Synonyms: denatured alcohol, ethyl alcohol, grain alcohol
Ingredients: Ethanol, water, denatonium benzoate
Manufacturing process. Fermentation followed by distillation.
Recommended retest date: 24 months after shipping.
Date manufactured:
Lot number: (note date and time is an easy format to use)

Characteristics	Specification	Results
Appearance	Clear, colorless liquid	
Odor	Alcohol	
Proof	> 160 – 190	

Approved by:

Name Date

Notice: This product is conditionally manufactured for hand sanitizer production in response to the Covid-19 pandemic. It contains grain derived alcohol specially denatured using only denatonium benzoate due to the current shortage of tert-butanol as permissible by current FDA guidance.

APPENDIX E: STATE ABC HAND SANITIZER GUIDANCE

Please be advised that there are other state laws and regulations that could apply to the production and distribution of hand sanitizer. We are monitoring state notices for information related to producing hand sanitizer in response to COVID-19 and will update this chart as we become aware of additional notices and policies. **UPDATED 4/21/20**	
STATE	**HAND SANITIZER GUIDELINES**
California	Distilled Spirits Manufacturers Providing High-Proof Spirits for Disinfection Purposes The Department has no objection to the production of denatured high proof spirits produced by licensed distilled spirits manufacturers (Type 04) and craft distillers (Type 74) if such distilled spirits are produced for use in accordance with guidance from the Food and Drug Administration, which may be found in the FDA's Policy (PDF). Nor does the Department object to licensees providing such distilled spirits for free to any person, including retail licensees, if they are not used to promote the manufacturer's alcoholic beverage products and are not provided in exchange for an agreement to purchase anything produced or distributed by the manufacturer. Undenatured distilled spirits, regardless of proof, are not included in this specific guidance as they are "alcoholic beverages" and thus subject to the normal requirements regarding manufacture, distribution, and sale. Licensees should also be aware of guidance from the TTB regarding this subject, which may be found in the TTB's March Newsletter. In addition, if licensees choose to produce and sell high-proof undenatured spirits (through usual channels) intended for use in hand sanitizer or as a disinfectant, they should be aware of potential tax issues, which should be addressed with the appropriate taxing authorities.
Connecticut	"Governor Lamont has also waived the registration requirement to produce alcohol-based hand sanitizer and personal protective equipment (PPE). The manufacturing of alcohol based hand sanitizer must still follow Food and Drug Administration (FDA) guidance…." Governor Ned Lamont's FAQs on the State of Connecticut's Actions Related to COVID-19 at p. 15 Connecticut Department of Consumer Protection - Resources and Guidelines for Businesses Manufacturing Hand Sanitizer During the COVID-19 Pandemic
Illinois	Illinois Liquor Control Commission COVID-19 FAQS *Q. As a distiller, may I convert my business to manufacturing hand sanitizer and continue to operate after the Stay at Home Order.*

	A. Yes. A distiller making hand sanitizer is an Essential Business per the Stay at Home Order: “Manufacturing companies, distributors, and supply chain companies producing and supplying essential products and services in and for industries such as pharmaceutical, technology, biotechnology, healthcare, chemicals and sanitization, waste pickup and disposal, agriculture, food and beverage, transportation, energy, steel and steel products, petroleum and fuel, mining, construction, national defense, communications, as well as products used by other Essential Businesses and Operations. Distillers must abide by federal distilled spirits plan guidelines as stated in this bulletin: https://www.fda.gov/media/136289/download. Also, see this link for further instructions: https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions. Distillers are also required to abide by any other relevant state and local law. Illinois Department of Revenue Advisory – April 8 The Illinois Department of Revenue (IDOR) is ensuring any alcohol purchases made for production be tax-exempt. Normally, distillers incur a tax liability based on the amount and strength of alcohol used in distillation. Last night, IDOR sent distillers guidance on how to claim a tax deduction on their alcohol purchases to remove any tax liability. **Are you a distiller or craft distiller converting your production to alcohol used for hand sanitizer?** ILCC-licensed distillers or craft distillers converting their current alcohol production to alcohol used in hand sanitizer due to the COVID-19 pandemic must report this alcohol as a deduction on Schedule RL-115 to accompany their monthly Form RL-26 tax return. The deduction should be noted as "COVID-19 Alcohol" on the reporting schedule. With this notation, the distillery can claim a deduction on those gallons, effectively making those gallons tax exempt. This deduction is only allowed during a specified time period (as yet undetermined). If you have any questions, please email us at REV.ATP-MFR@illinois.gov.
Iowa	Information on Manufacturing Hand Sanitizer The Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued guidance on the production of hand sanitizer by distilled spirits permittees here. Alcohol manufactured in Iowa pursuant to an experimental distilled spirits plant permit or its equivalent issued by TTB is not an “alcoholic liquor.” As such, ABD does not regulate this type of manufacturing. Therefore, ABD does not need to waive any regulations and does not have any additional requirements for Iowa liquor manufacturers and native distilleries manufacturing hand sanitizer.

Kentucky	Kentucky Alcoholic Beverage Control FAQs *25. Are businesses permitted to make or bottle hand sanitizer?* The Kentucky Distillers' Association (KDA) is providing guidance about distilleries producing hand-sanitizer. The KDA contact person is Colleen Thomas, Director of Member and Public Affairs. Her email is colleen@kybourbon.com.
Missouri	Hand Sanitizer Production – The division has received an increasing number of inquiries regarding the production of hand sanitizer. Please follow the links to the Alcohol and Tobacco Tax and Trade Bureau (TTB)webpagehttps://www.ttb.gov/public-guidance/ttb-pg-2020-1a, and the FDA's webpage, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost for more information on federal guidelines. In addition to the federal guidelines, ATC has the following guidelines: Licensees must be licensed as a manufacture at the state level to receive or produce bulk potable (drinkable) spirits, even if its intended use is for the production of hand sanitizer The percentage of alcohol cannot exceed their license type (ex. a 22% Manufacturer-Solicitor cannot utilize alcohol over 22% alcohol by weight) Records must be kept separate for the two operations (beverage vs. hand sanitizer), and bulk spirits used in the production of hand sanitizer must be reported under the 'remove for loss' field on their monthly excise tax report (no excise tax is due for spirits used in the production of hand sanitizer).
Montana	The Montana Department of Revenue is announcing that licensed Montana distillers may now manufacture sanitizer for use by the public. There will be no federal or state taxes on the production of sanitizer made with denatured alcohol. Please see guidance below from the U.S. Alcohol and Tobacco Trade and Tax Bureau (TTB). For more information, contact the Alcoholic Beverage Control Division at (406) 444-0728. https://mtrevenue.gov/2020/03/19/montana-distillers-may-make-sanitizer/
Nebraska	Nebraska Liquor Control Commission Hand Sanitizer Guidance **UPDATED - Guidance Document - Hand Sanitizer** Post date: March 27, 2020 **On 3/27/2020 the TTB issued an updated guidance that reflects the FDA's guidance regarding production of hand sanitizer. The TTB removed any federal excise tax from ethanol used in the production of hand sanitizer,**

	and changed their formulation recommendations to the FDA's formulas. The guidance document has been updated to reflect that. GUIDANCE DOCUMENT This guidance document is advisory in nature but is binding on an agency until amended by such agency. A guidance document does not include internal procedural documents that only affect the internal operations of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules and regulations made in accordance with the Administrative Procedure Act. If you believe that this guidance document imposes additional requirements or penalties on regulated parties, you may request a review of the document. 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. 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
New Jersey	New Jersey Division of Alcoholic Beverage Control Special Ruling Suspending Enforcement of any Violations by Plenary Distillery Licensees and Craft Distillery Licensees for Production of Hand Sanitizer or Distilled Spirits to be Used for Hand Sanitizer In light of the emergency, however, the Division will exercise its discretion and will take no regulatory action against such activity. The TTB waiver is effective through June 30, 2020, and that may be extended as necessary. The Division will suspend enforcement of any violations by Plenary Distillery Licenses and Craft Distillery Licenses related to the manufacture of hand sanitizer and distilled spirits to be used in hand sanitizer for as long as the TTB guidance remains in effect.

	Licensees are required to follow all TTB guidance, regulations and requirements. In addition, licensees who manufacture hand sanitizer and distilled spirits to be used in hand sanitizer shall review and adhere to guidance issued by the FDA. Plenary Distillery Licensees and Craft Distillery Licensees may manufacture hand sanitizer as well as distilled spirits which are intended to be used in hand sanitizer for such time as the TTB waiver is in effect. Distilleries wishing to manufacture hand sanitizer or ethanol to be used for hand sanitizer must notify the Division at ABCpublic@NJOAG.GOV. The email shall include the name, address and ABC License No. of the distillery, a description of the product to be manufactured and the intended disposition of the product (i.e. sold or donated and to whom). Otherwise, no formal application or request need be submitted to the Division. All TTB and FDA requirements must be followed. **Hand Sanitizer Taxes**: The tax imposed pursuant to the "Alcoholic Beverage Tax Law," R.S. 54:41-1 et seq. shall not apply to the sale or delivery of alcohol used by a distillery in the production of hand sanitizer for the duration of the exemption period. A distillery shall be entitled to a refund for the alcoholic beverage tax paid on alcohol used by the distillery in the production of hand sanitizer during the exemption period. The application for a refund shall be submitted to the Division of Taxation in the Department of the Treasury, in a form and manner as prescribed by the Director of the Division of Taxation.
Oregon	**Hand Sanitizer Resource Guide for Oregon** 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.
Tennessee	Tennessee Alcoholic Beverage Commission Coronavirus Distilleries FAQs *Q. May a distillery engage in the production of ethanol-based hand sanitizer?* A. Yes, a licensed distillery may produce ethanol-based hand sanitizer without other licenses or permits from the TABC. However, licensees must continue to maintain all records of production and depletion of such inventory and comply with applicable TTB and FDA guidance and Regulations. *Q. From whom may a distillery obtain alcoholic beverages for making hand sanitizer?*

	A. A distillery can obtain alcoholic beverages for blending, including for making hand sanitizer, from other licensed manufacturers, licensed wholesalers, or licensed non-resident sellers or non-manufacturing non-resident sellers. Alcohol that has been denatured or otherwise made unfit for human consumption is not considered an alcoholic beverage and is not subject to TABC jurisdiction.
Texas	Texas Alcoholic Beverage Commission Hand Sanitizer Guidance TABC Licensing The Texas Alcoholic Beverage Code authorizes distillers to manufacture alcohol, convert it into a medicinal product such as hand sanitizer, and then sell it without additional TABC licenses or permits *(See TX Alc. Bev. Code Chapter 38)*. Excise Taxes There is no Texas excise tax or TABC reporting required for hand sanitizer (but keep records because there may be federal tax implications). TABC Label Approval There are no TABC label approval requirements for hand sanitizer. State and Federal Requirements Distiller seeking to produce and sell hand sanitizer should make sure they consult with other state and federal entities: • The Texas Department of State Health Services recommends that a distiller ensures that the resultant product remains at least 60% alcohol content. • The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued public guidance. • The U.S. Food and Drug Administration has published a temporary policy for producing hand sanitizer during the public health emergency. Selling and Donating Unfit Alcohol Products to a Distillery Any TABC licensee or permittee may sell or donate their unfit products to a distillery for use in the production of hand sanitizer. Manufacturing tier members may also arrange for a distiller to turn their unfit product into hand sanitizer, which will remain the property of the manufacturer. Transferring the Unfit Product to a Distillery A brewery, distillery, or winery may transfer an alcoholic beverage in bulk that it produced to another brewery, distillery, or winery so long as the alcoholic beverage is used only for manufacturing purposes, and if the transfer is allowed under federal law. (TX Alc. Bev. Code. Sec. 109.63). The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) defines bulk product as being "in containers having a capacity in excess of one wine gallon." Neither party to the transfer is required to submit a report to TABC related to the transfer. However, both parties must document the transfer and retain operational records in accordance with TABC Rules 41.23 and 41.35. Additionally, you may

	need to keep documentation for the TTB. TABC Tax Credit If the product has already been packaged, canned, bottled, or kegged, the product manufacturer can apply for a TABC tax credit. Follow the same process that you would if you were applying for a standard product destruction credit by filling out an Application for Destruction of Alcoholic Beverages form and submit it to your local TABC office. Please contact your local TABC office or email excise.tax@tabc.texas.gov if you have any questions. Federal Guidelines for Shipping Alcohol-based Hand Sanitizer Several federal regulations apply to distilleries transporting hand sanitizer in their own vehicles and to common carriers like FedEx and UPS. The regulations cover things like the size of the containers, labeling, placards on shipping vehicles, and the shipping papers that must accompany shipments. Training provided by the U.S. Department of Transportation is available here.
Utah	Utah Department of Alcoholic Beverage Control Hand Sanitizer Guidance COVID-19 PANDEMICHAND SANITIZER MANUFACTURING NOTICE Due to the extreme need for handwashing and the use of hand sanitizer to combat the spread of Covid-19, and the extreme scarcity of hand sanitizer through normal sources, many local businesses have expressed a desire to manufacture hand sanitizer for use in the community. As indicated below, a state permit is required to purchase alcohol for scientific or manufacturing purposes. That process takes time, and once a permit is issued, the DABC has no control over the quality or distribution of products manufactured with the alcohol. Distilleries who want to manufacture hand sanitizer, as well as any person or entity who wants to purchase alcohol to manufacture hand sanitizer, are required to obtain a state special use permit pursuant to Utah Code Ann. §32B-10-404. During the time period that the emergency health department orders are in effect, the DABC will not take action against any person or entity manufacturing hand sanitizer for failure to secure a special use permit under Utah Code Ann. §32B-10-404. However, the DABC highly encourages these manufacturers or those who seek to manufacture hand sanitizer to apply for a special use permit. You may find the necessary information here: https://abc.utah.gov/license/permits_special_use.html Note: Anyone who produces hand sanitizer is subject to federal requirements of both the TTB and FDA. Even during the COVID-19 pandemic, the DABC expects all entities to adhere to FDA and TTB requirements, including conformity with any federal regulations regarding claims of the efficacy of hand sanitizers. It is the sole responsibility of the hand sanitizer manufacturer, or anyone seeking to do so, to ensure compliance with federal law.

	The US Food and Drug Administration (FDA) has issued a directive regarding the production of hand sanitizer. A link to that directive may be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-duringAdditionally, the Alcohol and Tobacco Tax and Trade Bureau (TTB) has modified the approval requirements for Alcohol Fuel Plants (AFPs) and Beverage Distilled Spirits Plants (DSPs) that are currently TTB permittees. A copy of that guidance may be found here: https://www.ttb.gov/news/covid-19-hand-sanitizer Disclaimer: Anyone manufacturing hand sanitizer is solely responsible for the products which they manufacture. Additionally, the DABC makes no representation as to the actions of any other agency which may have jurisdiction over the persons or their products.
Virginia	**Topic 8: (03/18/20) ABC response to Distilleries producing hand sanitizer * Updated to include pharmacies and pharmacists (03/24/20)** **Purpose:** Pursuant to Executive Order 51 dated March 12, 2020, the Virginia Alcoholic Beverage Control Authority is offering the following interpretation on the producing of hand sanitizer product by licensed Distilleries. **Background:** Currently under the Code of Virginia, a licensed Distiller may produce alcoholic beverages other than wine and beer on their premises and sell to those that can legally receive it out of state, to the VA ABC Board or at their designated ABC Distillery Store. § 4.1-200; Exemptions for licensure allows the manufacture, sale and delivery or shipment of toilet, medicinal and antiseptic preparations and solutions not intended for internal human use nor to be sold as beverages. § 4.1-100 defines alcohol as "Alcohol" means the product known as ethyl or grain alcohol obtained by distillation of any fermented liquor, rectified either once or more often, whatever the origin, and shall include synthetic ethyl alcohol, but shall not include methyl alcohol and alcohol completely denatured in accordance with formulas approved by the government of the United States. **Held:** The Authority acting under the abilities granted within Executive Order 51 has made the following interpretation in regard to Distilleries producing, selling or giving away hand sanitizer, producing grain alcohol, selling of industrial alcohol. Hand Sanitizer: Distilleries that want to produce hand sanitizer that contain ingredients (not just straight ethanol or grain alcohol) that make the product rendered unfit for consumption or completely denatured, may give away or sell hand sanitizer to communities, hospitals, patrons, etc. provided the product: 1) Meets appropriate federal guidelines regarding manufacturing of such products; 2) Meets appropriate VDACS and VDH guidelines where applicable; 3) If bottled, contain a statement that the product is not intended for consumption; Grain Alcohol:

	If the distillery wants to sell grain alcohol to customers then they must bottle, sell under appropriate guidelines for grain alcohol products (designated in MIPS, customer has a permit**, etc.) Pursuant to § 4.1-119 E. No Class 1 neutral grain spirit or alcohol, as defined by federal regulations, that is without distinctive character, aroma, taste or color shall be sold in government stores at a proof greater than 151 except upon permits issued by the Board for industrial, commercial, culinary, or medical use. **Virginia ABC Authority will waive the grain alcohol permit requirement for any Virginia licensed pharmacy or pharmacist while Executive Order 51 remains applicable.** Industrial Alcohol: ***Virginia ABC Authority will waive the following industrial permit requirement for any hospital while Executive Order 51 remains applicable.** **Virginia ABC Authority will waive the following industrial permit requirement for any Virginia licensed pharmacy or pharmacist while Executive Order 51 remains applicable.** If the distillery wants to produce industrial alcohol for hospitals*, manufacturing**, etc. then the buyer must follow the applicable permitting process for industrial alcohol pursuant to 3VAC5-70-60 in which The board may issue a yearly permit authorizing the shipment and transportation direct to the permittee of orders placed by the board for alcohol or other alcoholic beverages for any of the following purposes: 1. For industrial purposes; 2. For scientific research or analysis; 3. For manufacturing articles allowed to be manufactured under the provisions of § 4.1-200 of the Code of Virginia; or 4. For use in a hospital or home for the aged (alcohol only). Should you have any questions on the above processes or need to further discuss, please contact your assigned Compliance agent or call 804-213-4632 or compliance@abc.virginia.gov.
Washington	**Guidance for Distillers Producing Hand Sanitizer** • Applies to: Distillers Information is available here for distillers who wish to use their facilities and equipment to temporarily make hand sanitizer, or for distillers wishing to sell distilled alcohol for sanitizing purposes. Note about Taxes: If the alcohol is being sold for non-consumptive purposes (denatured) then there would be no spirits taxes or fees. This has its roots in the statutory definition of spirits, which defines spirits as a beverage. If the alcohol is not being sold for the purposes of consumption (e.g. to a hospital), or is used in the production of something that is not intended for consumption (sanitizer), then it would not meet the definition of spirits and no state spirits taxes or fees would be assessed. **Guidance for Distillers Producing Hand Sanitizer** March 24, 2020

	With COVID-19, we know distillers are eager to do what they can to assist their communities, and that you've got the immediate capability to produce hand sanitizer and sell distilled alcohol to other entities that can do the same. Under normal circumstances, an entity that will be producing hand sanitizer needs to have a Class 2 Permit. However, during the COVID-19 pandemic, entities may produce hand sanitizer prior to obtaining the Class 2 Permit. Before beginning production you must: □ Notify customerservicelicensing@lcb.wa.gov □ Register with the Food and Drug Administration (FDA) o Follow an approved recipe o Apply an approved label to the product The FDA has created a guidance document called Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) that explains exactly what you will need to do. **Tax information for production/sale of sanitizer and/or selling distilled alcohol** If you choose to sell distilled alcohol (denatured or not) to a medical or permitted facility for non-consumptive purposes, they will not be required to pay the spirits distributor fees. Only normal B&O taxes will apply. **B&O tax** Distilleries are subject to B&O tax both for production activities (manufacturing classification) and selling activities (retailing or wholesaling classification). o The Manufacturing B&O tax rate is 0.484 percent (0.00484) of the gross receipts. o The Retailing B&O tax rate is 0.471 percent (.00471) of the gross receipts. o The Wholesaling B&O tax rate is 0.484 percent (.00484) of the gross receipts. o Distilleries will be allowed the Multiple Activities Tax Credit against the applicable selling B&O tax for the Manufacturing B&O tax (RCW 82.04.440). o If a bona fide donation of the alcohol is made, rather than a sale, amounts derived from the donated alcohol may be deducted from the B&O tax (RCW 82.04.4282). **Retail Sales Tax** Sales to hospitals are subject to retail sales tax. The retail sales tax rate is the state portion of 6.5 percent plus the applicable local sales tax rate for the locality, currently as high as 4 percent. Accordingly, the combined retail sales tax rate can be as high as 10.5 percent. The location of receipt will determine the tax rate. For example, if alcohol is delivered by a distiller to a hospital location, then the combined sales tax rate at the location would apply.

	o The seller of alcohol needs to collect the retail sales tax from the hospital and remit the collected tax to the Department of Revenue. o Items purchased by a hospital for the purpose of being resold to patients may be purchased without paying sales tax if the hospital provides a valid reseller permit. o The retail sales tax exemption for sales of prescription drugs likely does not apply. The exemption is only applicable to sales of drugs for human use dispensed to patients pursuant to a prescription. The prescription must be transmitted by an authorized duly licensed practitioner. o If the sales are made to a free hospital, the sales may be exempt under RCW 82.08.02795. A free hospital is a hospital that does not charge patients for health care provided by the hospital. o If the alcohol is donated, rather than sold, retail sales tax would not apply. If the hospital is a nonprofit charitable organization or state or local governmental entity, the use by the hospital may also be exempt from use tax under RCW 82.12.02595. **Differences in taxes due** o **Products sold directly by distillers to hospitals** Products sold directly by a distiller to a hospital are generally retail sales, as long as absent there being a purchase for resale without intervening use. These sales are subject to retail sales tax and distillers are obligated to collect the retail sales tax from the hospital. The applicable selling B&O tax classification for these sales would be retailing. o **Products sold by distillers to distributors, and then to hospitals** Products sold by distillers to distributors are generally wholesale sales. Sales to distributors are not subject to retail sales tax if a distributor furnishes a valid reseller permit to verify the wholesale nature of the transaction. The applicable selling B&O tax classification for the distiller is wholesaling. Sales from distributors to hospitals are generally retail sales subject to retail sales tax absent there being a purchase for resale without intervening use. Distributors need to collect retail sales tax from hospitals, and be subject to B&O tax under the retailing classification.

APPENDIX F: U.S. PHARMACOPEIA HAND SANITIZER TOOLKIT

Copied April 15, 2020 available at https://www.usp.org/news/sanitizer-toolkit

Hand sanitizer toolkit

Information for compounders, drug manufacturers and other facilities

For consumers, hand washing with soap and water provides effective hand hygiene against COVID-19 and should be utilized as the primary mode of hand hygiene. Hand sanitizers, made properly with the correct ingredients, also are effective but should be utilized only when soap and clean water are not available for hand washing. It is important to conserve hand sanitizers for settings where soap and clean water are not available. The CDC provides guidance on good hand washing practices.

In the healthcare setting, CDC states that hand washing mechanically removes pathogens, while laboratory data demonstrate that 60% ethanol and 70% isopropanol, the active ingredients in CDC-recommended alcohol-based hand sanitizers, inactivates viruses that are genetically related to, and with similar physical properties as, the 2019-nCoV.

This web page is for informational purposes and is intended to address shortages of alcohol-based hand sanitizers associated with the COVID-19 pandemic. USP is actively monitoring the evolving situation and will update this document accordingly. Parties relying on the information in this document bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements.

Demand for alcohol-based hand sanitizers from traditional large-scale commercial manufacturing has surpassed its supply and some of the ingredients traditionally used in hand sanitizers are in shortage. In response to this, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and other public health organizations have developed important guidance for compounding hand sanitizers, and for the preparation of hand sanitizers by manufacturers and other facilities, such as distilleries. USP has also issued recommendations developed by its Compounding Expert Committee for the compounding of hand sanitizers, including different formulations and utilizing alternative ingredients.

Get information and guidelines for:
Compounders OTC drug manufacturers Other facilities USP standards for hand sanitizer ingredients

Information for compounders

- **WHO**

The WHO provides a practical guide for use at the pharmacy bench during the actual preparation of the hand sanitizer formulations. Information in the guide includes materials required for small volume production and 10-liter preparations. Formulations include starting material of **ethanol 96%** for final product concentration of **ethanol 80% (v/v)** or starting material of **isopropyl alcohol 99.8%** for final product concentration of **isopropyl alcohol 75% (v/v)**.

Legal Stuff: The use of these materials is at your own risk. DISCUS and other contributors accept no liability for your reliance on any of these materials. Nothing in this document constitutes legal advice. We suggest that you consult with your attorney and other subject matter advisors for any specific guidance on legal or regulatory compliance.

- **FDA**

The FDA issued "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency" Immediately in Effect Guidance for Industry." The guidance explains that FDA does not intend to take action against compounders that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency provided certain circumstances are present. The circumstances include the following:

- The hand sanitizer is compounded according to the following formula consistent with WHO recommendations:
  - **alcohol (ethanol) (80%, v/v)** in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or **isopropyl alcohol (75%, v/v)** in an aqueous solution
    - alcohol (ethanol) (if derived from synthetic processes, is used only if it meets **USP or FCC grade**), that is **not less than 94.9% ethanol by volume**;
  - glycerol (1.45%, v/v)
    - glycerin (glycerol) USP or FCC (also known as "food grade")
  - hydrogen peroxide (0.125%, v/v)
    - USP Hydrogen Peroxide Concentrate or USP Hydrogen Peroxide Topical Solution
  - sterile water (e.g., by boiling, distillation or other process that results in water that meets the specifications for *Purified Water* USP).
- The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. See Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21.
- The hand sanitizer is prepared under conditions routinely used by the compounder to compound similar nonsterile drugs (USP General Chapter <795>).

- **USP**

USP created a document outlining recommendations from its Compounding Expert Committee intended to address shortages of alcohol-based hand sanitizers associated with the COVID-19 pandemic. The document includes three formulations for the compounding of hand sanitizer and appropriate ingredient substitutions based on shortage issues.

- Formulation 1 – starting ingredient of **ethanol 96%** for final product concentration of **ethanol 80% (v/v)**
- Formulation 2 - starting ingredient of **isopropyl alcohol 99%** for final product concentration of **isopropyl alcohol 75% (v/v)**
- Formulation 3 – starting ingredient of **isopropyl alcohol 91%** for final product concentration of **isopropyl alcohol 75% (v/v)**

The starting ingredients for Formulations 2 and 3 provide alternatives to WHO's formula using isopropyl alcohol 99.8%, due to shortage concerns.

The hand sanitizer should be prepared under conditions routinely used by the compounder to compound similar nonsterile drugs (USP General Chapter <795>).

- **NASPA**

The National Alliance of State Pharmacy Associations (NASPA) is providing information from the States related to compounding hand sanitizers.

Information for OTC drug manufacturers

- **FDA**

FDA issued "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)" Guidance for Industry. The guidance explains that FDA does not intend to take action against firms that register as over-the-counter (OTC) drug manufacturers that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency provided certain circumstances are present. The circumstances, in part, include the following:

- The hand sanitizer is manufactured according to the following formula consistent with WHO recommendations:
  - **alcohol (ethanol) (80%, v/v)** in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or **isopropyl alcohol (75%, v/v)** in an aqueous solution
    - alcohol (ethanol) (if derived from synthetic processes, is used only if it **USP or FCC grade**), that is **not less than 94.9% ethanol by volume**;
  - glycerol (1.45%, v/v)
    - glycerin (glycerol) USP or FCC (also known as "food grade")
  - hydrogen peroxide (0.125%, v/v)
    - USP Hydrogen Peroxide Concentrate or USP Hydrogen Peroxide Topical Solution
  - sterile water (e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP).
- The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. See Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21.

Information for other facilities (e.g. distilleries)

- **FDA**

FDA issued "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry."The guidance explains that FDA does not intend to take action against alcohol production firms that register their facilities with FDA and that manufacture alcohol for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency provided certain circumstances are present. The circumstances include the following:

- The **alcohol (ethanol)** is **not less than 94.9% ethanol by volume**, consistent with USP and FCC requirements for purity (if purity lower than USP and grade requirements, the product meets this condition if labeled accordingly and the content is sufficient to enable the finished hand sanitizer to meet the ethanol volume to content concentration of 80%.)
- Sterile water (e.g., by boiling, distillation or other process that results in water that meets the

specifications for Purified Water USP).
- The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. See Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21.

- **Alcohol and Tobacco, Tax, and Trade Bureau (TTB)**

The TTB posted guidance that it would waive provisions of internal revenue law with regard to distilled spirits and provide exemptions to distilled spirits permittees who wish to produce ethanol-based hand sanitizers to address the demand during the public health emergency.

USP standards for hand sanitizer ingredients

We are offering a resource of *USP-NF* and *FCC* standards related to alcohol-based hand sanitizers. In addition to the monographs themselves, it also includes standards referenced within the monographs.
Download the document

APPENDIX G: Department of Homeland Security CISA Hand Sanitizer Raw Materials Advisory

U.S. Department of Homeland Security
Cybersecurity & Infrastructure Security Agency
Office of the Director
Washington, DC 20528

MEMORANDUM ON HAND-SANITIZER RAW MATERIALS AND RECOMMENDATIONS FOR PRIORITIZATION

FROM: Christopher C. Krebs
Director
The Cybersecurity and Infrastructure Security Agency (CISA)

The Cybersecurity and Infrastructure Security Agency (CISA) executes the Secretary of Homeland Security' s authorities to secure critical infrastructure. Consistent with these authorities, CISA uses trusted partnerships with both the public and private sectors to deliver infrastructure resilience assistance and guidance and to recommend measures to a broad range of partners.

In accordance with these authorities, and in collaboration with other federal agencies and the private sector, CISA recognizes that the demand for hand sanitizer has significantly increased and that hand sanitizer is in short supply for many industries, including healthcare and food production. As the Nation comes together to slow the spread of COVID-19 there is a need to address the shortages related to raw materials needed to produce hand sanitizer.

Through CISA's coordination and work with our trusted partners in both the public and private sectors, CISA has identified that the problem lies primarily in the supply chain of raw materials to make hand sanitizer to the necessary specifications so that hand sanitizer can be used in the healthcare and food production industries. To this end, CISA – as the Sector-Specific Agency for the Chemical Sector – has developed the attached recommendations to address the shortages of related raw materials. These recommendations also provide a suggested prioritization of available hand sanitizer products once the raw materials shortage has been alleviated.

These recommendations are advisory in nature. They are not, nor should they be considered, federal directives or standards. They do not constitute orders or contracts on behalf of the federal government and compliance with these recommendations does not entitle an entity to compensation of any kind.

Should you have questions about this guidance, please contact CISA at CISA.CAT@cisa.dhs.gov.

Attachment:
COVID-19 Advisory: Hand-Sanitizer Raw Materials and Recommendations for Prioritization

APRIL 2, 2020

COVID-19 ADVISORY: HAND-SANITIZER RAW MATERIALS AND RECOMMENDATIONS FOR PRIORITIZATION

PURPOSE

The purpose of this advisory is to share recommendations - developed by the Cybersecurity and Infrastructure Security Agency (CISA) as the Sector-Specific Agency for the Chemical Sector - to address the shortages related to raw materials needed to produce hand sanitizer. These recommendations also provide a suggested prioritization for available hand sanitizer products once the raw materials shortage has been alleviated. The recommendations included in this advisory are intended to support state, local, tribal, territorial and industry partners in addressing the shortages related to raw materials needed to produce hand sanitizer and prioritizing the hand sanitizer supply once it is produced.

BACKGROUND

CISA executes the Secretary of Homeland Security's authorities to secure critical infrastructure. Consistent with these authorities, CISA uses trusted partnerships with both the public and private sectors to deliver infrastructure resilience assistance and guidance and to recommend measures to a broad range of partners.

In accordance with these authorities, and in collaboration with other federal agencies and the private sector, CISA recognizes that the demand for hand sanitizer has significantly increased and that hand sanitizer is in short supply for many industries, including health care and food production.

Through CISA's coordination and work with our trusted partners in both the public and private sectors, CISA has identified that the problem lies primarily in the supply chain of raw materials required to make hand sanitizer to the necessary specifications so that hand sanitizer can be used in the healthcare and food production industries. To this end, CISA developed the following recommendations to address the shortages related to raw materials needed to produce hand sanitizer. These recommendations also provide a suggested prioritization for available hand sanitizer products once the raw materials shortage has been alleviated to help ensure the continued operation of these vital industries.

RECOMMENDATIONS

Based on its collaboration and engagement with partners, and additional analysis, CISA recommends that:

1) All producers of ethanol of appropriate purity for use in and not already targeted for the production of hand sanitizer are strongly encouraged to divert 1-2% or more of that ethanol to manufacturers of hand sanitizer.
2) In addition, all denaturant (i.e. isopropyl alcohol, BITREX, and others) producers are strongly encouraged to divert 0.25% or more of their production not already targeted for the production of hand sanitizer to that use.
3) Once hand sanitizer products become available, it is highly encouraged that available supplies be distributed with first priority to the following industries:
    a) Hospitals, healthcare, long-term care, retirement homes, hospice, and other health providing establishments.
    b) Food and agriculture industry, specifically focusing on the following components – human and animal food manufacturers/producers, grocery stores, food retail, food service, food storage and distribution.

DISCLAIMER

These recommendations are advisory in nature. They are not, nor should they be considered, federal directives or standards. They do not constitute orders or

contracts on behalf of the federal government and compliance with these recommendations does not entitle an entity to compensation of any kind.

UPDATES

CISA will continue to work with our partners in the critical infrastructure community to update this advisory if necessary, as the Nation's response to COVID-19 evolves.

ADDITIONAL INFORMATION

Should you have questions about this advisory, please contact CISA at CISA.CAT@cisa.dhs.gov.

APPENDIX H: FUEL ETHANOL REDISTILLING GUIDANCE

Fuel Ethanol Redistilling to Address Ethanol Shortage for Hand Sanitizers

There is a reported ethanol shortage for use in the hand sanitizers and disinfectant products necessary to address the COVID-19 pandemic. There is also a surplus of fuel grade ethanol, which may be used in sanitizers if it is redistilled and brought up to the allowable USP or FCC standards.

To assist those interested in redistilling fuel ethanol, this document provides a case study and guidance from one distiller who has successfully redistilled fuel ethanol up to USP grade.

THRESHOLD ISSUES AND OTHER CONSIDERATIONS

Equipment Specifications

190° Proof Equipment – It is advisable to use equipment that can bring product up to 190° Proof. Achieving this proof helps to clean the product by separating out the distillates.

Distillation Copper – Copper leaches sulfites, so it is recommended that copper equipment is utilized. Removing the sulfites is a key step to mitigating the odor of the source material.

Testing

Requires access to testing to verify that impurities have been removed; it is recommended that a distillery either use their own GC or an accredited GC laboratory to perform the tests outlined below.

Cleaning Cost and Time

Requires significant cleaning and some part replacement before returning to beverage production. Any metal surface can be cleaned with normal caustic cleaning, but all gaskets and hoses should be replaced.

TECHNICAL INFORMATION RE REDISTILLING FUEL ETHANOL

The information included below is a case study from one distiller who has successfully redistilled fuel ethanol up to the acceptable USP grade standards. If you have additional questions for the distiller or the fuel provider their contact information is included below.

Contacts:

Distiller: Middle West Spirits, Columbus, Ohio
Ryan Lang, Principle/Distiller
704-315-9164
ryan.lang@middlewestspirits.com

Fuel Ethanol Provider: POET Marion, Ohio
Josh Luton, Manager, Business Development
Joshluton@poetep.com

Middle West Spirits Case Study: Process Control and Instructions

Operation Performed: Re-distillation of POET Fuel Ethanol Plant Distillate

Where Performed: Middle West Spirits, Columbus, Ohio

Feed material: POET Ethanol from Marion, Ohio

The following lists an overview of tests performed and a procedure for re-distillation of corn fuel ethanol for refinement at Middle West Spirits, a consumable alcohol distillery. Middle West has successfully refined fuel grade ethanol sourced from POET up to meet or exceed USP Grade Specifications:

USP Grade Specifications *vs.* Fuel Grade Ethanol Typicals

Parameter/Analyte	Units	USP Grade Specs	Fuel Grade Typicals
Methanol, max	mg/L (ppm)	200	100-200
Acetaldehyde, max	mg/L (ppm)	10	100-200
Sum of All Other Impurities, max	mg/L (ppm)	300	2,000-4,000
Benzene, max	mg/L (ppm)	2	<2

Other impurities include, but are not limited to:
1-Propanol
2-Butanol
Ethyl Acetate
2-Methyl-1-Propanol
1-Butanol
3-Methyl-1-Butanol
2-Methyl-1-Butanol

Note: These impurities need to be distilled and refined out to bring it into the USP grade ranges noted above.

STEP 1: Product Selection and Procurement

The necessary process to bring fuel ethanol up to USP standards will depend on the impurities that are in the feed material. It is recommended that a distiller take this into consideration when procuring ethanol. We recommend requesting a test of the feed from a reputable laboratory and assurances that the test was conducted on that specific feed as it is important to know what is in feed before agreeing to take it in.

- Middle West recommends that fuel ethanol plant material be shipped without corrosion inhibitor or any denaturing agent. POET was able to alter their procedures to allow for shipment of material post distillation at 190 proof before dehydration to 200 proof and before any inhibitor is added.

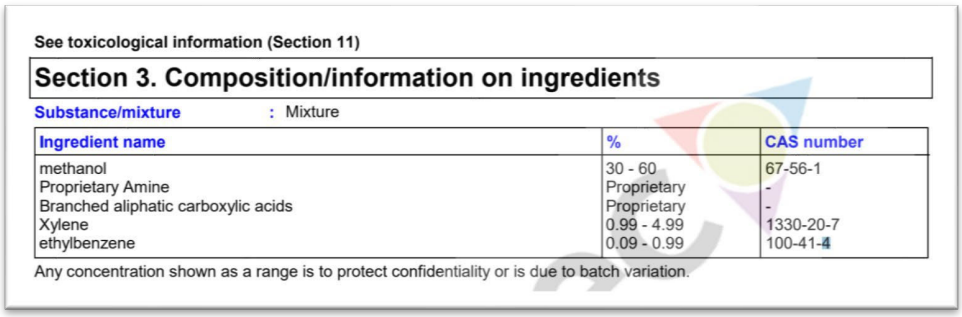
- NOTE: To make the process easier, Middle West recommends that distillers purchase distillate at the 190 proof before dehydration and before the inhibitor is added.

- Reminder: this source may never be used for beverage alcohol. Fuel ethanol could have been produced using Urea, which can form ethyl carbamate.

- Other factors to consider:
    - Is the ethanol denatured with gasoline?
    - Did it contain rust inhibitor (at any point in the process)?
    - Was the ethanol loaded through a common line that also carried alcohol denatured gasoline?
    - If the answer to any of these questions is YES, you will want to look for a different supply

- NOTE: Concentrations of these inhibitors are exceptionally low by volume. These items can be removed but will be detected by GC analysis. That said, it is recommended the alcohol be purchased without these inhibitors in the solution.

Below is an example of corrosion inhibitors MSDS Section 3 for Composition.



See toxicological information (Section 11)

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
methanol	30 - 60	67-56-1
Proprietary Amine	Proprietary	-
Branched aliphatic carboxylic acids	Proprietary	-
Xylene	0.99 - 4.99	1330-20-7
ethylbenzene	0.09 - 0.99	100-41-4

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

STEP 2: Delivery & Dilution

- A POET Fuel ethanol delivery at 200 Proof was received and immediately reduced to 120 proof for storage safety and to prepare for transfer to distillation system for refinement and removal of unwanted materials.
- A certified wash on the tanker truck and any hoses/pumps on the truck is recommended prior to hauling ethanol going for further distillation, unless the truck was in prior service for same product or grade of ethanol. For example, a truck shouldn't be required to wash before every undenatured ethanol haul, presuming it was washed before the first trip in that service.

STEP 3: Re-distillation

- A pot/column combination still was charged with the 120 proof diluted fuel ethanol.
  - The distillation equipment utilized is constructed of a copper pot, 22 plate copper column set. The condenser and vapor lines are stainless steel.

- Middle West's GNS process program was utilized for heat and condensing procedures during the entire run.

- The initial heating phase of the still was reduced to aid in the separation of the heads due to the Acetaldehyde concentration.

- A drastic head cut was performed. Volume of head removal increased 5% over normal removal rates of total volume for safety of material concentrations (see table below).

- **NOTE – Copper and Sulfite Removal**: Copper was chosen specifically for its ability to remove sulfites in operation. Most fuel ethanol plants operate carbon steel distillation units and therefore cannot leech sulfur impurities in operation. Given that the FDA approved formula (based on WHO formula) can have zero fragrance additives, copper must be used to remove the sulfur odor. Note that sulfate ppm levels vary by samples tested but are exceptionally noticeable when exposing the distillate to air.

- **NOTE – Cut Analysis:** Fuel ethanol has larger concentrations of Acetaldehyde and Methanol than what would be visible in a potable ethanol production plant. **Thus, a heads cut analysis must be performed at each plant to determine the exact amount of volume by percentage that must be removed to ensure these items are reduced to USP standards.**

Results before distillation, heads run, hearts run:

Customer:	Middle West Distillery						
Contact:	Ryan Lang						
Analyte	Method	Diluted 140p Sample Before redistillation Results	Diluted sample heads run at 190 + proof Results	Diluted Sample Hearts run at 192.10 proof Results		USP Limits	
Total Impurities	Calculation	275	3,768	94	mg/kg	300.00	3/30/2020
Acetaldehyde	GC-FID	70	1,414	17	mg/kg	10	3/30/2020
Methanol	GC-FID	10	197	62	mg/kg	200	3/30/2020
Benzene	GC-FID	BDL	3	BDL	mg/kg	2	3/30/2020
LOD = Limit of Detection							
BDL = Below Detection Limit							
mg/kg = ppm (parts per million)							
					Approval:	[redacted]	
Additional Analytical Comments:						Chemist	
					Date:	April 1, 2020	

NOTE – Acetaldehyde Removal: Further process controls are being placed to further reduce the acetaldehyde and it is recommended that a distillery follow their own procedures to understand the removal. Acetaldehyde boiling point is 68° F, removal will require appropriate heating times and cuts to make USP grade.

STEP 3: Testing

Final ethanol analysis should be performed to verify USP (or FCC) standards are met before using for hand sanitizer.

Testing methods used:

- ASTME D5501 Ethanol
- Compare GC - FID Method – Undenatured Alcohol impurities

APPENDIX H-2: Guidance on Distilling Unused Beer for Hand Sanitizer

Distilling Unused Beer to Address Ethanol Shortage for Hand Sanitizers

There is a reported ethanol shortage for use in the hand sanitizers and disinfectant products necessary to address the COVID-19 pandemic. There is also a reported surplus of kegged beer that was produced for the on-premise market, which now will soon go to waste and may be used in sanitizers if it is distilled and brought up to appropriate proof per the FDA guidance.

To assist those interested in turning this unused beer into hand sanitizer, this document provides some guidance from one distiller who has successfully distilled beer for hand sanitizer production. We also have set forth below TTB's related guidance on the destruction or transfer of beer for the purpose of distilling during COVID-19.

Complicating and Threshold Factors to Consider

- **Size of Operations**: Distilling beer may not be worthwhile for smaller operations.
  - Column stills are better suited to process the high volume of beer necessary to make this a worthwhile pursuit. Due to the continuous feed compensating for input proof, these stills have an easier time distilling to the proof required by FDA.
  - Distilling beer is most likely not efficient for small pot still-only operators unless they can get smaller quantities of higher gravity mashes or have other high proof alcohol that can be added to the beer to increase the proof prior to distillation.
  - NOTE: Pot stills can be useful though for stripping runs to convert beer to low wines for storage.

- **Degassing**: The beer should be recirculated to degas the solution, which will remove the carbon dioxide and foam. Antifoams should be used to prevent foam build up in your still. Depending on the beer, you also may need to continue the fermentation process to remove the residual sugars.

- **Low Alcohol Content**: As the alcohol content of the beer will be lower than your usual mash, it may be necessary to increase the alcohol content prior to distillation. This extra alcohol content can come from the added yeast (if you chose to referment) or high proof alcohol can be added to the beer to bring the alcohol content up to a level that your column or pot still can more easily run.

- **Temperature**: As these kegs are typically coming from distributors, they have been refrigerated and so the temperature of the beer will be much lower than your usual mash. This will result in more steam being needed (column stills) or a slower heat up time (pot stills). If you recirculate the beer or add yeast, this may also help bring the beer up to a higher temperature.

Full List of Steps:

Step One: Receive and Process Feed
- Empty kegs into totes, record volume and concentration/tote
- Transport tote to processer
- Process tote for distillation, fortification, or re-fermentation

Step Two: Prepare Feed for Distillation
- De-Gas: Recirculate the beer to de-gas the feed
- Fortify: Calculate the approximate proof and adjust to your preferred input proof for your equipment. If your still is not able to run an input that low, add excess high proof alcohol to increase concentration if needed.

Step Three: Distillation
- Distillation: Use your standard processes to bring it up to the necessary proof and grade.
- Product temperature will be lower than your usual feed, so you might need more steam for your column still or a longer heat up in the pot still.
- You can use the resulting low wines to fortify beer for the future runs, or just run the low wines on the column themselves when you have enough.

TTB FAQs – Destruction of Beer During COVID-19
Released May 1, 2020/Updated June 23

Below is the relevant guidance provided to date by TTB regarding the usage and transmittal of beer to DSPs for use as distillation material. These FAQs can be accessed here.

Frequently Asked Questions - Destruction of Beer During COVID-19

We are providing you with this guidance to help you and your business respond to COVID-19.

COV-B1: Because of COVID-19, I have unmerchantable beer in the marketplace. Can that taxpaid or tax-determined beer be destroyed without returning it to my brewery and can I be relieved of the tax on that beer?

Current regulations require that brewers destroying taxpaid beer off brewery premises submit to TTB a notice of intent (NOI) containing specific information about the destruction at least 12 days prior to the destruction (see 27 CFR 25.222).

However, due to the business disruptions brewers are facing during COVID-19, TTB is waiving the requirement that brewers submit NOIs to TTB to destroy taxpaid beer in the marketplace, thus eliminating the 12-day waiting period under the regulation. Under this waiver, in lieu of submitting the NOI, brewers must maintain records showing the information required to be submitted on the NOI (see 27 CFR 25.222(c)), including a serial number for each destruction that is then identified by reference on any claims or adjustments, and must include the information required on NOIs and proof of destruction when submitting a claim to TTB for refund of tax (see COV-B6 below).

We are providing this waiver through July 1, 2020*, under our authority at 27 CFR 25.52(b), and we may consider extending it as needed to address COVID-19-related circumstances.

***UPDATED as of June 23, 2020:** This waiver was initially provided through July 1, 2020. However, due to the ongoing and significant business disruptions due to COVID-19, TTB is extending the waiver through September 1, 2020.*

COV-B2: Do I have to notify TTB before I destroy taxpaid beer off brewery premises as described in COV-B1 above?

Current regulations require that brewers destroying taxpaid beer off brewery premises submit to TTB a notice of intent (NOI) containing specific information about the destruction at least 12

days prior to the destruction (see 27 CFR 25.222).

However, due to the business disruptions brewers are facing during COVID-19, TTB is waiving the requirement that brewers submit NOIs to TTB to destroy taxpaid beer in the marketplace, thus eliminating the 12-day waiting period under the regulation. Under this waiver, in lieu of submitting the NOI, brewers must maintain records showing the information required to be submitted on the NOI (see 27 CFR 25.222(c)), including a serial number for each destruction that is then identified by reference on any claims or adjustments, and must include the information required on NOIs and proof of destruction when submitting a claim to TTB for refund of tax (see COV-B6 below).

We are providing this waiver through July 1, 2020, under our authority at 27 CFR 25.52(b), and we may consider extending it as needed to address COVID-19-related circumstances.

COV-B3: Because of COVID-19, I have beer on hand at my brewery premises that I am not going to be able to sell. Can beer on my premises be transferred to a distilled spirits plant (DSP) for use in the production of hand sanitizer without payment of tax?

Yes, under existing law, brewers may transfer beer without payment of tax from the brewery to a DSP for use as distilling material (see IRC provision 26 U.S.C. 5053(f)), which DSPs may subsequently use in the production of hand sanitizer. If applicable, such transfers also may be made by pipeline from the brewery to a DSP under current regulations (see 27 CFR 25.201).

Brewers transferring beer to a DSP must record the removal in their daily records, report it on their Brewer's Report of Operations, and maintain supporting documents, such as a record of transfer to the DSP, under the requirements of Subpart U—Records and Reports.

COV-B4: Because of COVID-19, some of my beer in the marketplace has reached or exceeded its freshness date. Can that taxpaid or tax-determined beer be transferred to a DSP for use in the production of hand sanitizer and can I be relieved of the tax for beer transferred to a DSP?

Yes, it is possible for brewers to transfer beer in the marketplace to a DSP and be relieved of or refunded tax.

Beer that is received at a DSP for use as distilling material is considered, for purposes of the TTB regulatory requirements, to be beer destroyed off brewery premises. The tax paid by a brewer on beer produced in the United States and received at a distilled spirits plant may be refunded or credited to the brewer, without interest (see 26 U.S.C. 5056(a) and (c); 27 CFR 25.224). If the tax has not been paid, the brewer may be relieved of liability for the tax (see 26

U.S.C. 5056(a) and (c); 27 CFR 25.224).

For information about how to be relieved of or refunded the tax on taxpaid beer that is transferred to a DSP, see COV-B6 below.

COV-B5A: Do I have to notify TTB before I destroy taxpaid beer off brewery premises as described in COV-B4 above?

In cases where beer is considered destroyed off brewery premises because it is used by a DSP as distilling material, TTB is waiving the requirement under 27 CFR 25.222 to submit to TTB an NOI under the same terms as described in COV-B2 above. Specifically, TTB is waiving the requirement that brewers submit NOIs to TTB to destroy taxpaid beer in the marketplace, which also alleviates the 12-day waiting period described in this regulation. Under this waiver, in lieu of submitting the NOI, brewers must maintain records showing the information typically required to be submitted on the NOI (see 27 CFR 25.222(c)), including a serial number for each destruction that is then identified by reference on any claims or adjustments.

We are providing this waiver through July 1, 2020*, under our authority at 27 CFR 25.52(b), and we may consider extending it as needed to address COVID-19-related circumstances.

*UPDATED as of June 23, 2020: This waiver was initially provided through July 1, 2020. However, due to the ongoing and significant business disruptions due to COVID-19, TTB is extending the waiver through September 1, 2020.

COV-B6: What must I do to be relieved of or refunded the tax on taxpaid beer that is destroyed off brewery premises?

Under current regulations (see Subpart T of 27 CFR part 25), brewers who wish to recoup the tax they paid on beer that is destroyed may file a claim for refund. Brewers must submit to TTB a completed claim on TTB Form 5620.8 with all of the information and supporting documentation required under 27 CFR 25.283(a). If the brewer does not submit the NOI, TTB is requiring under 27 CFR 25.283(d) that brewers submit the information required on NOIs under 27 CFR 25.222 and proof of destruction, through commercial records or statements under penalties of perjury.

If filing a claim, we strongly encourage brewers to send claims electronically by submitting a completed claim on TTB Form 5620.8 and all supporting documentation through TTB's online claims submission process. Due to COVID-19, to ensure the safety and well-being of our employees, and in accordance with federal, state, and local guidelines, we will be very limited

in our ability to receive and process paper submissions sent to our office locations, which could result in significant delays in processing claims submitted by mail.

Under normal circumstances, claims must be filed within 6 months after the date of the destruction. Due to COVID-19, we have postponed certain due dates. To find out whether the due date for filing a claim on beer you destroyed has been postponed, please see TTB Industry Circular 2020-2, Tax Payment and Other Filing Due Dates Postponed for Industry Members Affected by COVID-19.

Alternatively, in lieu of filing a claim for refund of tax, a brewer may instead make an adjustment (without interest) to the next excise tax return on TTB Form 5000.24 under current regulations (see 27 CFR 25.224(b) and 25.284).

For questions about the trade practice implications of returns of beer from the marketplace, see TTB G 2020-2, Returns of Alcohol Beverage Products Purchased for Events Cancelled Due to COVID-19 Emergency.

COV-B7: I am a brewer that produced and paid taxes on beer that is in kegs in the marketplace, and I would like to destroy that beer without returning it to my brewery. To save costs, can the beer be removed from the kegs and transferred to a DSP or otherwise destroyed by a wholesaler on behalf of my brewery?

Yes, TTB regulations do not prohibit a brewer from having a wholesaler destroy beer on a brewer's behalf by, for example, removing beer from kegs and transferring that beer to a DSP for destruction. Note that brewers must support any claim for refund or adjustment of tax for all beer destroyed, including beer destroyed on its behalf.

Brewers must maintain records showing the same information required to be submitted on the notice of intent to destroy (see 27 CFR 25.222(c)), including a serial number for each destruction that is then identified by reference on any claims or adjustments. Claims or adjustments on tax returns must reference the serial number for the destruction subject to the claim or adjustment, as the case may be (see COV-B6).

In cases where wholesalers arrange for the destruction of beer on the brewer's behalf, wholesaler records, such as commercial records, statements under penalties of perjury, and other evidence of destruction that the wholesaler maintains, are adequate records of destruction.

Page last reviewed: May 1, 2020
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APPENDIX I: PRICE GOUGING LAWS BY STATE

Created by FindLaw's team of legal writers and editors | Last updated March 24, 2020. Copied April 29, 2020 – can be accessed at https://consumer.findlaw.com/consumer-transactions/price-gouging-laws-by-state.html.

When disaster strikes, whether it's a Category 5 hurricane, a pandemic, or an uncontrollable wildfire, consumers are often left scrambling for basic necessities such as drinking water and medical supplies. When retailers take advantage of these spikes in demand (often coupled with supply bottlenecks) by charging exorbitant prices for necessities, it's referred to as "price gouging."

In most states, price gouging during a time of emergency is considered a violation of unfair or deceptive trade practices law. Most of these laws provide for civil penalties, as enforced by the state attorney general, while some state laws also enforce criminal penalties for price gouging violations. There is no federal "price gouging" law.

The definition of "excessive" or "unconscionable" pricing is generally determined by looking at average prices in the affected area over a given look-back period prior to the emergency, typically six months or so. If prices are 10 or 15 percent higher (some states have different thresholds), then it may be determined that price gouging has occurred.

State-by-State Guide to Price Gouging Laws

Below are summaries of state laws prohibiting acts of price gouging in the event of a declared emergency. Keep in mind that laws are always subject to change.

	Summary of the Law: What Is Prohibited & Penalties	Statute
Alabama	• Charging "unconscionable" prices for commodities or rental facilities during a declared state of emergency. • Civil penalty of $1,000 per incident. *The governor of Alabama declared a state of emergency to prevent the spread of COVID-19	§ 8-31-1, et seq.
Alaska	n/a. *You can file a Consumer Complaint	
Arizona	n/a.	
Arkansas	• Selling commodities, household essentials, fuel, etc. after a declared state of emergency for more than	§ 4-88-301, et seq.

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	10% over the cost of these items immediately preceding the declaration. • Class A misdemeanor (up to $2,500 fine and up to one year in jail per violation). * The governor has declared a state of emergency to prevent the spread of COVID-19. The state of emergency prohibits unjustified increases in the price of essential consumer goods and services	
California	• Selling commodities, household essentials, fuel, etc. after a declared state of emergency for more than 10% over the cost of these items immediately preceding the declaration. • Misdemeanor, punishable by up to 1 yr. in jail and/or up-to a $10,000 fine; civil penalties of up to $2,500 per violation (plus injunction and restitution). *The Attorney General, in response to COVID-19, issued a price gouging alert, declared a state of emergency and issued an executive order. The governor also declared a state of emergency prohibiting an unjustified and excessive increase of more than 10% of necessary goods and services.	PEN § 396
Colorado	n/a	
Connecticut	• Selling commodities, household essentials, fuel, etc. after a declared state of emergency for more than acceptable market prices (as determined by the state). • Penalties range from $99 - $1,000 and/or up-to one year in jail per offense. *A public health and civil preparedness emergency was recently declared to help slow down the COVID-19 pandemic. It states that no person can sell any product in short supply (as designated by the governor) at a price that exceeds the normal, course of business, sale price.	§ 42-230, et seq.
Delaware	n/a *Delaware has declared a state of emergency to prevent the spread of COVID-19. The state of emergency prohibits increasing the price of goods by more than 10%.	

District of Columbia	• Selling commodities, household essentials, fuel, etc. after a declared state of emergency for more than 10% over the price at which similar services/products were sold during the 90-day period preceding the emergency. • Civil infraction, punishable by up to $1,000 in fines and license/permit revocation/suspension (where applicable). *The mayor has declared a public emergency, which automatically brings § 28-4101 into effect regarding price gouging. It prohibits price increases of more than 10%.	§ 28-4101 - 4103
Florida	• Selling commodities, household essentials, rentals, fuel, etc. after a declared state of emergency at "unconscionable" prices("grossly exceeding" average prices in the 30-day period preceding the emergency). • 2nd-degree misdemeanor, punishable by a fine of up to $1000 and/or up-to 60 days in jail for a first offense; $25,000 for multiple violations within a 24-hour period. *The governor declared a state of emergency in response to the COVID-19 pandemic, activating § 501.160. The price gouging hotline has also been activated.	§ 501.160
Georgia	• Selling items or services determined by the Governor during a declared state of emergency to be necessary for public safety at a higher cost than they were immediately prior to the declaration. • Charged as a deceptive or unfair trade practice (and investigated by the AG as such); an additional civil penalty of up to $10,000 for each violation if "disaster-related." *Georgia declared a state of emergency in response to the COVID-19 pandemic, which activated the provisions listed above.	§ 10-1-393.4, et seq.; § 10-1-438
Hawaii	• "Any increase in the selling price of any commodity" after the Governor declares a state of emergency; also, landlords may not terminate tenancy for residential dwellings in an area subject to severe weather warning or emergency declaration	§ 127A-30; § 480-2

	• Charged as an unfair or deceptive trade act, subject to fines between $500 and $10,000 per violation *The governor has issued a state of emergency prohibiting any increase in the selling price of any commodity during the time the state of emergency is in force.	
Idaho	• Selling "fuel or food, pharmaceuticals, or water for human consumption at an exorbitant or excessive price" (based on a comparison of prices immediately before and after the declaration) during a declared state of emergency • Charged as an unfair trade practice; subject to civil penalties of up to $5,000 per violation, recovery of actual damages suffered by the consumer(s), and/or an order for specific performance *Idaho declared a state of emergency in response to COVID-19, which activates the above provisions.	§ 48-603
Illinois	• "During any market emergency, for any petroleum-related business to sell or offer to sell any petroleum product for an amount that represents an unconscionably high price" (defined as a "gross disparity" between the prices immediately before and after the emergency) • Charged as an unfair business practice; subject to injunctive relief, restitution, and civil penalties of up to $50,000 per violation *Illinois has declared a state of emergency due to COVID-19. *House Bill 2882 is pending. It provides that a "manufacturer or wholesale drug distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug."	815 ILCS 505/2; Illinois Administrative Code: 465.10, et seq.
Indiana	• Price-gouging on fuel sales during (and 24 hours before) a declared state of emergency; defined as charging a price that "grossly exceeds" the average price of fuel in the immediate area during the 7 days immediately preceding the declaration • Attorney General may investigate complaints, seek appropriate injunctive relief, seek restitution for	§ 4-6-9.1-1, et seq.

	victims, and collect a civil penalty of up to $1,000 per violation *Indiana has declared a public health emergency in response to COVID-19.	
Iowa	• Charging "an excessive price for merchandise to be provided to persons within an area declared to be a disaster area during the period of any declaration of emergency and for the subsequent recovery period." • Charged as an unfair business practice; up to $40,000 per violation (an additional $5,000 if victims were elderly), injunctive relief, and restitution. *Iowa declared a state of emergency to prevent the spread of COVID-19 pandemic activating 61-31.1 (714) of the Administrative Code.	§ 714.16; Iowa Administrative Code (IAC): 61-31.1 (714)
Kansas	• For any supplier of a "necessary property or service" to "profiteer from a disaster" by charging 25% or more than the pre-disaster price for such goods/services. • Charged as an unconscionable business act or practice; punishable by up to $10,000 per violation (an additional $10,000 if victims were elderly), injunctive relief, and restitution. *Kansas declared a state of emergency in response to COVID-19 pandemic, prohibiting any supplier from "profiteering from a disaster"	§ 50-6,106
Kentucky	• Selling or renting goods or services (food, emergency supplies, medical supplies, heating oil, housing, gasoline, etc.) "for a price which is grossly in excess of the price prior to the declaration and unrelated to any increased cost to the seller." • Punishable by a civil penalty of up to $5,000 for the first violation and up to $10,000 for each additional violation. *Kentucky governor declared a state of emergency in response to the COVID-19 pandemic.	§ 367.372, et seq.
Louisiana	• Selling goods/services during a declared state of emergency (within the designated emergency area) in	Tit. 29, § 732, et seq.

	excess of the ordinary price range immediately before the declaration. • Attorney General may bring an action to enjoin (cease) the offending act; subject to civil action (including payment of attorney fees) and criminal penalties (up to 5 yrs. hard labor for damage exceeding $5,000, up to 10 yrs. for violations resulting in death). *The governer has issued a public health emergency, activating the provisions stated above.	
Maine	• Selling or offering for sale "necessities at an unconscionable price" when there is an abnormal market disruption (typically a declaration by the Governor). • Charged as an unfair act (civil violation); civil fine of up $10,000; criminal penalties of up to $1,000 and/or up to 3 yrs. in prison. *The governor of Maine has declared a state of emergency to help prevent the spread of COVID-19.	Title 10, § 1105; § 207
Maryland	n/a *House Bill 1663 has been introduced prohibiting sellers from engaging in any unfair, abusive, or deceptive trade practices.	
Massachusetts	• Selling "any petroleum product" at an unconscionably high price "during any market emergency" (as declared by the Governor). • A civil penalty of $5,000 per violation. *The governor has declared a state of emergency to help prevent the spread of COVID-19. Bill S.712 has also been introduced aiming to "promote transparency and prevent price gouging of pharmaceutical drug prices".	Code of Massachusetts Regulations (CMR): 940 CMR 3.18
Michigan	"Charging the consumer a price that is grossly in excess of the price at which similar property or services are sold" -- regardless of whether there is a declared emergency. • Civil penalty of up to $25,000 per violation.	§ 445.903

	* The governor Michigan passed an executive order that focuses on enhanced restrictions on price gouging	
Minnesota	n/a *The governor signed an executive order to address price gouging amid the COVID-19 pandemic. The order prohibits "selling, offering to sell, or causing to sell in the state any essential consumer goods or services for an amount that represents an unconscionably excessive price."	
Mississippi	• Selling goods and services at above the prices normally charged during a declared state of emergency (or what was charged immediately preceding the declaration). • Civil penalty of up $10,000 per violation, plus legal costs; criminal penalties ranging from a misdemeanor (up to $1,000 and 6 months in jail) to a felony (1 to 5 yrs. in prison and/or fine of up to $5,000). *Mississippi has declared a state of emergency over COVID-19.	§75-24-25
Missouri	• Charging within a disaster area an excessive price for any necessity (or that which the seller has reason to believe will likely be provided to consumers within a disaster area). • $1,000 civil penalty per violation, injunctive relief, restitution; may be charged as a Class D felony (1-7 yrs. in prison and up to $10,000 fine).	§ 407.020; Missouri Code of State Regulations (CSR): 15 CSR 60-8.030
Montana	n/a	
Nebraska	n/a	
Nevada	n/a *You can file a complaint of price gouging online or through calling the Attorney General Office at 775-684-1100.	
New Hampshire	n/a *Bill NH SB688, which addresses price gouging of generic prescription drugs, has been introduced.	

New Jersey	• During a declared emergency, selling goods and services at a price that is at least 10% higher than it was immediately preceding the declaration. • Civil penalty of up to $10,000 for first violation, up to $20,000 for each subsequent violation, *New Jersey has declared a state of emergency in response to COVID-19, activating the provisions above.	56 § 8-107, et seq.
New Mexico	• It is illegal to misrepresent the price of goods or take advantage of consumers to a grossly unfair degree. *The Attorney General has issued a consumer advisory warning regarding price gouging following the COVID-19 pandemic, indicating that price gouging is unconscionable and any price gouging resulting in illegal profit will be prosecuted.	
New York	• Selling "goods and services vital and necessary for the health, safety, and welfare of consumers" at an "unconscionably excessive price" (as determined by the court) when there is an abnormal disruption of the market. • Up to $25,000 civil penalty per violation, restitution. *New York has declared a state of emergency due to the COVID-19 pandemic.	GBS § 396-r
North Carolina	• Selling or renting goods and services "used to preserve, protect, or sustain life, health, safety..." at unreasonably excessive prices after an emergency declaration or abnormal market disruption. • Civil penalty of up to $5,000 per violation. *The governor of North Carolina has declared a state of emergency to prevent the spread of COVID-19.	§ 75-38
North Dakota	n/a	
Ohio	• 1345.03 Unconscionable consumer sales acts or practices prohibit suppliers from committing unconscionable acts or practices in connection with a consumer transaction	

	*Due to COVID-19, Ohio declared a state of emergency, informing people who have been subjected to price gouging to contact the office of the Ohio Attorney General.	
Oklahoma	• Selling, renting, or leasing goods, services, dwelling units, or storage space after the declaration of an emergency at a price of more than 10% above the rate charged before the declaration. • Charged as a violation of the Oklahoma Consumer Protection Act, punishable by up to $10,000 per claim; may also be charged as a misdemeanor (up to $1,000 fine and/or 1 yr. in jail) or felony (up to $5,000 fine and/or up to 10 yrs. in prison). *The Oklahoma governor issued a state of emergency as a response to COVID-19 pandemic, activating the above provisions.	15 OK St. §§ 777.1, et seq. (download title 15 and scroll to page 169)
Oregon	• Selling essential consumer goods or services after the declaration of an emergency at a price of more than 15% above the rate charged before the declaration. • Considered an unlawful trade practice, subject to injunctive relief and private civil action by individuals for damages. *A state of emergency is declared in the state of Oregon due to the COVID-19 pandemic.	§ 401.960, et seq.
Pennsylvania	• Selling consumer goods or services in a geographic region subject to a declared emergency at an "unconscionably excessive price" (at least 20% higher than the normal price range immediately prior to the declaration). • Violations subject to a civil penalty of up to $10,000 for each act, in addition to injunctive relief and restitution. *The governor has issued a state of emergency in response to the COVID-19 pandemic.	Title 73 § 232.1, et seq.
Puerto Rico (U.S. territory)	n/a	
Rhode Island	• Selling "essential commodities" (i.e. heating fuel, motor fuels, food, water, ice, lumber, etc.) after the	§ 6-13-21

	declaration of an emergency at an "unconscionably high price." • Violations subject to civil penalty of up to $1,000 per violation (and up to $25,000 in total penalties for violations within any 24-hour period). *Rhode Island declared a state of emergency amid the COVID-19 pandemic.	
South Carolina	• After an emergency is declared, renting or selling a commodity at an unconscionable price or imposing unconscionable prices for the rental or lease of a dwelling unit, including a motel or hotel unit, or other temporary lodgings, or self-storage facility. • Subject to civil penalties of up to $5,000 per violation (up to $15,000 per violation if an injunction has been issued); may be charged as a misdemeanor (fine of up to $1,000 and/or 30 days in jail). *The state has declared a state of emergency in response to the COVID- 19 pandemic.	§ 39-5-145
South Dakota	n/a	
Tennessee	• Upon the declaration of a state emergency, charging "grossly excessive" prices for food, construction services, emergency supplies, or other vital goods or services. • Subject to civil penalty of between $1,000 and $3,000 per violation. *The governor issued an executive order due to the COVID-19 pandemic. The order addresses price-gouging protections on medical and emergency supplies.	§ 47-18-5101, et seq.
Texas	• After a declared emergency, "selling or leasing fuel, food, medicine, or another necessity at an exorbitant or excessive price." • Subject to civil penalty of up to $20,000 per violation (up to $250,000 if the victim was over 65 yrs. old) and injunctive relief. *The governor declared a state of disaster due to COVID-19.	§ 17.46(b)(27)

Utah	• After a declared emergency, charging an "excessive price" for consumer goods and services (10% higher than normal, or 30% higher for goods and services that were *not* provided immediately before the declaration). • Punishable by the issuance of a cease and desist order and civil penalties of up to $10,000 per day. *The governor declared a state of emergency in preparation for COVID-19.	§ 13-41-201, et seq.
Vermont	• After a declared "market emergency," charging "unconscionably high" prices for petroleum or heating fuel-related products or services. • Aggrieved parties have the private right of action under the Consumer Protection Act to sue the offending party.	§ 2461d
Virginia	• During a time of disaster, selling, leasing, or licensing "any necessary goods and services at an unconscionable price." • Punishable by a civil penalty of up to $2,500 per violation (up to $5,000 if in violation of an injunction). * The governor has issued a state of emergency in response to COVID-19. There is also a price-gouging complaint form available.	§ 59.1-525, et seq.
Washington	n/a *Senate Bill 6699 has been introduced prohibiting price gouging at the time of disaster.	
West Virginia	• After a declared state of emergency, selling consumer food items, medical supplies, heating oil, building supplies, etc. at more than 10% of the average cost of those items prior to the declaration. • Charged as a misdemeanor (up to $1,000 fine and/or up to 1 yr. in jail). *West Virginia declared a state of emergency to prevent the spread of COVID-19.	§ 46A-6J-1, et seq.

Wisconsin	• Selling, or offering to sell, in this state at wholesale or at retail, consumer goods or services at unreasonably excessive prices after an emergency declaration (15% higher than the average price immediately prior to the declaration) • Civil penalty of up to $10,000 and/or permanent injunction against the seller's actions. *Wisconson had declared a state of emergency due to the COVID-19 pandemic.	§ 100.305; Wisc. Administrative Code: ATCP 106.01, et seq.
Wyoming	n/a	

Note: *State laws are always subject to change. Make sure to do your own research or contact a local attorney if you have additional questions about a particular state law.*

APPENDIX J: DISCUS FDA Sanitizer Over-The-Counter Monograph User Fee Program FAQs

FDA Sanitizer Over-The-Counter Monograph User Fee Program FAQs

I'm a distiller who temporarily produced hand sanitizer in 2020 in response to the pandemic, does the OTC Monograph User Program facility fee apply to me?

- No, the Department of Health and Human Services (HHS) has clarified "that persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID-19 Public Health Emergency are not subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act)."

- The FDA Over-The-Counter Monograph User Fee Program facility fees ("OTC fee") were originally set to apply to distilleries that manufactured or processed hand sanitizer products under the FDA temporary policies during the COVID-19 pandemic. However, due to the advocacy efforts of DISCUS and others in the industry, HHS has since determined that persons who entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID-19 public health emergency are **not subject to the facility fees** the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act). As explained further in this pre-publication Federal Register notice, HHS is declining to identify these entities as OTC drug manufacturing facilities since "distilleries are not primarily in the drug manufacturing business" and "imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act."

Is there an expiration date or any other limitations to the HHS exception to the OTC fee?

- This exception from the OTC fees does not apply to those "that (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the COVID-19 Public Health Emergency is terminated. In those cases, the Department may identify such persons as OTC drug manufacturing facilities." Thus, if the public health emergency is declared to be over at some point in 2021, distilleries would be exempted from paying these facility fees through December 31, 2022.

Can I still continue to make and sell hand sanitizer in 2021?

- Yes, distilleries are still allowed to produce hand sanitizer for the duration of the public health emergency per FDA's temporary policies (*Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry* and *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry*). Your facility must be registered with FDA, as outlined in those policies, to continue producing hand sanitizer to assist with the COVID-19 pandemic.

I de-registered my facility to avoid incurring the 2022 OTC facility fee, do I need to re-register?

- If you de-registered your facility to avoid the fee prior to the exemption and wish to continue producing hand sanitizer according to the temporary policies, you should re-register before you restart any production activities. FDA should not require the OTC drug facility fee per the HHS Notice outlined above.

I produced hand sanitizer in 2020 but do not expect to continue production into 2021. I currently have some sanitizer stock remaining that I would like to deplete either through donation or sale. Do I need to renew our registration to deplete this stock or should I de-register the facility?

- If you are no longer manufacturing hand sanitizer and do not expect to continue production, you should deregister your establishment and can continue to distribute the product previously produced. FDA eDRLS Staff has provided the following instructions in that regard:

  > If you are no longer manufacturing the hand sanitizer, you should deregister the establishment. You can include a future end marketing date (date you expect the inventory to finish) for the products you are still distributing to properly delist to those products.
  >
  > Please see the following link to our webpage with instructions on the registration and listing process, which includes information on deregistration.
  >
  > https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instruction
  >
  > In order to properly delist the products you are still marketing, you can follow the section on "Updates to listing" and include future end marketing dates in the listing SPLs (at the step where you need to modify the listing data elements).

Please refer to 21 CFR 207 for the requirements regarding reviewing, updating and the deadlines for registration and listing information.

Who should I contact with specific questions about my registration or practices?

- If you have further questions about your specific registration or practices, please reach out to edrls@fda.hhs.gov, CDERCollections@fda.hhs.gov or call 301-796-7900.

APPENDIX K: OTHER HELPFUL RESOURCES

DISCUS Webinars Related to the Production of Hand Sanitizer:

Part 1: Production and Compliance of Hand Sanitizer to Address the COVID-19 Pandemic (Presentation) - March 31, 2020

GrayRobinson's team of Alcohol Beverage Industry specialists will present, in practical terms, on the compliance-critical areas of record keeping, bond to bond transfers, and processes approval as it pertains to distillers and the production of hand sanitizer. They will also discuss and share recommended best practices for distilleries as many jump into this new business model nationwide. We will be joined by DISCUS' Chief Legal Officer, Courtney Armour, to review the regulatory resources DISCUS is providing via the COVID-19 Portal, and by the DISCUS Federal Government Relations Team to provide an update on legislative efforts and recent bills.

About the Presenters:

David Bateman a member of GrayRobinson's Alcohol Industry Team, has over 40 years of federal alcohol regulatory service, experience and contacts. Dave works with GrayRobinson's Alcohol Industry Team to advise and assist industry clients in a wide range of compliance activities, including record-keeping requirements, tax audits, compliance investigations and more.

Richard Blau is the chair of GrayRobinson's Alcohol Beverage and Food Department and presides over the firm's Alcohol Industry Team. Richard works with all three tiers of the alcohol beverage industry. He has represented international importers and domestic manufacturers, statewide wholesaler trade groups and regional distributors, and retailers (including multistate restaurant and hotel chains) across the United States.

Elizabeth A. DeConti is one of the original members of the firm's Alcohol Beverage and Food Team and has spent more than 20 years focusing her law practice on the unique area of alcohol beverage and food regulation. Elizabeth concentrates on litigation, compliance, and promotions matters related to the rules, regulations and business practices governing the marketing, sale and consumption of malt beverages, wine, distilled spirits and other regulated products in the alcohol and food industry.

John J. Harris has a foundation of knowledge in alcohol beverage and tobacco regulations; government processes; government decision makers; alcohol beverage dealer training; and liquor and business licensing he developed during his 28-year government career. John's clients include all tiers of the alcohol industry (manufacturers, importers, wholesalers, exporters, brand owners, and retailers); capital fund managers, regarding ownership structure and compliance with state alcohol "tied house" policies; the food industry; and professionals and businesses required to be licensed.

Lisa A. Specht is member of the Securities Practice Group and focuses on corporate, partnership and limited liability company matters, including formation and governance, purchases and sales, reorganizations, and federal and state tax planning. Lisa also has experience obtaining private letter rulings from the Internal Revenue Service and handling federal and state tax controversy matters at both the administrative and trial court levels.

Charles Tull most recently served as the Beer Industry Analyst for the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), until his retirement from the agency in May of 2014. Charlie has been involved in the major ATF/TTB trade practice investigations including being the lead investigator in the most recent TTB investigation that focused on category management practices. Charlie spent the last two years serving as the Bureau's trade practice coordinator.

Anna M. Wiand is a member of the firm's Nationwide Alcohol Beverage & Food Law Department. She focuses her practice on matters relating to regulated products, including laws governing the alcohol beverage, food, cosmetics, cannabis, and tobacco industries. Anna counsels companies about how to comply with the complex variety of federal, state, and local rules and regulations that govern the manufacturing, distribution, marketing, sale, and consumption of these heavily regulated products.

PART 2: Production and Compliance of Hand Sanitizer to Address the COVID-19 Pandemic – April 9, 2020 (Webinar) (Presentation)

On April 9, DISCUS was joined by a team of GrayRobinson Alcohol Beverage Industry specialists for a special edition COVID-19 webinar on the production and compliance of hand sanitizer.
The team will be discussing in detail:

- The CARES Act and recommended tips for distillery grant/loan applicants
- FDA & TTB authorizations and requirements
- Hand sanitizer production logistics: formulations, packaging, OSHA requirements
- Storage & distribution of hand sanitizer
- Marketing and advertising, especially for DSPs that choose to produce for sale (rather than as in-kind charitable contributions to states, hospitals, etc.)

DOT Training for Transporting Hazardous Materials (presentation) - April 3rd, 2020

DISCUS will be hosting a webinar with Elizabeth LaDow of the Department of Transportation (DOT) Hazardous Materials Safety Assistance Team to provide hazardous materials training for the transportation of alcohol-based hand sanitizers during the COVID-19 public health emergency.

The U.S. Department of Transportation has released its temporary policy regarding the handling and transportation of hand sanitizer products, you can find the document **here.** Details of the document will be discussed during the webinar.

Presenters

Elizabeth "Liz" LaDow joined the Pipeline and Hazardous Materials Safety Administration (PHMSA) in March of 2019, as a Transportation Specialist (HMSAT) at the Southern Regional Field Office. Prior to joining PHMSA, Liz, was a federal investigator with the U.S. Department of Veterans Affairs for 11 years. She was primarily responsible for conducting misuse investigations related to veteran benefit compensation; and served as Subject Matter Expert, Trainor and mentor for all new investigators, as well as a software beta tester for VA Central office in Washington, DC. Liz was instrumental in development of formalized on-boarding process training for all new investigators focusing on the use of technology, classroom focused training and structuralized on-the-job training pairing new investigators with SME location specific to the territories where work was assigned.

WEBINAR: OSHA Guidance for Distillers Operating Retail and Manufacturing Facilities – April 30, 2020. (Presentation)

DISCUS is joined by Maureen Ruskin, Deputy Director of Standards and Guidance for the Occupational Safety and Health Administration, as she reviews guidance for distilleries operating manufacturing and retail locations during COVID-19. Maureen will also be discussing issues distillers need to account for when shifting to production of hand sanitizer. If you are looking for more information prior to the webinar, please see the supporting documents issued by OSHA below.

- Guidance on Preparing Workplaces for COVID-19
- Worker Exposure Risk to COVID-19
- COVID-19 Guidance for the Manufacturing Industry Workforce
- COVID-19 Guidance for Retail Workers

WEBINAR: Compliance and Mitigating Legal Risk While Producing Hand Sanitizer – May 5, 2020

Join us for an interactive discussion about hand sanitizer regulatory compliance and how to mitigate potential legal liability with Brian Christensen, Editor & Publisher of Artisan Spirit Magazine and Richard Blau, Chair of the Gray-Robinson Alcohol Food & Beverage practice, and his team. Brian will lead a discussion with the Gray-Robinson legal team on the potential risks surrounding liability as distillers shift toward sanitizer production.

- **WEBINAR**: Advice on Registering Your Product with the FDA