DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

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

DISCUS has been working 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 an outline of the current available guidance and practices that should be followed when producing hand sanitizer. We will continue to update this guidance as we gain more clarity from TTB and FDA. The Department of Transportation is also developing streamlined guidance and training on complying with regulations related to handling and shipping hazardous materials.

## 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).

### Formula Guidance

Permittees are directed to follow the FDA guidance for formulating hand sanitizer, which is the WHO Formula with additional FDA requirements. **"**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."

### 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."

- 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.

**NOTE**: We are still advocating for a waiver of the ***any*** alcohol used to make hand sanitizer. We applaud the support of TTB and Congress in this effort and urge FDA to update its policies to allow the use of undenatured alcohol during this unprecedented crisis.

DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

## 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 March 27, FDA revised its prior guidance (from March 19) a *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry*, 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.

- ***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).
    - **Alcohol Grade:** Ethanol used can be USP, FCC or technical grade, provided no additives would remain in the product. FDA has specified that alcohol (ethanol) used for this purpose must be derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes can be used only if it meets USP or FCC grade.
    - **Glycerin and Glycerol:** FDA clarified that these are the same chemical and that both USP and FCC grade glycerin is acceptable.
    - **Hydrogen peroxide**: Technical grade hydrogen peroxide falls within this policy if the concentration is within that of Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP. 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).
- ***Denatured:*** This 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.

  - FDA is continuing to evaluate other potential formulas, including the inclusion of acetone (TTB Formula 23-A), for denaturing, and will update their documents as they conduct that analysis. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.

- ***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: This is not in the FDA policy, but given FDA's concern related to children inadvertently ingesting this product, producers should consider adding a clear warning that this product should be kept out of reach of children.**

## Manufacture of Alcohol to be Used in Hand Sanitizer

On March 27, FDA revised its prior guidance (from March 24) a *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry,* 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.

  - FDA is continuing to evaluate other potential formulas, including the inclusion of acetone (TTB Formula 23-A), for denaturing, and will update their documents as they conduct that analysis. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.

- ***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%.

- ***Alcohol Grade*:** Ethanol used can be USP, FCC or technical grade, provided no additives would remain in the product. FDA has specified that alcohol (ethanol) used for this purpose must be derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes can be used only if it meets USP or FCC grade.

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

**NOTE: DISCUS is working to urge FDA to update these policies to provide greater flexibility, particularly with regard to the denaturing requirement.**

- We are urging FDA to remove or, in the alternative, relax the required denaturants. We understand that there is a shortage of many denaturants and even large producers are having trouble sourcing them for these purposes. Denaturing may also significantly slow the production rate, depending on availability of supply, necessary testing, etc. The WHO Guidelines recommend not denaturing and many denaturants are toxic.

- Risk to Children: FDA is concerned about the risk to children consuming this product if it is not denatured and has pointed to increased rates of children consuming hand sanitizer during the COVID-19 pandemic.

    - We urge the FDA to explore alternative safeguards, such as additional warnings, public education campaigns, and restricted distribution for undenatured product. We appreciate this concern, but believe there are other ways to safeguard children AND provide much needed sanitizer to first responders and essential workers.

    - Given the increase in use of this product (denatured or not) in response to COVID-19, we urge the FDA to explore additional ways to educate the public on the risks to children if this product is ingested. DISCUS stands ready to assist the FDA as they deem appropriate.

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

## 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.

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Maintained by: Regulations and Rulings Division

**Appendix B-1: March 27, 2020 FDA Public Guidance**

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

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

## 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 March 27, 2020**
**Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)**

[1] This guidance was implemented immediately without prior comment.

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

## Guidance for Industry

Public Comment

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 "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19 and from the FDA webpage titled "Search for FDA Guidance Documents" *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. 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.

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

**March 2020**
**Updated March 27, 2020**
**Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)**

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*Contains Nonbinding Recommendations*

# Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry[2]

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.

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 hand sanitizer products by firms that register as over-the-counter (OTC) drug manufacturers 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.[3] At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance.

[2] 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), that describes the Agency's policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State 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.

[3] 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, 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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency 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 that was first detected in Wuhan City, Hubei Province, China, and that has now spread globally, to include the United States. 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 a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[4] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[5]

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 alcohol (also referred to as ethanol or ethyl alcohol).[6]

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[4] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[5] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[6] Isopropyl alcohol and ethyl alcohol are two of the active ingredients currently being evaluated by FDA as part of its review of over-the-counter (OTC) monographs for hand sanitizers for use in reducing bacteria on the skin that potentially can cause disease or decreasing 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-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).

## III. DISCUSSION

We understand that some consumers and health care professionals 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[7] 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 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)* (1) Alcohol (ethanol)[8] that is not less than 94.9% ethanol by volume[9]; **OR** (2) Isopropyl Alcohol
    b. Glycerin (glycerol) United States Pharmacopeia (USP) or Food Chemical Codex (also known as "food grade")
    c. Hydrogen peroxide[10]
    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.

2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.[11] Alcohol and Tobacco Tax and Trade

[7] 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, 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).

[8] 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 United States Pharmacopoeia (USP) or Food Chemical Codex (FCC) grade.

[9] 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 volume to content concentration of 80%.

[10] Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP. Technical grade hydrogen peroxide falls within this policy if the concentration is within that of Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP.

[11] 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).*

Bureau regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol. Formulas for use in hand sanitizers include:[12]

a. Formula 40A or 40B with or without the tert-butyl alcohol
b. Formula 3C (isopropyl alcohol)

3. The hand sanitizer is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations:[13]
    a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution.[14]
    b. Glycerin (glycerol) (1.45% v/v).[15]
    c. Hydrogen peroxide (0.125% v/v).[16]
    d. Sterile distilled water or boiled cold water.

    **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.**

4. 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. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.

5. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.[17]

6. 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

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[12] FDA is continuing to evaluate other potential formulas, including the inclusion of acetone, for denaturing. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.

[13] 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.

[14] Consistent with the 1994 TFM, alcohol should be used in a final product concentration between 60-95% (v/v) in an aqueous solution denatured in accordance with this guidance (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)*; isopropyl alcohol should be used in a concentration between 70-91.3% (v/v). This guidance is consistent with WHO's recommended formulation specifications of 80% alcohol and 75% isopropyl alcohol.

[15] Although WHO's recommended formulation includes glycerol 1.45% (v/v), reports indicate that glycerol negatively impacts effectiveness of isopropyl alcohol (https://www.ncbi.nlm.nih.gov/pubmed/28670452), and reports studying the effectiveness of WHO's formulation have suggested a reduction from 1.45% to 0.725% (https://www.ncbi.nlm.nih.gov/pubmed/23388358/).

[16] 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).

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

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.

7. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use).[18]

8. 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). 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 they begin to manufacture and 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.

This policy does not extend to other types of products, such as: products (1) that use different active ingredients; (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., pathogen-specific disease claims): (4) that are surgical hand rubs; or (5) whose labeling is false or misleading in any particular.

Firms will need to have a way to accept adverse event reports for any products they manufacture, and submit 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).[19]

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

[18] The label should include the name and contact information of the manufacturer. We do not intend to take action against manufacturers who have already ordered or printed their labels without this information.
[19] See Section 760 of the FD&C Act (21 U.S.C. § 379aa).

## Appendix A. Labeling for Ethyl Alcohol 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

## Appendix C. Labeling for Ethyl Alcohol 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

## 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

**Appendix B-2: March 27, 2020 FDA Public Guidance**

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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# 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 March 27, 2020**
**Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)**

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# 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 "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19, and from the FDA web page titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. 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.

## TABLE OF CONTENTS

*Contains Nonbinding Recommendations*

# 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 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.

FDA is issuing this guidance in response to a number of queries from entities that are not currently registered drug manufacturers that would like to produce alcohol[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]

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) for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.[4] At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance.

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[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, and as used in this guidance. These monographs establish test methods and acceptance criteria for identity and purity. The definition of *alcohol* does not include isopropyl alcohol.

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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency 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 that was first detected in Wuhan City, Hubei Province, China, and that has now spread globally, including the United States. 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.[5] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[6]

We understand that some consumers and health care professionals 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) (compounding guidance) that describes the Agency's policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities.[7] FDA has also 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) that describes the Agency's temporary policy for preparation of certain alcohol-based hand sanitizer products by

[5] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[6] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[7] 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.

firms that register as over-the-counter (OTC) drug manufacturers to prepare alcohol-based hand sanitizers.[8]

## III. 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[9] that manufacture alcohol (i.e., ethanol or ethyl 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 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 manufactured as an API is not less than 94.9% ethanol by volume.[10,11]

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.

3. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol. Formulas for use in hand sanitizers are included in Appendix C of this document and include:[12]

    a. Formula 40A or 40B with or without the tert-butyl alcohol
    b. Formula 3C (isopropyl alcohol).

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[8] 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.

[9] 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, 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, and 360eee-1).

[10] 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.

[11] 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.

[12] FDA is continuing to evaluate other potential formulas, including the inclusion of acetone, for denaturing, and will update Appendix C as we conduct that analysis. Firms who wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.

Denaturing is critical because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children. The alcohol may be denatured at the point of production by the alcohol production firm or the point of manufacture or compounding of the hand sanitizer, but the alcohol intended for incorporation into a finished product must be 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 the API may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.**

4. The alcohol production firm ensures the ethanol content in the finished API before being denatured is at least 94.9% by volume[13] (see United States Pharmacopeia National Formulary [USP-NF] or Food Chemical Codex [FCC])). If the alcohol is to be distributed to another firm for 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.

5. The alcohol is prepared under sanitary conditions and equipment used is well maintained and fit for this purpose.[14]

6. 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 use in 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 as an API) or before actual use in producing the hand sanitizer.

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

8. 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). Upon completion of registration and listing, firms receive automatic confirmation from FDA and do not need to wait for further communication from FDA before they begin to manufacture and 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

[13] Or of sufficient content to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v.
[14] Facilities must prevent insanitary conditions under section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)).

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.

If alcohol production firms receive adverse event reports, they are encouraged to submit them 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.

**Appendix A. Labeling for Undenatured Alcohol for Incorporation Into Alcohol-Based Hand Sanitizers (Antiseptic Hand Rubs)** [15]

**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>**

[15] 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) [16]**

**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**

[16] 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**

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

To every 100 gallons of alcohol add:

One-sixteenth avoirdupois ounce of denatonium benzoate,[17] 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, [18] N.F.

**Alternative Formulas**

**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

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

To every 100 gallons of alcohol add:

Five gallons of isopropyl alcohol

[17] Denatonium benzoate can be added as either a solid or in liquid form, provided the added amount is calculated on a dry basis.
[18] See note 17.