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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)

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## 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)**

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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 "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](mailto: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](mailto: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<sup>1</sup>**

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 (ethanol)<sup>2</sup> 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.<sup>3</sup>

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)<sup>4</sup> for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020,<sup>5</sup> 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 withdraw this guidance. FDA is

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<sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research at the Food and Drug Administration.

<sup>2</sup> *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.

<sup>3</sup> Isopropyl alcohol is manufactured by different chemical processes and is therefore not discussed in this guidance.

<sup>4</sup> This includes firms that repackage or relabel ethanol manufactured consistent with FDA policies outlined in this guidance.

<sup>5</sup> The HHS Public Health Emergency Declaration is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

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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.

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 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, the Secretary of HHS declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>6</sup> In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.<sup>7</sup>

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, August 7, 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.<sup>8</sup> FDA has also

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<sup>6</sup> 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>.

<sup>7</sup> 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/>.

<sup>8</sup> 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>.

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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 firms that register as an over-the-counter (OTC) drug manufacturer, re-packager, or re-labeler to prepare alcohol-based hand sanitizers.<sup>9</sup>

### **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<sup>10</sup> 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.<sup>11,12</sup>
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):**

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<sup>9</sup> 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>.

<sup>10</sup> 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 sanitizer products at the border and in distribution in the U.S. for quality issues, including potential contamination and impurity levels.

<sup>11</sup> 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)*.

<sup>12</sup> 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.

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Alcohol (ethanol)<sup>13</sup> 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.<sup>14</sup>

Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if it meets USP or FCC<sup>15</sup> 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<sup>16,17</sup> 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.<sup>18</sup>

Ingredients that are described as only meeting American Chemical Society (ACS) grade standards should generally not be used in hand sanitizers.<sup>19</sup>

### **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

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<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> 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.

<sup>16</sup> See note 15.

<sup>17</sup> 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>.

<sup>18</sup> Special caution should be taken to ensure any other chemicals on site are not introduced into the ethanol either intentionally or via cross-contamination.

<sup>19</sup> 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](mailto: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.

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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. 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.<sup>20</sup> Such alcohol (ethanol) material should be destroyed, and the manufacturer should contact FDA regarding the material and its source.<sup>21</sup>

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, 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 are included in Appendix C of this document and include:<sup>22</sup>
  - a. Formula No. 40A or No. 40B with or without the tert-butyl alcohol<sup>23</sup>
  - b. Formula No. 3C (isopropyl alcohol).<sup>24</sup>

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

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.<sup>26</sup> The

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<sup>20</sup> 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)*.

<sup>21</sup> Contact FDA at [COVID-19-Hand-Sanitizers@fda.hhs.gov](mailto: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-sanitizers-methanol>.

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

<sup>23</sup> 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>.

<sup>24</sup> Using technical grade isopropyl alcohol that meets the requirements of 27 CFR 21.113 as a denaturant is consistent with this policy.

<sup>25</sup> 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>.

<sup>26</sup> 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 of 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger.



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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, with the alcohol intended for 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 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<sup>27</sup> (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.<sup>28</sup>
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>).<sup>29</sup> 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 manage product recalls, among other important FDA public safety activities. Our help desk is standing

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<sup>27</sup> Or of sufficient content to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v.

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

<sup>29</sup> 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).

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by to assist with facilitating this process and can be contacted by sending an email to: [edrls@fda.hhs.gov](mailto: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.

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](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 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>.

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### **Attachment 1**

#### **Use of Fuel or Technical Grade Alcohol (Ethanol)<sup>30</sup>**

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.<sup>31</sup>

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.<sup>32</sup> Therefore, FDA is working with industry 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 that manufacture 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 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.

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<sup>30</sup> 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)).

<sup>31</sup> 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.

<sup>32</sup> See <https://www.cdc.gov/handwashing/hand-sanitizer-use.html>.

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Accordingly, we are clarifying that fuel or technical 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:

- 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 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

\*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.<sup>33</sup> 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.

<sup>33</sup> See <https://www.cdc.gov/handwashing/hand-sanitizer-use.html>.

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- 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

- 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.<sup>34</sup>

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<sup>34</sup> Submissions should be sent to [COVID-19-Hand-Sanitizers@fda.hhs.gov](mailto: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 Labeling for  
Incorporation Into Alcohol-Based Hand Sanitizers (Antiseptic Hand Rubs) <sup>35</sup>**

**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 Milliliters (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>**

**Lot/Batch Number**

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<sup>35</sup> 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)<sup>36</sup>**

**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>**

**Lot/Batch Number**

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<sup>36</sup> 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.

*Contains Nonbinding Recommendations*

**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,<sup>37</sup> 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,<sup>38</sup> N.F.<sup>39</sup>

**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<sup>40</sup>

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

To every 100 gallons of alcohol add:

Five gallons of isopropyl alcohol<sup>41</sup>

**4. Formula using 3% triethyl citrate (w/w)<sup>42</sup>**

To every 100 gallons of alcohol add:

9239.5 g (20.4 pounds) triethyl citrate (USP or FCC grade)

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<sup>37</sup> Denatonium benzoate can be added as either a solid or in liquid form, provided the added amount is calculated on a dry basis.

<sup>38</sup> See footnote 37.

<sup>39</sup> See footnote 23.

<sup>40</sup> See footnote 23.

<sup>41</sup> See footnote 24.

<sup>42</sup> See footnote 25.