
Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19¹) Guidance for Industry

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

March 2020

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

¹This guidance was implemented immediately without prior comment.

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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: CDERCompliance@fda.hhs.gov.

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Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry²

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.

²This 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>.

³The HHS Public Health Emergency Declaration is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

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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

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).

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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 firms⁷ 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 United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:⁸
 - a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution.⁹
 - b. Glycerol (1.45% v/v).¹⁰
 - c. Hydrogen peroxide (0.125% v/v).
 - d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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 The 1994 TFM is available at <https://www.gpo.gov/fdsys/pkg/FR-1994-06-17/html/94-14503.htm>. 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.

⁹ Consistent with the 1994 TFM, alcohol should be used in a final product concentration between 60-95% (v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; 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.

¹⁰ 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/>).

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2. 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.
3. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.¹¹
4. The firm uses the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.
5. 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).
6. 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>).¹²

¹¹ Facilities must prevent insanitary conditions under section 501(a)(2)(A) of the FD&C Act (21 U.S.C. § 351(a)(2)(A)).

¹² See Section 760 of the FD&C Act (21 U.S.C. § 379aa).

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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.

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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] Alcohol 80% v/v	Purpose 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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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**

3785 mL

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% v/v	Purpose 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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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] Alcohol 80% v/v	Purpose 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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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] Isopropyl alcohol 75% v/v	Purpose Antiseptic
Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	