*Contains Nonbinding Recommendations*

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

## Guidance for Industry

**March 2020**
**Updated April 15, 2020.**

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

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

# Preface

## Public Comment

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

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

## Additional Copies

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

## Questions

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

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

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

## I. INTRODUCTION

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

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.[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.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research at the Food and Drug Administration. FDA has issued a separate guidance for industry entitled Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 2020, Updated March 27, 2020 and April 15, 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.

[2] 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). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. On January 31, 2020, (HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[3] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[4]

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).[5]

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[3] 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).

[4] 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/.

[5] 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[6] that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs[7] 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) that is not less than 94.9% ethanol by volume[8]; **OR** (2) United States Pharmacopeia (USP grade) Isopropyl Alcohol[9]
    b. Glycerin (glycerol) USP or Food Chemical Codex (FCC) (also known as "food grade")

[6] 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).

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

[8] This is consistent with the USP and FCC grade requirements for purity. Lower ethanol content alcohol falls within this policy so long as it is labeled accordingly, and the finished hand sanitizer meets the ethanol concentration of 80%.

[9] Isopropyl alcohol used as the active ingredient should be USP grade (see 1a above). If a firm wishes to use other sources of isopropyl alcohol as an active ingredient, provide analytical data of the isopropyl alcohol tested against all of the elements of the USP monograph, including listed impurities, to COVID-19-Hand-Sanitizers@fda.hhs.gov and include "ISOPROPYL ALCOHOL DATA" in the subject line, for FDA's assessment regarding the use of this ingredient under this policy.

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.

**Additional Considerations for Ingredients in Preparation of the Product:**

Alcohol (ethanol) used for hand sanitizer 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.

Ethanol produced in facilities normally producing fuel or technical grade may be considered for use if the ethanol is produced from fermentation and distillation as would be typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol. Further, special caution should be taken to ensure any other chemicals on site are not introduced into the ethanol either intentionally or via cross contamination. Because of the potential for the presence of potentially harmful impurities due to the processing approach, fuel or technical grade ethanol should only be used if it meets USP or FCC grade requirements and the ethanol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements.[11]

Ingredients that are described as only meeting American Chemical Society (ACS) grade standards should generally not be used in hand sanitizers. 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.[12]

2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.[13] Alcohol and Tobacco Tax and Trade

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

[11] If a firm wants to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should submit information on the ethanol with regard to 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 to COVID-19-Hand-Sanitizers@fda.hhs.gov with "ETHANOL DATA" in the subject line for FDA's assessment regarding the use of the ethanol under this policy.

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

[13] 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:[14]

a. Formula 40A or 40B with or without the tert-butyl alcohol
b. Formula 3C (isopropyl alcohol[15])

Denaturing is critical because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children.[16] The alcohol should be denatured at either (1) the point of production by the alcohol production firm or (2) the point of manufacture or compounding of the hand sanitizer. Attachment I provides more information on the formulas used to denature alcohol before it is used in alcohol-based hand sanitizers. It reproduces Appendix C from FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19).”*

3. The hand sanitizer is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations:[17]
    a. Alcohol (ethanol) (formulated to 80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (formulated to 75%, v/v) in an aqueous solution.[18],[19]
    b. Glycerin (glycerol) (1.45% v/v).[20]
    c. Hydrogen peroxide (0.125% v/v).[21]

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

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

[16] 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% compared to March of 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger.

[17] 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.

[18] 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.

[19] One benefit of FDA’s policy relying on use of the WHO formula is that minor errors in production are still likely to result in a finished hand sanitizer product that exceeds 60% alcohol content (see FDA’s 1994 TFM and the CDC Statement for Healthcare Personnel on Hand Hygiene during the Response to the International Emergence of COVID-19).

[20] 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/).

[21] Formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP, Hydrogen Peroxide Topical Solution USP or technical grade hydrogen peroxide, ensuring that the alcohol (ethanol

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.[22]

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 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 product is produced as an aqueous solution and not as a gel, foam, or aerosol spray.[23] The firm packages the finished hand sanitizer product in packaging appropriate for liquid drug products that will seal sufficiently to prevent evaporation of the alcohol or IPA.[24] Manual pump sprays that seal sufficiently to prevent evaporation are consistent with this policy.

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or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol.

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

[23] This policy does not apply to hand sanitizer gel or foam products because different or additional ingredients may impact the quality and potency of the product. This policy does not apply to aerosol sprays because aerosol sprays with propellent added to the formulation can result in altered potency of the finished hand sanitizer. Aerosol sprays with propellent outside of the formulation (bag on valve) may have safety and potency concerns due to the increased flammability risks of ethanol in an aerosol, risk of overspraying, variability of delivery of the product, rapid evaporation of alcohol, and inhalational toxicities.

[24] We note that hand sanitizer offered for transportation or transported in commerce may be subject to the applicable requirements of the U.S. Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171-180) or guidance issued by the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA). More information is available on PHMSA's website at: https://www.phmsa.dot.gov/news/phmsa-issues-temporary-relief-companies-transporting-hand-sanitizer-highway. These regulations include classification, packaging, marking, labeling and other requirements relevant to transportation.

8. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethanol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethanol Formulation Health Care Personnel Hand Rub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand Rub Use).[25,26]

9. 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 patient antiseptic skin preparations; 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).[27]

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

[25] 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.
[26] See footnote 24.
[27] See Section 760 of the FD&C Act (21 U.S.C. § 379aa).

**Attachment I**

**From FDA guidance for industry *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*: 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,[28] 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,[29] 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[30]**

[28] Denatonium benzoate can be added as either a solid or in liquid form, provided the added amount is calculated on a dry basis.
[29] See note 28.
[30] See footnote 15.

## Appendix A. Labeling for Ethanol Formulation Consumer Use

### PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

**Alcohol Antiseptic 80%**
**Topical Solution**

**Hand Sanitizer**
**Non-sterile Solution**

**[Insert Volume of Product in mL]**

### DRUG FACTS LABEL

***Drug Facts***

***Active ingredient[s]*** ***Purpose***

Alcohol 80% v/v..... Antiseptic

***Use[s]***

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

***Warnings***

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

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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

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

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

***Directions***

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

***Other information***

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

***Inactive ingredients*** glycerin, hydrogen peroxide, purified water USP

## Appendix B. Labeling for Isopropyl Alcohol Formulation Consumer Use

**PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):**

**Isopropyl Alcohol Antiseptic 75%**
**Topical Solution**

**Hand Sanitizer**
**Non-sterile Solution**

**[Insert Volume of Product in mL]**

**DRUG FACTS LABEL**

***Drug Facts***

***Active ingredient[s]*** ***Purpose***

Isopropyl alcohol 75% v/v.....Antiseptic

***Use[s]***

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

***Warnings***

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

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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

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

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

***Directions***

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

***Other information***

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

***Inactive ingredients*** glycerin, hydrogen peroxide, purified water USP

## Appendix C. Labeling for Ethanol Formulation Health Care Personnel Hand Rub 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 Hand Rub 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