Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

The Do’s and Don’ts for Compounding Alcohol-based Hand Sanitizer Safely

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Alcohol-Based Hand Sanitizer Formulas
Learning Objectives

At the completion of this activity, the participant will be able to:

1. Describe the formulation requirements for compounding hand sanitizer
2. Review labeling requirements for patients and health care providers
3. Discuss distribution to patients, at risk individuals and front line workers within the community
4. Define the storage requirements of compounded hand sanitizer
Key Abbreviations

- ACS - American Chemical Society
- CDC - Centers for Disease Control and Prevention
- FCC - Food Chemical Codex
- FDA - Food and Drug Administration
- IPA - Isopropyl Alcohol
- NF - National Formulary
- USP - United States Pharmacopeia
- WHO - World Health Organization
Hand Hygiene

- Hand washing
  - Wash often with soap and water
  - Wash for at least 20 seconds

- Hand sanitizer
  - For use if soap and water are not readily available
  - Doesn’t get rid of all types of germs
  - May not be as effective if hands are dirty or greasy
How to Handrub?

RUB HANDS FOR HAND HYGIENE! WASH HANDS WHEN VISIBLY SOILED

Duration of the entire procedure: 20-30 seconds

1a Apply a palmful of the product in a cupped hand, covering all surfaces;

1b

2 Rub hands palm to palm;

Application Recommendations From WHO

3. Right palm over left dorsum with interlaced fingers and vice versa;

4. Palm to palm with fingers interlaced;

5. Backs of fingers to opposing palms with fingers interlocked;

Application Recommendations From WHO

6. Rotational rubbing of left thumb clasped in right palm and vice versa;

7. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;

8. Once dry, your hands are safe.

World Health Organization
Patient Safety
SAVE LIVES
A World Alliance for Safer Health Care
Clean Your Hands

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May 2009

Guidance Documents

Information to Address Shortage

USP

USP Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

FDA

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

Keeping the Basics While Meeting a New Need

- Compounding is performed by trained personnel
- Source of ingredients
  - USP
  - NF
  - FCC
Compounding Requirements

Keeping the Basics While Meeting a New Need

- Proper equipment, use and maintenance
- Prepare a master formulation record and compounding record
- Label preparation appropriately
- Assign a proper BUD
Formulation Overview

Alcohol Antiseptic Topical Solution

- Alcohol
  - Isopropyl alcohol
  - Ethanol (ethyl alcohol)

- Hydrogen Peroxide
  - 3%
  - 30%

- Glycerin or glycerol

- Purified Water
Alcohol-Based Hand Sanitizer Formulas

Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

Demand for alcohol-based hand sanitizers has surpassed its supply due to the rapidly evolving COVID-19 pandemic. In response, the U.S. Pharmacopeia has provided an informational resource document on compounding hand sanitizer to help address the shortages. Please visit usp.org/compounding for more info.

Packaging and Storage: Package in well-closed, suitable containers and store at controlled room temperature.

Formulation 1
- 96% Ethanol: 200 mL
- 5% Hydrogen Peroxide: 407 mL
- 0.8% Glucose: 143 mL
- Water: sufficient quantity to make 1,000 mL

Formulation 2
- 90% Isopropyl Alcohol: 703 mL
- 5% Hydrogen Peroxide: 407 mL
- 0.8% Glycerin: 143 mL
- Water: sufficient quantity to make 1,000 mL

Formulation 3
- 70% Isopropyl Alcohol: 1,042 mL
- 5% Hydrogen Peroxide: 407 mL
- 0.8% Glycerin: 143 mL
- Water: sufficient quantity to make 1,000 mL

Packaging and Storage: Package in well-closed, suitable containers and store at controlled room temperature.

Labelling: Label it to state for external use only, the percentage of active ingredient (i.e., ethanol, isopropyl alcohol), and the Beyond-Use Date.

Beyond-Use Date: NMT 30 days after the date on which it was compounded when stored at controlled room temperature.

https://www.usp.org/covid-19/hand-sanitizer-information
Alcohol-Based Hand Sanitizer Formulas

FDA Guidance

1. The following ingredients are used
   - Alcohol (ethanol) that is not less than 94.9% ethanol by volume; OR Isopropyl Alcohol, USP
   - Glycerin (glycerol) USP or FCC
   - Hydrogen peroxide
   - Sterile water
2. The alcohol is denatured
3. The following formula is used
   - 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
   - Glycerin (glycerol) (1.45% v/v)
   - Hydrogen peroxide (0.125% v/v)
   - Sterile distilled water or boiled cold water
Alcohol-Based Hand Sanitizer Formulas

FDA Guidance

4. The compounder ensures active ingredient is correct and correct amount used
5. The compounder prepares hand sanitizer under conditions used to compound similar nonsterile drugs
6. The hand sanitizer is prepared as an aqueous solution, not a gel, foam or aerosol spray
7. Product labeling is consistent with FDA guidance
8. Report adverse events as soon as possible but no later than 15 days after receipt of information
Alcohol

Ingredient Selection

- Isopropyl Alcohol USP (99%)
- Ethyl Alcohol (ethanol)
  - Denature prior to use
    - Ethyl Alcohol USP, 190 Proof USP
    - Ethyl Alcohol USP, 200 Proof USP
- Do not use
  - ACS
  - Ingredients with unknown grade or quality

Alcohol Calculations

- Understand how to calculate volume needed for concentration of final preparation
  - Based on the potency of your active ingredient

\[
\frac{(\text{final } \% \text{ alcohol}) \times (\text{final volume of preparation})}{(\text{starting } \% \text{ alcohol})} = \text{volume of starting ingredient required}
\]
Denaturing Ethanol

Understanding the importance

- Nondenatured ethanol
  - Adverse events from accidental ingestion
  - Can be deadly, especially in small children

- Denatured ethanol
  - Bad tasting additives can deter consumption
  - Choose formula based on facility’s need/availability
    • Ex.) For 10,000 mL of ethanol, add 500 mL of IPA

| Table A: Preferred formula for denaturing ethanol based on 27 CFR 21.76 Formula 40-B |
|-----------------------------------------------|---------------------------------------------|
| **27 CFR 21.76 Formula No. 40-B** | **Conversion to metric units** |
| To every 100 gallons of alcohol add: | For 10 L of ethanol add: |
| • One-sixteenth avoirdupois ounce of denatonium benzoate, N.F. and 1/8 gallon of tert-butyl alcohol | • 0.0468 g of denatonium benzoate, N.F., and |
| OR | • 12.5 mL of tert-butyl alcohol* |
| To every 100 gallons of alcohol add: | OR |
| • One-sixteenth avoirdupois ounce of denatonium benzoate, N.F. | For 10 L of ethanol add: |
| | • 0.0468 g of denatonium benzoate, N.F. |

| Table B: Alternative Formula for denaturing ethanol based on 27 CFR 21.75 Formula 40-A |
|-----------------------------------------------|---------------------------------------------|
| **27 CFR 21.75 Formula No. 40-A** | **Conversion to metric units** |
| To every 100 gallons of alcohol add: | For 10 L of ethanol add: |
| • One pound of sucrose octaacetate and 1/8 gallon of tert-butyl alcohol | • 11.98 g of sucrose octaacetate |
| OR | • 12.5 mL of tert-butyl alcohol |
| To every 100 gallons of alcohol add: | OR |
| • One pound of sucrose octaacetate | For 10 L of ethanol add: |
| | • 11.98 g of sucrose octaacetate |

| Table C: Alternative Formula for denaturing ethanol based on 27 CFR 21.37 Formula 3-C |
|-----------------------------------------------|---------------------------------------------|
| **27 CFR 21.37 Formula No. 3-C** | **Conversion to metric units** |
| To every 100 gallons of alcohol add: | For 10 L of ethanol add: |
| • Five gallons of isopropyl alcohol | • 500 mL of isopropyl alcohol |

April 28, 2020
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Purified Water

- Distilled
- Cold boiled potable
- Reverse osmosis
- Filtered
- Sterile water USP

https://www.hawkinsinc.com/groups/pharmaceutical/usp-purified-water/ Accessed 2-7-21
Formulation- Mixing

Mixing process
- Make sure measuring device is appropriate
  - Graduated cylinder grade and size
  - Syringes
  - Beaker
- Use an airtight cover to prevent evaporation when mixing
Packaging

Lid Options

Finger Tip Sprayer

Flip Top Cap

Bottle Top Adapter

https://pccarx.com/products/FINGERTIPSPRAYER24MMSPRFNGRTPSSA24-4106-1-8DTL/35-1540/DEVICES Accessed 2-7-21
https://pccarx.com/products/EASYFILLADAPTER28MM%28E%29/35-2217/DEVICES Accessed 2-7-21
Packaging

Bottle Options

Boston Round  Amber Bottle  Spray Bottle

https://pccarx.com/products/BOTTLE%2C4OZBOSTONROUNDNATURAL24-410/35-1539/_DEVICES Accessed 2-7-21
https://pccarx.com/products/SPRAYMISTBOTTLE%2C32OZ-/35-1603/_DEVICES 2-7-21
Packaging

Bottle Options
# Drug Facts Label

## 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
  - 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 at 1-800-222-1222.

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

## Inactive ingredients

- Glycerin, hydrogen peroxide, purified water USP
## DRUG FACTS LABEL

### Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient(s)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol 80% v/v</td>
<td>Antiseptic</td>
</tr>
</tbody>
</table>

### 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.

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

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### Inactive ingredients

- Glycerin
- Hydrogen peroxide
- Purified water USP
Distribution

Based on Community Needs

- Available for purchase
  - Appropriate sized containers for expiration date
- Donations
  - Local clinics
  - First Responders
  - High risk patients
Distribution

Donations
Storage

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

BUD
- 30 days
- Room temperature
References


Thank You

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