

---

# Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

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

Tracy Acosta, Pharm.D., BCSCP,  
Compounding Pharmacist Preston Road Pharmacy



# 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**

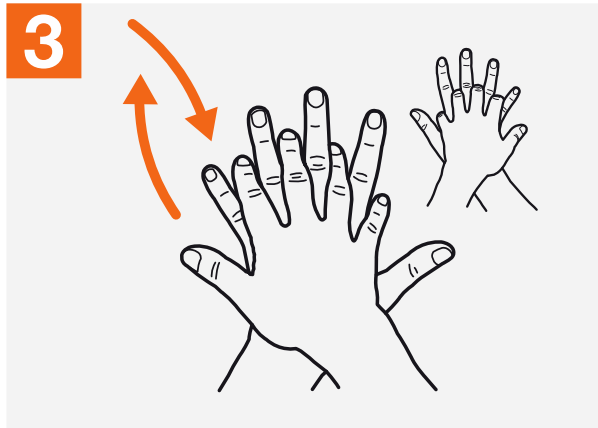


**2**



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;

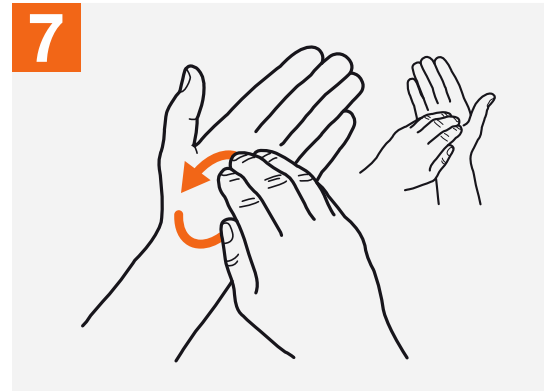


**5** Backs of fingers to opposing palms with fingers interlocked;

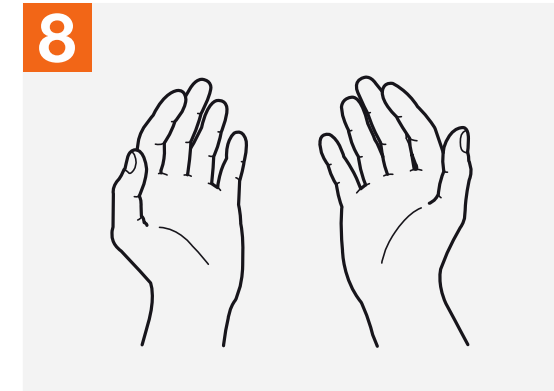
# Application Recommendations From WHO



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



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



Once dry, your hands are safe.



**World Health  
Organization**

**Patient Safety**

A World Alliance for Safer Health Care

**SAVE LIVES  
Clean Your Hands**

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this document. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

May 2009



## 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

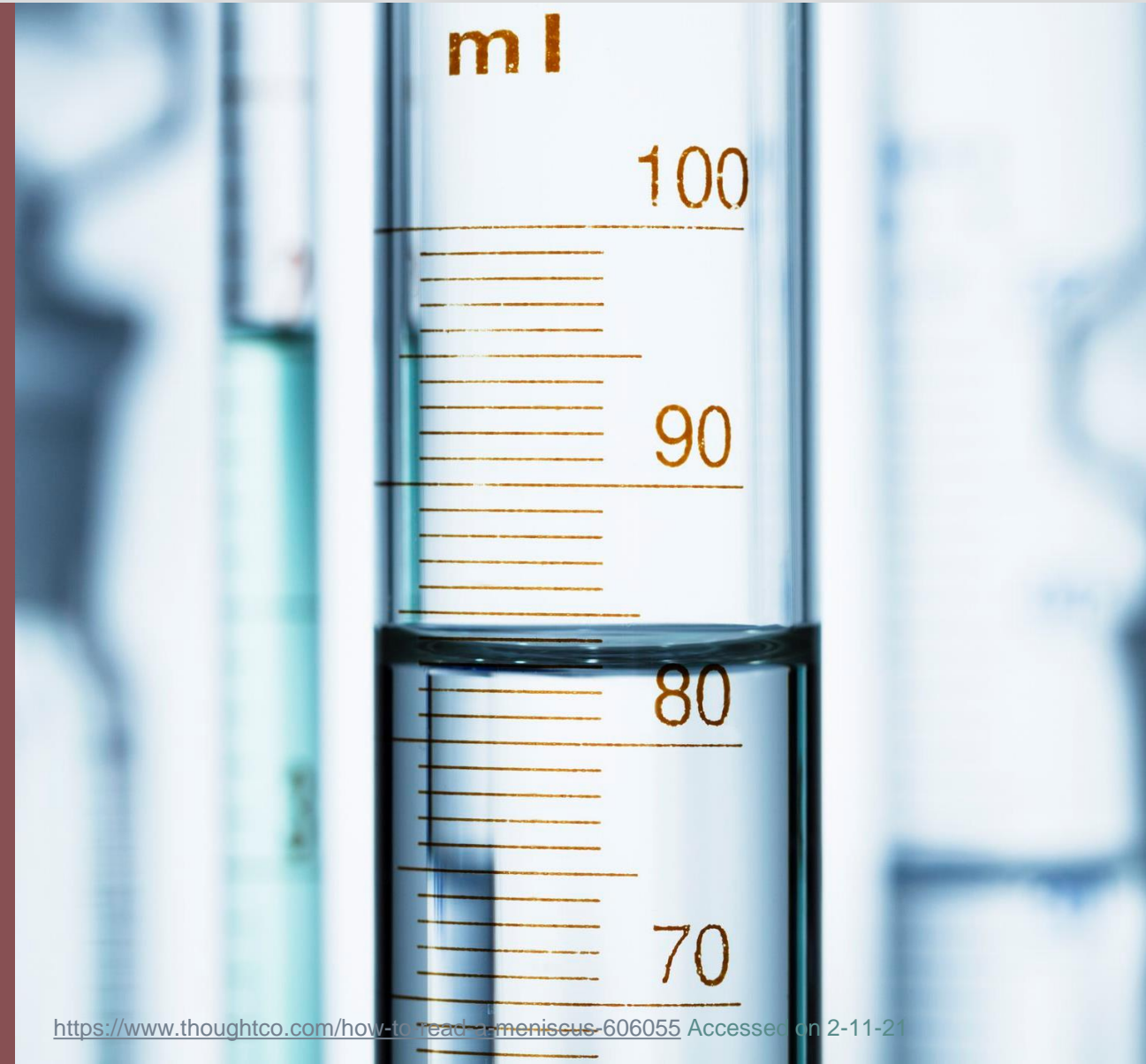
- ▶ Proper equipment, use and maintenance
- ▶ Prepare a master formulation record and compounding record
- ▶ Label preparation appropriately
- ▶ Assign a proper BUD

# 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](https://www.usp.org/compounding) for more info.\*



- **Ethanol<sup>1,2</sup>**  
96%  
8333 mL
- **Hydrogen peroxide 3%**  
417 mL
- **Glycerol<sup>3</sup>**  
98%  
145 mL
- **Water<sup>4</sup>**  
a sufficient quantity to make  
10,000 mL



- **Isopropyl Alcohol<sup>1</sup>**  
99%  
7576 mL
- **Hydrogen peroxide 3%**  
417 mL
- **Glycerol<sup>3</sup>**  
98%  
75 mL
- **Water<sup>4</sup>**  
a sufficient quantity to make  
10,000 mL



- **Isopropyl Alcohol<sup>1</sup>**  
91%  
8242 mL
- **Hydrogen peroxide 3%**  
417 mL
- **Glycerol<sup>3</sup>**  
98%  
75 mL
- **Water<sup>4</sup>**  
a sufficient quantity to make  
10,000 mL

<sup>1</sup> When the concentration of alcohol in the starting ingredient is not exact, follow the calculation on the USP hand sanitizer resource document to ensure a final concentration of at least 80% ethanol or 75% isopropyl alcohol.

<sup>2</sup> It is recommended to use denatured ethanol instead of nondenatured ethanol because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children. If it is not denatured, package in a child-resistant container.

<sup>3</sup> Glycerin and glycerol are synonymous and may be interchanged. Glycerin and glycerol are added as humectants.

<sup>4</sup> Water may be distilled, cold boiled potable, reverse osmosis, or filtered.



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



**Labeling:** 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.

EA825G\_04\_20



<https://www.usp.org/covid-19/hand-sanitizer-information>

[usp.org](https://www.usp.org)

# 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

$$\frac{(final\ \% alcohol) \times (final\ volume\ of\ preparation)}{(starting\ \% alcohol)} = volume\ of\ starting\ ingredient\ required$$

# 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: <ul style="list-style-type: none"><li>• One-sixteenth avoirdupois ounce of denatonium benzoate, N.F. and 1/8 gallon of tert-butyl alcohol</li></ul>	For 10 L of ethanol add: <ul style="list-style-type: none"><li>• 0.0468 g of denatonium benzoate, N.F., and</li><li>• 12.5 mL of tert-butyl alcohol*</li></ul>
OR	OR
To every 100 gallons of alcohol add: <ul style="list-style-type: none"><li>• One-sixteenth avoirdupois ounce of denatonium benzoate, N.F.</li></ul>	For 10 L of ethanol add: <ul style="list-style-type: none"><li>• 0.0468 g of denatonium benzoate, N.F.</li></ul>

**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: <ul style="list-style-type: none"><li>• One pound of sucrose octaacetate and 1/8 gallon of tert-butyl alcohol</li></ul>	For 10 L of ethanol add: <ul style="list-style-type: none"><li>• 11.98 g of sucrose octaacetate</li><li>• 12.5 mL of tert-butyl alcohol</li></ul>
OR	OR
To every 100 gallons of alcohol add: <ul style="list-style-type: none"><li>• One pound of sucrose octaacetate</li></ul>	For 10 L of ethanol add: <ul style="list-style-type: none"><li>• 11.98 g of sucrose octaacetate</li></ul>

**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: <ul style="list-style-type: none"><li>• Five gallons of isopropyl alcohol</li></ul>	For 10 L of ethanol add: <ul style="list-style-type: none"><li>• 500 mL of isopropyl alcohol</li></ul>

April 28, 2020

USP Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic. April 28, 2020;2:1-5

# Purified Water



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



# 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

## 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/FLIPTOPCAP24MM24-410/35-1538/DEVICES> Accessed 2-7-21

<https://pccarx.com/products/EASYFILLADAPTER28MM%28E%29/35-2217/DEVICES> Accessed 2-7-21

## Bottle Options



**Boston Round**



**Amber Bottle**



**Spray Bottle**

# Packaging



## Bottle Options



# Patient Label



## DRUG FACTS LABEL

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Isopropyl alcohol 75% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.	
<b>Directions</b>	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b>	
<ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



# Healthcare Personnel Label



## DRUG FACTS LABEL

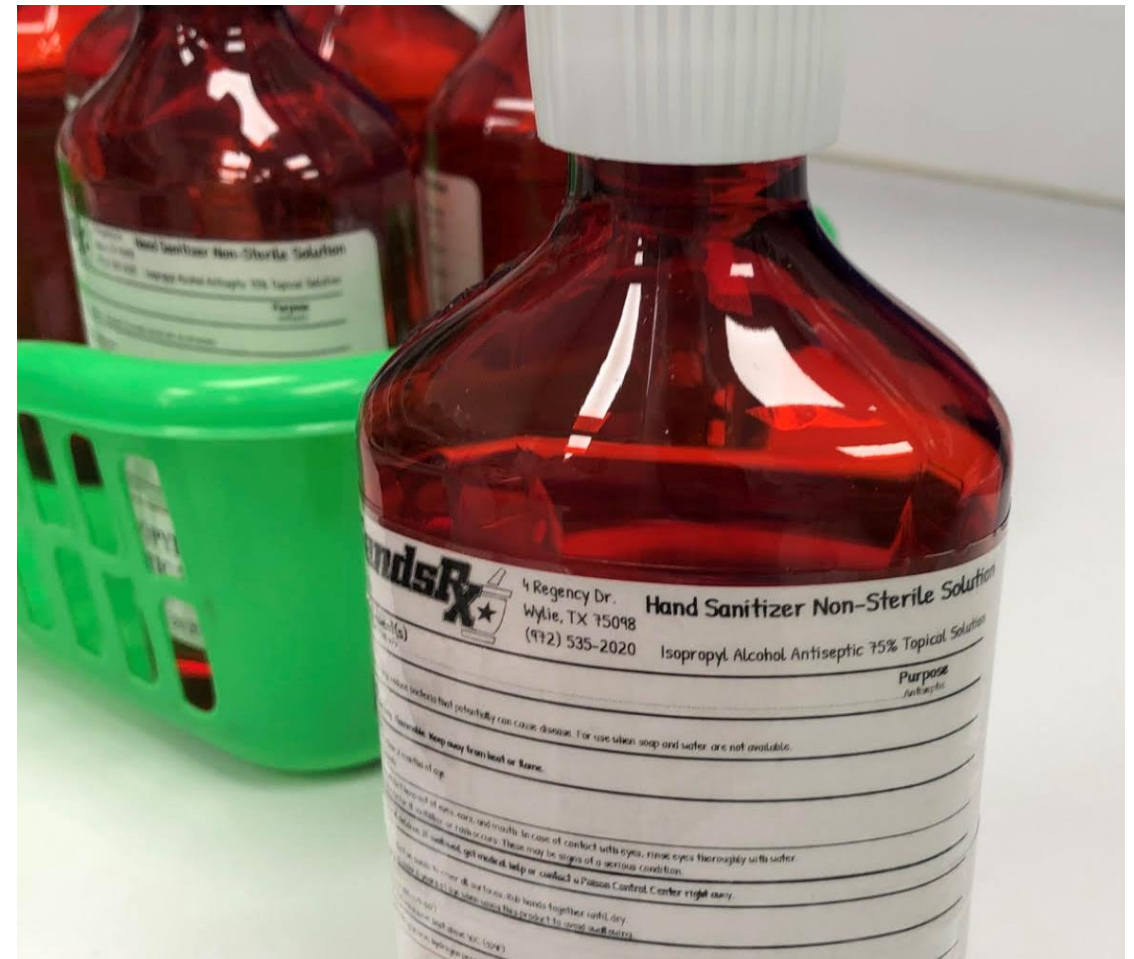
<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v.....	<b>Purpose</b> .....Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b> <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> 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



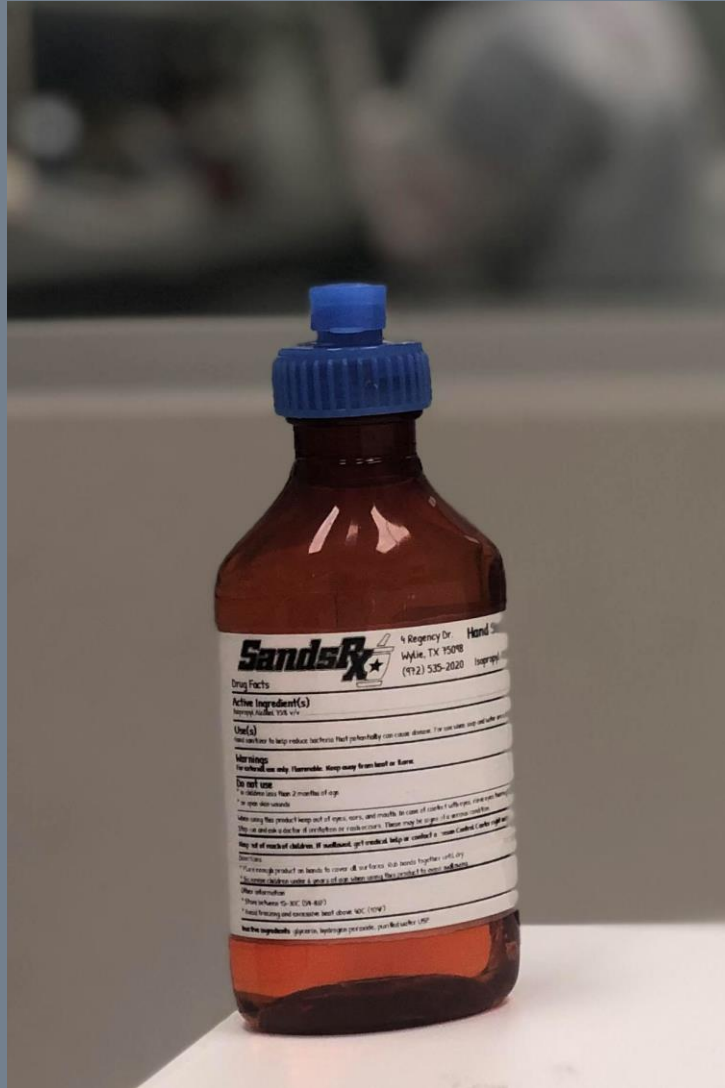
# Distribution



## Donations



# Storage



## Temperature

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

## BUD

- ▶ 30 days
- ▶ Room temperature

# References

- ▶ Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry. Aug 7, 2020;2:1-20.
- ▶ USP Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic. April 28, 2020;2:1-5
- ▶ ASTM E960-93(2021), Standard Specification for Laboratory Glass Beakers, ASTM International, West Conshohocken, PA, 2021, [www.astm.org](http://www.astm.org)



**Empowering a healthy tomorrow**

# Thank You



**Empowering a healthy tomorrow**

# Stay Connected

Phone | Social Media | Email



**Empowering a healthy tomorrow**