

**HAND RUB FOR HEALTHCARE- hand rub liquid**  
**Alchemical Solutions, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Hand Rub for Healthcare Provider**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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:

- 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.
- b. Glycerol (1.45% v/v).
- 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.

**Active Ingredient(s)**

<b>Drug Facts</b>	
<b>Active Ingredients:</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Uses:</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
• For external use only. Flammable. Keep away from heat or flame.	
<b>Do Not Use</b>	
• on children less than 2 months of age • on open skin wounds.	
When using this product keep out of	

d formulas. FDA-OTC compliant.

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eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask 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:**

Denatured Alcohol - 80%,  
Hydrogen Peroxide, Food Grade  
Glycerin, USP - Sterile Water

World Health Organization (WHO) recommends

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Alcohol 80%

v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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**INIC ALCOHOL CO. • ASHLAND, OR • ORGANICALCOHOL.**

## **Inactive Ingredients:**

**Denatured Alcohol - 80%,  
Hydrogen Peroxide, Food Grade  
Glycerin, USP - Sterile Water**

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ORGA**

Hand

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

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### **Other information**

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### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Display panel 76992-020-02**

# antiseptic hand rub

NON-STERILE SOLUTION



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## HAND RUB FOR HEALTHCARE

hand rub liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76992-020
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	47.2 mL in 59 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.8732 mL in 59 mL
WATER (UNII: 059QF0KO0R)	10.8531 mL in 59 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.0738 mL in 59 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76992-020-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

**Labeler** - Alchemical Solutions, LLC (130205128)

**Registrant** - Alchemical Solutions, LLC (130205128)

## Establishment

Name	Address	ID/FEI	Business Operations
Alchemical Solutions, LLC		130205128	manufacture(76992-020)

Revised: 5/2020

Alchemical Solutions, LLC