

**HAND SANITIZER- handsanitizer 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.*

**Handanitizer gallon**

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.

<b>Drug Facts</b>	
<b>Active Ingredients:</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Uses:</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap & water are not available.	
<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 eyes, ears, and mouth. In case of	

nded formulas. FDA-OTC compliant.

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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) recommen  
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**Active Ingredient(s)**

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**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

3785.41 mL NDC: 76992-010-03

# hand sanitizer

NON-STERILE SOLUTION



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World Health Organization (WHO) recommended formulas. FDA-OTC compliant.  
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## HAND SANITIZER

handsanitizer liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76992-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3154.382 mL in 3785.41 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	571.4039 mL in 3785.41 mL
GLYCERIN (UNII: PDC6A3C0OX)	54.8884 mL in 3785.41 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.7349 mL in 3785.41 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:76992-010-03	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
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## 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(76992-010)

Revised: 5/2020

Alchemical Solutions, LLC