

HAND SANITIZER- alcohol spray
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.

Renewal - No change Notification

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)

Drug Facts	
Active Ingredients:	Purpose
Alcohol 80% v/v.....	Antiseptic
Uses: Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap & water are not available.	
Warnings	
• For external use only. Flammable. Keep away from heat or flame.	
Do Not Use	
• 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 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 - Purified Water

Alcohol 80% v/v.

Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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Other information

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Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

hand sanitizer

NON-STERILE SOLUTION : unscented



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World Health Organization (WHO) recommended formulas. FDA-OTC compliant.
ORGANICALALCOHOL.COM



000 mL NDC: 00000-000-00

HAND SANITIZER			
alcohol spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76992-500
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.8
Inactive Ingredients			
Ingredient Name			Strength
GLYCERIN (UNII: PDC6A3C0OX)			0.0145
WATER (UNII: 059QF0K00R)			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.00125
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76992-500-01	1 in 1 JUG; Type 0: Not a Combination Product	05/01/2020	
2	NDC:76992-500-02	5 in 1 PAIL; Type 0: Not a Combination Product	05/01/2020	
3	NDC:76992-500-03	55 in 1 DRUM; Type 0: Not a Combination Product	05/01/2020	
4	NDC:76992-500-04	270 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/01/2020	
5	NDC:76992-500-05	350 in 1 TANK; 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 (130205128)

Establishment

Name	Address	ID/FEI	Business Operations
Alchemical Solutions, LLC		130205128	manufacture(76992-500)

Revised: 1/2021

Alchemical Solutions, LLC