# HAND SANITIZER- is opropyl alcohol liquid Pack & Ship Mail Center, 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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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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

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.

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## **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**

glycerin, hydrogen peroxide, purified water USP

Drug	Facts

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NDC 75057-413-20



Isopropyl Alcohol Antiseptic 75% Topical Solution Hand Sanitizer Non-sterile Solution 236ml



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236 ml NDC: 75057-413-20

## isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75057-413	
Route of Administration	TOPICAL, ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	ISOPROPYL ALCOHOL	75 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

ı	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1	NDC:75057-413-20	3000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
ı	2	NDC:75057-413-21	100 mL in 1 CAN; Type 0: Not a Combination Product	04/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2020	

## Labeler - Pack & Ship Mail Center, LLC (080246265)

## Registrant - Clyde E Sumner (080246265)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pack & Ship Mail Center, LLC		080246265	manufacture(75057-413)	

Revised: 4/2020 Pack & Ship Mail Center,LLC