

## **HAND SANITIZER- isopropyl alcohol spray**

**Scientia Labs, 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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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

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

60 ml NDC: 75342-0001-1

**Canapa Cares**

This little bottle of hand sanitizer is Canapa's effort to help stop the spread of Covid-19. As the world pauses to deal with this pandemic, Canapa has pivoted our team and equipment to produce hand sanitizer.

As part of our Canapa Cares Initiative, for each bottle of hand sanitizer purchased, Canapa will donate a bottle to those that need it most - front line health care professionals, elderly care facilities, and prisons. We hope that this initiative and hand sanitizer can help to flatten the curve, and save lives.





**Hand Sanitizer**

**ISOPROPYL ALCOHOL ANTISEPTIC 75%**

Drug Facts	
<b>Active Ingredient(s)</b> Isopropyl Alcohol 75% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> -in children less than 2 months of age -on open skin wounds	
<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.	
<b>Directions</b> -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.	
<b>Other Information</b> -Store between 15-30C (59-86F) -Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients:</b> Purified Water, Vegetable Glycerin, Hydrogen Peroxide	
NDC 75342-0001-1	



2 FL OZ (60ML)

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MANUFACTURED BY:  
SCIENTIA LABS, LLC  
7095 3RD STREET SE  
TURNER, OR 97392

## HAND SANITIZER

isopropyl alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75342-0001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75342-0001-1	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/20/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/20/2020	

**Labeler** - Scientia Labs, LLC (116937691)

Establishment			
Name	Address	ID/FEI	Business Operations
Scientia Labs, LLC		116937691	manufacture(75342-0001)