

## **HAND SANITIZER- isopropyl alcohol gel**

**Fumari, Inc.**

*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

## Package Label - Principal Display Panel

500 ml NDC: 75514-9202-1



**INSTANT  
HAND SANITIZER**

KILLS 99.99% OF GERMS\*



Manufactured and distributed by Fumari, Inc.  
675 Gateway Center Dr., Suite A  
San Diego, CA 92102

Made in the U.S.A. with U.S. and foreign  
components. This product is produced in  
accordance with the World Health Organization  
("WHO") recommendations utilizing specific  
United States Pharmacopeia grade ingredients,  
no additional active or inactive ingredients have  
been added.

Questions or comments: (619) 331-3535

\*Kills 99.99% of Most Common Germs That  
Cause Illness.

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**Drug Facts**

<b>Active Ingredient(s)</b> Isopropyl alcohol 73% w/v	<b>Purpose</b> Antiseptic
<b>Uses</b> • to decrease bacteria on the skin that could cause disease • recommended for repeated use	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. When using this Product • keep out of eyes. In case of contact with eyes, flush thoroughly with water • avoid contact with broken skin • do not inhale or ingest Stop use and ask a doctor if skin irritation develops.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • wet hands thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision • not recommended for infants	
<b>Other information</b> • do not store above 104°F • may discolor some fabrics • harmful to wood, finishes and plastics	
<b>Inactive ingredients</b> glycerin, distilled water and hydrogen peroxide	



0 36663 95660 1 6  
ITEM NO.  
96000

FRAGRANCE-FREE
17 FL OZ (500 mL)

## HAND SANITIZER

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75514-9202
<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)	

### Product Characteristics

<b>Color</b>		<b>Score</b>
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Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75514-9202-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	



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**Drug Facts**

<b>Active ingredient(s)</b> Isopropyl alcohol 75% w/v	<b>Purpose</b> Antiseptic
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• to decrease bacteria on the skin that could cause disease</li> <li>• recommended for repeated use</li> </ul>	
<b>Warnings</b>	
For external use only. <b>Flammable. Keep away from heat or flame.</b>	
<b>When using this Product</b>	
<ul style="list-style-type: none"> <li>• keep out of eyes. In case of contact with eyes, flush thoroughly with water</li> <li>• avoid contact with broken skin</li> <li>• do not inhale or ingest</li> </ul>	
Stop use and ask a doctor if skin irritation develops.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• wet hands thoroughly with product and allow to dry without wiping</li> <li>• for children under 6, use only under adult supervision</li> <li>• not recommended for infants</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• don't store above 104°F</li> <li>• may discolor some fabrics</li> <li>• harmful to wood finishes and plastics</li> </ul>	
<b>Inactive ingredients</b> glycerin, distilled water and hydrogen peroxide	



95660  
36663

ITEM NO.  
90000

FRAGRANCE-FREE
17 FL OZ (500 mL)

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

**Labeler** - Fumari, Inc. (080368370)

### Establishment

Name	Address	ID/FEI	Business Operations
Fumari, Inc.		080368370	manufacture(75514-9202)

Revised: 4/2020

Fumari, Inc.