

HAND SANITIZER- isopropyl alcohol spray

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.

Hand Sanitizer Spray 100mL

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

Manufactured and distributed by Fumari, Inc.
675 Gateway Center Dr., Ste. 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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ITEM NO. 95000

Drug Facts	
Active Ingredient(s) Isopropyl alcohol 75% v/v.....	Purpose Antiseptic
Uses • to decrease bacteria on the skin that could cause disease • recommended for repeated use	
Warnings 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.	
Directions • wet hands thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision • not recommended for infants	
Other information • do not store above 104°F • may discolor some fabrics • harmful to wood finishes and plastics	
Inactive ingredients glycerin, distilled water and hydrogen peroxide	

100 ml NDC: 75514-9203-1

HAND SANITIZER

isopropyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75514-9203
Route of Administration	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

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75514-9203-1	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/01/2020	



INSTANT HAND SANITIZER SPRAY

KILLS 99.99%
OF GERMS*



FRAGRANCE-FREE

3.38 FL OZ (100 mL)

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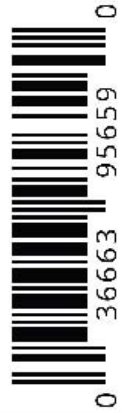
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Marketing Information

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(75514-9203)

Revised: 4/2020

Fumari, Inc.