DOCTORS OPTIMAL FORMULA HAND SANITIZER- is opropyl alcohol solution Golden Lab, 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.

Hand Sanitizer

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

3785 ml NDC: 74891-712-95

Drug Facts
Active Ingredient Purpose Isopropyl Alcohol75%Antiseptic
Uses Health care personnel hand rub to help reduce bacteria that potentially can cause disease.
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 eye 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 promptly and contact 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, Distilled Water

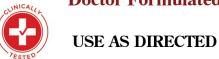
Distributed by:Doctors Optimal Formula, LLC
Jacksonville, FL 32246
www.drsoptimalformula.com

Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



Kills 99.99% of Germs

128 oz (3785 mL)

Package Label - Principal Display Panel

Drug Facts	
Active Ingredient Isopropyl Alcohol 75%	Purpose Antiseptic
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Distributed by: Doctors Optimal Formula, LLC Jacksonville, FL 32246 www.drsoptimalformula.com

Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



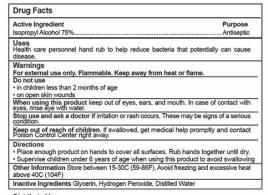
USE AS DIRECTED

Kills 99.99% of Germs

1 oz (30 mL)

Package Label - Principal Display Panel

59 ml NDC: 74891-712-02



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Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

2 oz (59 mL)

Package Label - Principal Display Panel



Hand Sanitizer



Kills 99.99% of Germs

8 oz (237 mL)

Drug Facts

Uses

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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 eye 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 promptly and contact Poison Control Center right away.

Directions

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- · 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, Distilled Water

Distributed by:

Doctors Optimal Formula, LLC Jacksonville, FL 32246 www.drsoptimalformula.com Non-Sterile Solution

Package Label - Principal Display Panel

Drug Facts Active Ingredient Purpose Isopropyl Alcohol75%. .Antiseptic Uses

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Other Information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients Glycerin, Hydrogen Peroxide, Distilled

Distributed by:

www.drsoptimalformula.com

Non-Sterile Solution





Hand Sanitizer



Kills 99.99% of Germs

16 oz (473 mL)

Package Label - Principal Display Panel

Drug Facts

Active Ingredient Isopropyl Alcohol 75%.....

Purpose Antiseptic

Uses Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings For external use only. Flammable. Keep away from fire or flame.

- Do not use
 in children less than 2 months of age
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Inactive Ingredients Glycerin, Hydrogen Peroxide, Distilled Water

Distributed by: Doctors Optimal Formula, LLC Jacksonville, FL 32246 www.drsoptimalformula.com

Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

32 oz (946 mL)

Package Label - Principal Display Panel

Drug Facts

Active Ingredient Purpose Isopropyl Alcohol 75%..... Antiseptic

Uses Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings For external use only. Flammable. Keep away from fire or flame.

Do not use

- in children less than 2 months of ageon open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye with water.

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Inactive Ingredients Glycerin, Hydrogen Peroxide, Distilled Water

Distributed by: Doctors Optimal Formula, LLC Jacksonville, FL 32246 www.drsoptimalformula.com

Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

64 oz (1,893 mL)

DOCTORS OPTIMAL FORMULA HAND SANITIZER

isopropyl alcohol solution

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HUMAN OTC DRUG NDC:74891-712 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

UNII:ND2M416302)	ALCOHOL	in 100 mL
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Inactive Ingredients						
Ingredient Name	Strength					
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL					
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL					
WATER (UNII: 059QF0KO0R)						

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:74891-712- 01	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/30/2020					
2	NDC:74891-712- 02	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/30/2020					
3	NDC:74891-712- 16	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020					
4	NDC:74891-712- 08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020					
5	NDC:74891-712- 32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020					
6	NDC:74891-712-64	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020					
7	NDC:74891-712- 95	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	03/30/2020					

Labeler - Golden Lab, LLC (013175652)

Establishment								
Name	Address	ID/FEI	Business Operations					
Golden Lab, LLC		013175652	manufacture(74891-712)					

Revised: 4/2020 Golden Lab, LLC