

DOCTORS OPTIMAL FORMULA HAND SANITIZER- isopropyl 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.

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.

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 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 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

Docto Rx's
Optimal Formula

Hand Sanitizer
Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

128 oz (3785 mL)

Package Label - Principal Display Panel

30 ml NDC: 74891-712-01

Drug Facts	
Active Ingredient	Purpose
Isopropyl Alcohol 75%.....	Antiseptic
Uses	
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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	

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Hand Sanitizer

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Kills 99.99% of Germs

1 oz (30 mL)



Package Label - Principal Display Panel

59 ml NDC: 74891-712-02

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 heat or flame.	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	

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Docto Rx's
Optimal Formula

Hand Sanitizer

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USE AS DIRECTED

Kills 99.99% of Germs

2 oz (59 mL)



Package Label - Principal Display Panel

237 ml NDC: 74891-712-08

Docto Rx's

Optimal Formula

Hand Sanitizer



Doctor Formulated

USE AS DIRECTED

Kills 99.99% of Germs

8 oz (237 mL)

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 heat or flame.	
Do not use <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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	

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Non-Sterile Solution

Package Label - Principal Display Panel

473 ml NDC: 74891-712-16

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 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	

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Doctors Optimal Formula, LLC
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Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

16 oz (473 mL)

Package Label - Principal Display Panel

946 ml NDC: 74891-712-32

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 <ul style="list-style-type: none"> • 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	

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Docto **Rx's**
Optimal Formula

Hand Sanitizer

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USE AS DIRECTED

Kills 99.99% of Germs

32 oz (946 mL)

Package Label - Principal Display Panel

1893 ml NDC: 74891-712-64

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 <ul style="list-style-type: none"> • 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	

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