

## **DOCTORS OPTIMAL FORMULA HAND SANITIZER- alcohol solution**

## **FOCUS HEALTH SUPPLY HAND SANITIZER- 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.*

-----

### **Ethanol 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 80% 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

30 mL NDC: 74891-713-01

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can 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> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye 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 promptly and contact Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing</li></ul>	
<b>Other Information</b> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> Glycerin, Hydrogen Peroxide, Purified Water USP	

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**

**1 oz (30 mL)**

### Package Label - Principal Display Panel

59 ml NDC: 74891-713-02

Drug Facts	
Active Ingredient Alcohol 80% v/v.....	Purpose Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can 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 eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	
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

2 oz (59 mL)



Package Label - Principal Display Panel

237 ml NDC: 74891-713-08



# Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

**Kills 99.99% of Germs**

**8 oz (237 mL)**

Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can 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> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye 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 promptly and contact Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing</li></ul>	
<b>Other Information</b> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> Glycerin, Hydrogen Peroxide, Purified Water USP	

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

**Non-Sterile Solution**

**Package Label - Principal Display Panel**

296 ml NDC: 74891-713-10

Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<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 eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	
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

10 oz (296 mL)



### Package Label - Principal Display Panel

473 ml NDC: 74891-713-16

Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from fire 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 eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	

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

16 oz (473 mL)



### Package Label - Principal Display Panel

946 ml NDC: 74891-713-32

Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	

**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**

**32 oz (946 mL)**

### Package Label - Principal Display Panel

1893 ml NDC: 74891-713-64

Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	

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

**Non-Sterile Solution**

Docto   
Optimal Formula

## Hand Sanitizer

Doctor Formulated



USE AS DIRECTED

**Kills 99.99% of Germs**

**64 oz (1,893 mL)**

**Package Label - Principal Display Panel**

3785 ml NDC: 74891-713-95



Drug Facts	
<b>Active Ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from fire or flame.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye with water.	
<b>Stop use and ask a doctor if</b> 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	

**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

237 ml NDC: 74891-714-08





## Hand Sanitizer



Doctor Formulated  
USE AS DIRECTED

Kills 99.99% of Germs

8 oz (237 mL)

Drug Facts	
Active Ingredient	Purpose
Alcohol 80% v/v.....	Antiseptic
<b>Uses</b> Health care personnel hand rub to help reduce bacteria that potentially can 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 and on open skin wounds.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eye 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 promptly and contact 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> Glycerin, Hydrogen Peroxide, Purified Water USP	

### Non-Sterile Solution

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

## DOCTORS OPTIMAL FORMULA HAND SANITIZER

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74891-713
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74891-713-	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination	05/01/2020	

1	01	Product	05/01/2020	
2	NDC:74891-713-02	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
3	NDC:74891-713-08	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	
4	NDC:74891-713-16	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	
5	NDC:74891-713-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
6	NDC:74891-713-64	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
7	NDC:74891-713-95	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

## FOCUS HEALTH SUPPLY HAND SANITIZER

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74891-714
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74891-714-08	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

**Labeler** - Golden Lab, LLC (013175652)

**Establishment**

Name	Address	ID/FEI	Business Operations
Golden Lab, LLC		013175652	manufacture(74891-713, 74891-714)

Revised: 5/2020 Golden Lab, LLC