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.

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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







1 oz (30 mL)

Package Label - Principal Display Panel

Artice la martinet	Democra		
Active Ingredient Alcohol 80% v/v	Purpose Antiseptic		
	Antiseptic		
Uses Hand sanitizer to help reduce bacteria that potentially can soap and water are not available.	cause disease. For use when		
Warnings			
For external use only. Flammable. Keep away from he	at 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 meyes, rinse eye with water.			
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a condition.			
Keep out of reach of children. If swallowed, get medica Poison Control Center right away.	al help promptly and contact		
Directions			
 Place enough product on hands to cover all surfaces. F Supervise children under 6 years of age when using th 			
Other Information Store between 15-30C (59-86F). Avoid above 40C (104F)	freezing and excessive heat		
Inactive Ingredients Glycerin, Hydrogen Peroxide, Purific	ed Water USP		
Distributed by: Doctors Optimal Formula, LLC Jacksonville, FL 32246	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

Doctor Formulated



USE AS DIRECTED

Kills 99.99% of Germs

8 oz (237 mL)

Drug Facts	
5	urpose tiseptic
Uses Hand sanitizer to help reduce bacteria that potentially can cause disease. For us soap and water are not available.	se when
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 cont eyes, rinse eye with water.	act with
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a condition.	serious
Keep out of reach of children. If swallowed, get medical help promptly and Poison Control Center right away.	contact
Directions	
 Place enough product on hands to cover all surfaces. Rub hands together up 	until dry.
 Supervise children under 6 years of age when using this product to avoid sy 	vallowing
Other Information Store between 15-30C (59-86F). Avoid freezing and excess above 40C (104F)	ive heat
Inactive Ingredients Glycerin, Hydrogen Peroxide, Purified Water USP	
Distributed by:	

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

Package Label - Principal Display Panel





473 ml NDC: 74891-713-16

Drug Facts	
Active Ingredient Alcohol 80% v/v	Purpose Antiseptic
Uses Health care personnel has bacteria that potentially can cause of	
Warnings For external use only. Flammable. Keep away from fire or flame.	
Do not use • in children less than 2 months of a • on open skin wounds	ge
When using this product keep mouth. In case of contact with eyes	
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, Purified Water USP	
Distributed by: Doctors Optimal Formula, LLC Jacksonville, FL 32246 www.drsoptimalformula.com	Non-Sterile Solution



946 ml NDC: 74891-713-32



Hand Sanitizer Doctor Formulated USE AS DIRECTED

Kills 99.99% of Germs 10 oz (296 mL)



Hand Sanitizer



Doctor Formulated

USE AS DIRECTED

Kills 99.99% of Germs

16 oz (473 mL)

Drug Facts	
Active Ingredient Alcohol 80% v/v	Purpose Antiseptic
Uses Health care personne bacteria that potentially can ca	•
Warnings For external use from fire or flame.	only. Flammable. Keep away
Do not use • in children less than 2 months • on open skin wounds	s of age
When using this product mouth. In case of contact with	
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.	
Other Information Store between 15-30C (59-86F). Available freezing and excessive heat above 40C (104F)	
Inactive Ingredients Glycerin, Hydrogen Peroxide, I	Purified Water USP
Distributed by:	Non-Sterile Solution

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

Non-Sterlie Solution



Hand Sanitizer



USE AS DIRECTED

Kills 99.99% of Germs

32 oz (946 mL)

Package Label - Principal Display Panel

Active Ingredient Purpose Ilcohol 80% v/vAntiseptic
Jses Health care personnel hand rub to help reduct acteria that potentially can cause disease.
Varnings For external use only. Flammable. Keep awa rom fire or flame.
)o not use in children less than 2 months of age on open skin wounds
When using this product keep out of eyes, ears, and nouth. In case of contact with eyes, rinse eye with water.
top use and ask a doctor if irritation or rash occurs. These nay be signs of a serious condition.
Geep out of reach of children. If swallowed, get medica elp promptly and contact Poison Control Center righ way.
Directions Place enough product on hands to cover a urfaces. Rub hands together until dry. Supervise children nder 6 years of age when using this product to avoid wallowing.
Other Information Store between 15-30C (59-86F). Avoid reezing and excessive heat above 40C (104F)
nactive Ingredients Slycerin, Hydrogen Peroxide, Purified Water USP

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

Non-Sterile Solution



Hand Sanitizer

Doctor Formulated



Kills 99.99% of Germs

64 oz (1,893 mL)

Package Label - Principal Display Panel

Drug Facts		
Active Ingredient Alcohol 80% v/v	Purpose Antiseptic	
Uses Health care personn bacteria that potentially can c	nel hand rub to help reduce ause disease.	
Warnings For external use only. Flammable. Keep away from fire or flame.		
Do not use • in children less than 2 month • on open skin wounds	hs of age	
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, Purified Water USP		
Distributed by:	Non-Sterile Solution	

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

128 oz (3785 mL)

Package Label - Principal Display Panel



Hand Sanitizer



Kills 99.99% of Germs

Drug Facts	
Active Ingredient Alcohol 80% v/v	Purpose Antiseptic
Uses Health care personnel hand rub help reduce bacteria that potentially c cause disease. For use when soap a water are not available.	
Warnings For exter Flammable. Keep awa flame.	mal use only. y from heat or
Do not use in childre months of age and on op	
When using this prod eyes, ears, and mouth. In with eyes, rinse eye with	n case of contact
Stop use and ask a doo rash occurs. These ma serious condition.	t or if irritation or y be signs of a
Keep out of reach swallowed, get medica and contact Poison right away.	help promptly
Directions Place enou- hands to cover all surfa together until dry. Sup under 6 years of age product to avoid swallow	ces. Rub hands pervise children when using this
Other Information Sto 30C (59-86F). Avoid excessive heat above 4	freezing and
Inactive Ingredients Gly Peroxide, Purified Water	

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

8 oz (237 mL)

DOCTORS OPTIMAL FORMULA HAND SANITIZER

alcohol solution

Product Inform	nation				
Product T ype		HUMAN OTC DRUG	Item Code (S	Source)	NDC:74891-713
Route of Administ	ration	TOPICAL			
Active Ingredie	ent/Active Moi	ety			
	Ingred	ient Name]	Basis of Strength	Strength
ALCOHOL (UNII: 31	K9958V90M) (ALC	OHOL - UNII:3K9958V90M)	AL	COHOL	80 mL in 100 mL
Inactive Ingred	lients				
	Ing	gredient Name		1	Strength
GLYCERIN (UNII: PI	-	gredient Name		1.45 mL in 100	Strength mL
GLYCERIN (UNII: PI HYDROGEN PERO 2	DC6A3C0OX)				mL
	DC6A3C0OX) XIDE (UNII: BBX06			1.45 mL in 100	mL
HYDROGEN PERO WATER (UNII: 059Q	DC6A3C0OX) XIDE (UNII: BBX06			1.45 mL in 100	mL
HYDROGEN PERO WATER (UNII: 059Q	DC6A3C0OX) XIDE (UNII: BBX06			1.45 mL in 100 0.125 mL in 10	mL 0 mL
HYDRO GEN PERO	DC6A3C0OX) XIDE (UNII: BBX06			1.45 mL in 100	mL

T	01	Pro du	ict	03/01/2020	
2	NDC:74891-713- 02	59 mI Produ	L in 1 BOTTLE, DROPPER; Type 0: Not a Combination loct	05/01/2020	
3	NDC:74891-713- 08	237 m Produ	nL in 1 BOTTLE, SPRAY; Type 0: Not a Combination act	05/01/2020	
4	NDC:74891-713- 16	473 m Pro du	nL in 1 BOTTLE, SPRAY; Type 0: Not a Combination	05/01/2020	
5	NDC:74891-713- 32	946 n	nL 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 Categ	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
0	TC monograph not	final	part333A	05/01/2020	

FOCUS HEALTH SUPPLY HAND SANITIZER

alcohol solution

Product Information

Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:74891-714
Route of Administration	TOPICAL		
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			
	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	0 5/0 1/20 20	

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