H2ONE HAND SANITIZER- ethyl-alcohol gel Samarian Products, 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.

H2One Hand Sanitizer 500mL

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 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)

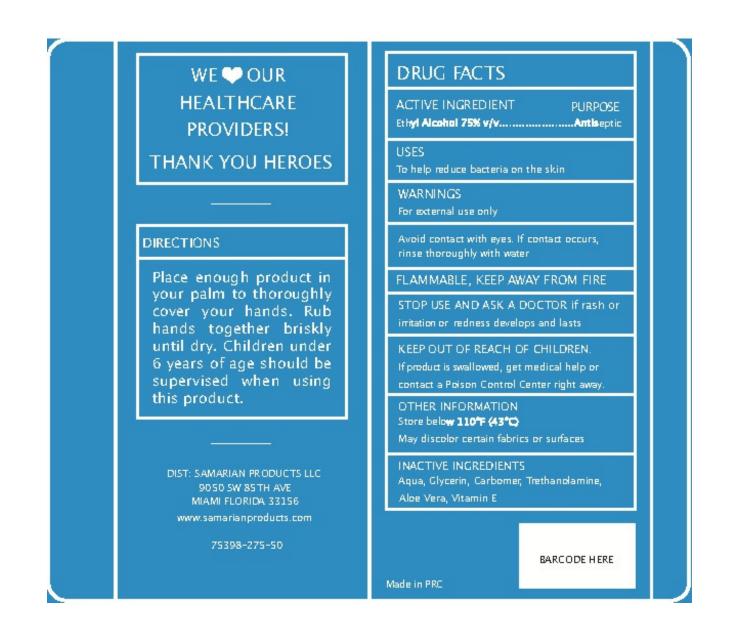
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

500mL 75% v/v

ADVANCED FORMULA HAND SANITIZER GEL	
H ₂ One ^m	
Premium Hand Sanitizer	
16.9fl .oz / 500 ml	



H2ONE HAND SANITIZER

ethyl-alcohol gel

		· · · · ·		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75398-275	(NDC:71712-002)
Route of Administration	TOPICAL			
Active Ingredient/Active N	Ioiety			
Ing	redient Name	Bas	is of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			HOL	75 mL in 100 mL
Inactive Ingredients				
Inactive Ingredients	gredient Name		Strer	ıgth
0	gredient Name	1.45 r	Strer nL in 100 mL	ıgth

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 1	NDC:75398-275-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2020					
M	larketing Inf	ormation						
	larketing Inf		Marketing Start Date	Marketing End Date				

Labeler - Samarian Products, LLC (117487303)

Establishment								
Name	Address	ID/FEI	Business Operations					
Samarian Products LLC`		117487303	relabel(75398-275)					

Revised: 4/2020

Samarian Products, LLC