HAND SANITIZER- alcohol liquid On Hand Lotions, 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 80%

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.

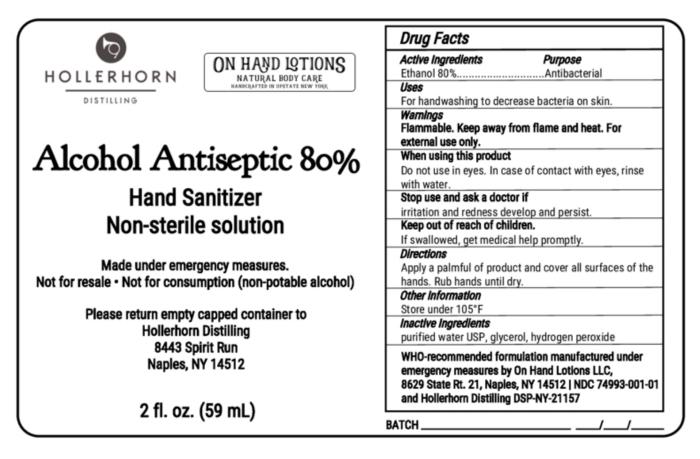
The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- 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



	Drug Facts
HOLLERHORN ON HAND LOTIONS	Active Ingredients Purpose Ethanol 80%Antibacterial
BANDCRAFTED IN UPSTATE NEW YORK	Uses For handwashing to decrease bacteria on skin.
	Warnings Flammable. Keep away from flame and heat. For external use only.
Alcohol Antiseptic 80%	When using this product Do not use in eyes. In case of contact with eyes, rinse
Hand Sanitizer	with water. Stop use and ask a doctor if
Non-sterile solution	irritation and redness develop and persist. Keep out of reach of children. If swallowed, get medical help promptly.
Made under emergency measures. Not for resale • Not for consumption (non-potable alcohol)	Directions Apply a palmful of product and cover all surfaces of the hands. Rub hands until dry.
Please return empty capped container to	Other Information Store under 105°F
Hollerhorn Distilling	Inactive Ingredients purified water USP, glycerol, hydrogen peroxide
8443 Spirit Run Naples, NY 14512	WHO-recommended formulation manufactured under emergency measures by On Hand Lotions LLC, 8629 State Rt. 21, Naples, NY 14512 NDC 74993-001-02 and Hollerhorn Distilling DSP-NY-21157
8 fl. oz. (236 mL)	BATCH

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

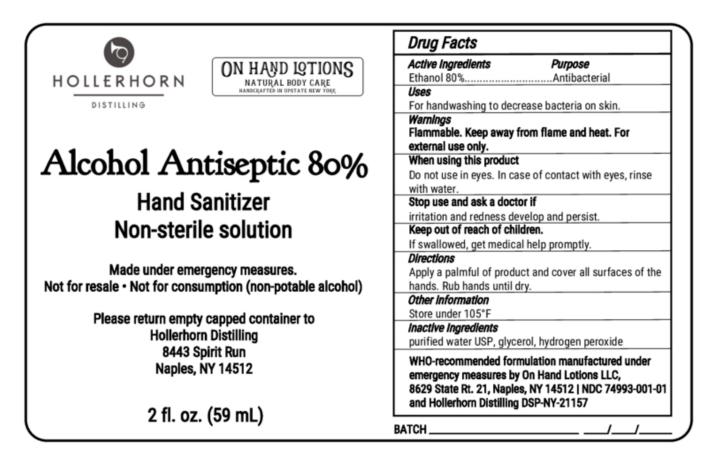
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

59mL NDC:74993-001-01



236ml NDC: 74993-001-02

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8443 Spirit Run Naples, NY 14512	purified water USP, glycerol, hydrogen peroxide WHO-recommended formulation manufactured under emergency measures by On Hand Lotions LLC, 8629 State Rt. 21, Naples, NY 14512 NDC 74993-001-02 and Hollerhorn Distilling DSP-NY-21157		
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HAND SANITIZ	ER						
alcohol liquid							
Product Informatio	n						
Product T ype		HUMAN OTC DRUG	Item Code (Source)		e)	NDC:74993-001	
Route of Administratio	n	TOPICAL					
A							
Active Ingredient/A		,					
	0				of Strength		
ALCOHOL (UNII: 3K9958	0	l ient Name COHOL - UNII:3K9958V90M)		Basis ALCOHO		80 mL in 100 mL	
ALCOHOL (UNII: 3K9958	0						
ALCOHOL (UNII: 3K9958 Inactive Ingredient	8V90M) (ALC						
	8V90M) (ALC S				DL		
•	8V90M) (ALC s Inį	COHOL - UNII:3K9958V90M)			DL	80 mL in 100 mL	
Inactive Ingredient	8 V90M) (ALC s Inį 3C0OX)	COHOL - UNII:3K9958V90M) gredient Name			DL	80 mL in 100 mL Strength) mL	
Inactive Ingredients GLYCERIN (UNII: PDC6A	8 V90M) (ALC s Ing .3C0OX) (UNII: BBX06	COHOL - UNII:3K9958V90M) gredient Name			DL 1.45 mL in 100	80 mL in 100 mL Strength) mL	
Inactive Ingredients GLYCERIN (UNII: PDC6 A HYDROGEN PEROXIDE	8 V90M) (ALC s Ing .3C0OX) (UNII: BBX06	COHOL - UNII:3K9958V90M) gredient Name			DL 1.45 mL in 100	80 mL in 100 mL Strength) mL	
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1 NDC:74993-001- 01	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product			03/30/2020	
2 NDC:74993-001- 02	236 mL in 1 Product	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product			
3 NDC:74993-001- 03	3785 mL in 1 Product	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product			
Marketing Information					
Marketing Cates	gory App	plication Number or Monograph Citation	Mar	rketing Start Date	Marketing End Date
OTC monograph not	final part33	33A	03/30)/2020	

Labeler - On Hand Lotions, LLC (095018279)

Establishment

Name	Address	ID/FEI	Business Operations
On Hand Lotions, LLC		095018279	manufacture(74993-001)

Revised: 5/2020

On Hand Lotions, LLC