#### HAND SANITIZER- alcohol liquid Kennay Farms Distilling 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.

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#### 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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## 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

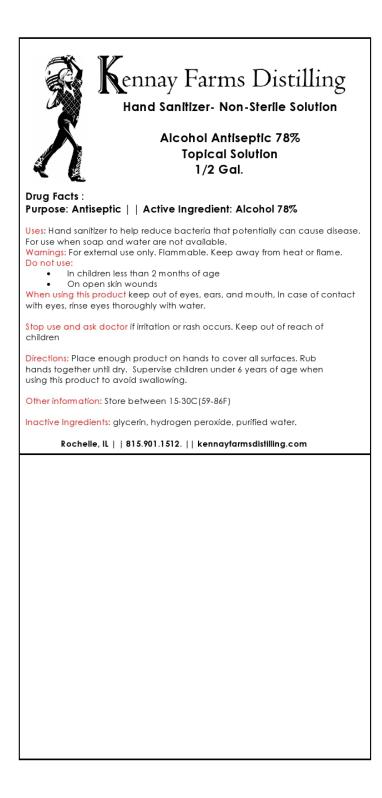
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

# Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

1892.71 mL NDC: 75069-111-13



alcohol liquid								
Product Inform	ation							
Product Type			HUMAN OTC DRUG Item Cod		de (Sourc	e)	NDC:75069-111	
Route of Administ	ration		TOPICAL					
Active Ingredie	nt/Act	tive Moie	atv					
Active Ingredient/Active Moiety Ingredient Name						of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)						) of Strength DL	80 mL in 100 mL	
Inactive Ingredients								
Ingredient Name						Strength		
GLYCERIN (UNII: PDC6A3C0OX)						1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)						0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)								
<b>D</b> 1 ·								
Packaging								
# Item Code		Package Description			Marketing Start Date		Marketing End Date	
1 NDC:75069-111- 13	1892.71 mL in 1 B Product		OTTLE; Type 0: Not a Combination		03/30/2020			
Marketing Information								
Marketing Category					Marketing Start Date		Marketing End Date	
OTC monograph not final		part333A			03/30/2020	)		

# Labeler - Kennay Farms Distilling LLC (105088352)

Establishment									
Name	Address	ID/FEI	<b>Business Operations</b>						
Kennay Farms Distilling LLC		105088352	manufacture(75069-111)						

Revised: 4/2020

Kennay Farms Distilling LLC