HAND SANITIZER- alcohol spray Lost Ark Distilling Company

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

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

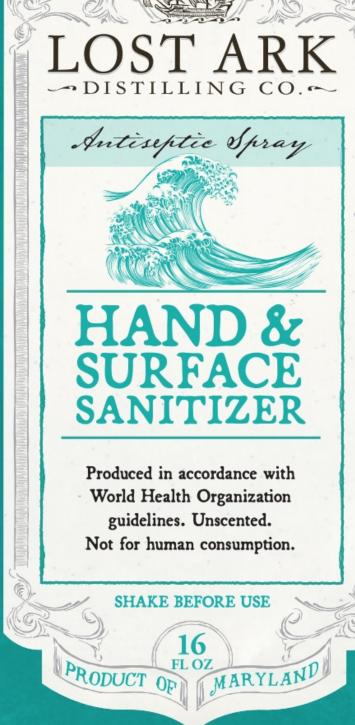
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

473 mL NDC: 77384-001-16



DRUG FACTS

Active Ingredient(s)	
Alcohol 80% v/v	

Purpose Antiseptic

Use(s)

Hand rub to help reduce bacteria that can potentially cause disease.

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 thoroughly with water.

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Directions

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Other Information

- Store between 59–86°F
- Avoid freezing and excessive heat above 104°F

Inactive Ingredients

Purified water, Hydrogen Peroxide, Glycerin

LOSTARKDISTILLING.COM

NDC 77384-001-16

HAND SANITIZER

alcohol spray

	ation						
Product T ype		HUMAN OTC DI	RUG	Ite m Code	(Source	:)	NDC:77384-001
Route of Administr	ation	TOPICAL					
Active Ingredie	nt/Active Moie	ty					
Ingredient Name				Basis	of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHC	L	80 mL in 100 mL	
Inactive Ingredi	ents						
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)							
Product Charact	teristics						
Color			Score				
Shape			Size				
Flavor			Imprint Code	2			
			-				
Contains							
Contains							
Contains							
Contains Packaging							
	1	Package Desc	ription		Mark	eting Start Date	Marketing End Date



Produced in accordance with World Health Organization guidelines. Unscented. Not for human consumption.

SHAKE BEFORE USE

FL OZ

MARYLAND

DRUG FACTS

Active Ingredient(s) Alcohol 80% v/v Purpose Antiseptic

Use(s)

Hand rub to help reduce bacteria that can potentially cause disease.

Warnings

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Do not use

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NDC 77384-001-16

Marketing Information

PRODUCT OF

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Lost Ark Distilling Company (101192918)

Registrant - Brad Blackwell (101192918)

Establishment							
Name	Address	ID/FEI	Business Operations				
Enter Establishment Name		10 119 29 18	manufacture(77384-001)				

Revised: 5/2020

Lost Ark Distilling Company