

## **HAND SANITIZER- alcohol liquid**

**Etz Hayim, SPC**

*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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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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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

473 mL NDC: 74485-007-01

FORMULATED WITHOUT  
PHTHALATES, PARABENS  
OR SLS

**WE GIVE 10% OF OUR  
HAND SANITIZERS TO  
FOOD BANKS, HOMELESS  
SHELTERS AND OTHER  
ORGANIZATIONS IN NEED.**

VISIT US AT  
**LAZARUSNATURALS.COM**  
TO LEARN MORE ABOUT  
OUR FULL LINE OF CBD  
PRODUCTS

**MANUFACTURED BY**  
Lazarus Naturals  
16427 NE Airport Way  
Portland, OR 97230  
**LAZARUSNATURALS.COM**  
support@lazarusnaturals.com

HSL473CL AA



STORE IN A DARK,  
COOL PLACE.



8 74485-XXX-XX 15084 7



PLEASE  
RECYCLE



**Lazarus  
Naturals™**

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**HAND SANITIZER**

ALCOHOL ANTISEPTIC  
80% TOPICAL SOLUTION

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**UNSCENTED  
FRAGRANCE FREE**

**NATURALLY KILLS  
99.9% OF GERMS**

NON-STERILE SOLUTION  
16 FL OZ / 473 ML

**Drug Facts**

Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic

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**Inactive ingredients** purified water USP, vegetable glycerin, hydrogen peroxide, tert-butyl alcohol, denatonium benzoate, lemon oil

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74485-007
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
1	NDC:74485-007-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/21/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

**Labeler** - Etz Hayim, SPC (116982648)

Establishment			
Name	Address	ID/FEI	Business Operations
Lazarus Naturals		116982648	manufacture(74485-007)