

## **LAZARUS PROVISIONS HAND SANITIZER- alcohol liquid**

### **Etz Hayim Holdings**

*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 Gallon**

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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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

8475 mL NDC: 74485-005-001

FRAGRANCE FREE

FORMULATED WITHOUT  
PHTHALATES, PARABENS,  
PETROLEUM OR SLS

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

STORE IN DARK,  
COOL PLACE.

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



Lazarus  
Naturals™

**HAND SANITIZER**

ALCOHOL ANTISEPTIC  
80% TOPICAL SOLUTION

FRAGRANCE FREE

**NATURALLY KILLS  
99.9% OF GERMS**

ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION  
1 GALLON / 3,785 ML

**Drug Facts**

<b>Active ingredient[s]</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. <b>Do not use</b> • 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. <b>Stop use and ask a doctor</b> 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.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> purified water USP, vegetable glycerin, hydrogen peroxide, tert-butyl alcohol, denatonium benzoate	

74485-xxx-xx



LAZARUS PROVISIONS HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74485-005
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	

<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74485-005-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

### 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 Holdings (116982648)

### Establishment

Name	Address	ID/FEI	Business Operations
Lazarus Naturals		116982648	manufacture(74485-005)

Revised: 4/2020

Etz Hayim Holdings