

## **LAZARUS PROVISIONS HAND SANITIZER HEALTHCARE PERSONNEL- 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 Health Professional**

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

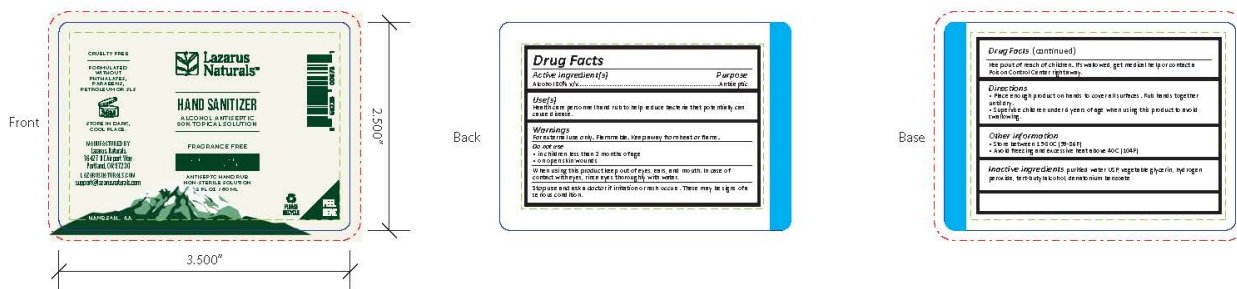
### Package Label - Principal Display Panel

60 mL NDC: 74485-002-01

## UNSCENTED -- Health Care Personnel Handrub Use

NOTE:  
DOCUMENT RASTER EFFECTS SETTINGS  
SHOULD BE SET AT 300 RESOLUTION

PLEASE OUTLINE ALL YOUR FONTS.



← PRESS DIRECTION / UNWIND →

Die Number: 10-0609	<b>DRAWING KEYS</b>	<b>OP is "Outside Panel"</b> <b>IP is "Inside Panel"</b>	<b>Some Notes to the Designer:</b>
Die Cut Size: 2.50"x 3.50"	<b>Cut/Fold Lines</b>		1. Hold all text 1/8" from Cut Marks. (Also critical graphic elements)
Corner Radius: .125"	<b>1/8" Bleed Lines</b>		2. Bleed full coverage background graphics 1/8" beyond Cut Marks.
	<b>Text Limit Lines</b>		3. PEEL HSEI verbiage recommended for upper right corner of OP1.
	<b>OP1 Bleed Line</b>		4. If OP1 has full coverage graphics, bleed 1/16" to 3/32" onto OP2.
			5. This Template is provided in 2 layers. Simply turn off the text layer to use the layout only as a placed image in your document.

## LAZARUS PROVISIONS HAND SANITIZER HEALTHCARE PERSONNEL

alcohol liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:74485-002

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:74485-002-01	60 mL in 1 BOTTLE, PLASTIC; 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(74485-002)

Revised: 4/2020

Etz Hayim Holdings