

## **HYALOLEX HAND SANITIZER- alcohol solution**

### **India Globalization Capital, Inc.**

*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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### **Hylolex 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.

Stop use if irritation appears.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- Wet hands with product and briskly rub hands together until dry
- Supervise children under 6 years in use of this product.

### **Other information**

- Store between 20-25C (68-77F)
- May discolor certain fabrics

### **Inactive ingredients**

glycerin, hydrogen peroxide, methyl cellulose, purified water USP

### **Package Label - Principal Display Panel**



# Hand Sanitizer

Sulfate + Paraben Free  
73% Ethyl Alcohol  
Antimicrobial  
Kills Germs

16 fl oz | 472 mL

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 73% v/v	Antimicrobial
<b>Use</b> to help reduce germs on the skin.	
<b>Warnings</b> For external use only.	
Flammable. Keep away from heat or fire.	
Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use if irritation appears.	
Keep out of reach of children.	
<b>Directions</b> • Wet hands with product and briskly rub hands together until dry • Supervise children under 6 years in use of this product	
<b>Other Information</b> • Store at 20°C to 25°C (68°F to 77°F) • May discolor certain fabrics	
<b>Inactive Ingredients</b> Distilled Water, Methyl Cellulose, Glycerin, Hydrogen Peroxide.	

Man./Dist. by Holi Hemp™ LLC.  
Vancouver, WA 98685  
1-855-34-HYALO | hyalolexhandsanitizer.com

NDC: 75540-436-16

472 mL NDC: 75540-436-16

HYALOLEX HAND SANITIZER			
alcohol solution			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75540-436
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>METHYLCELLULOSE, UNSPECIFIED</b> (UNII: Z944H5SN0H)	1.5 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	2 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	23.37 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75540-436-16	472 mL in 1 BOTTLE; 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	part333E	03/30/2020	

**Labeler** - India Globalization Capital, Inc. (364601877)

Revised: 2/2023

India Globalization Capital, Inc.