

## **HYALOLEX HAND SANITIZER- alcohol liquid**

**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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### **Hyalolex Hand Sanitizer**

**Alcohol Antiseptic 80%. Sulfate and Paraben Free**

**Non-Sterile Solution**

**Topical Solution**

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.

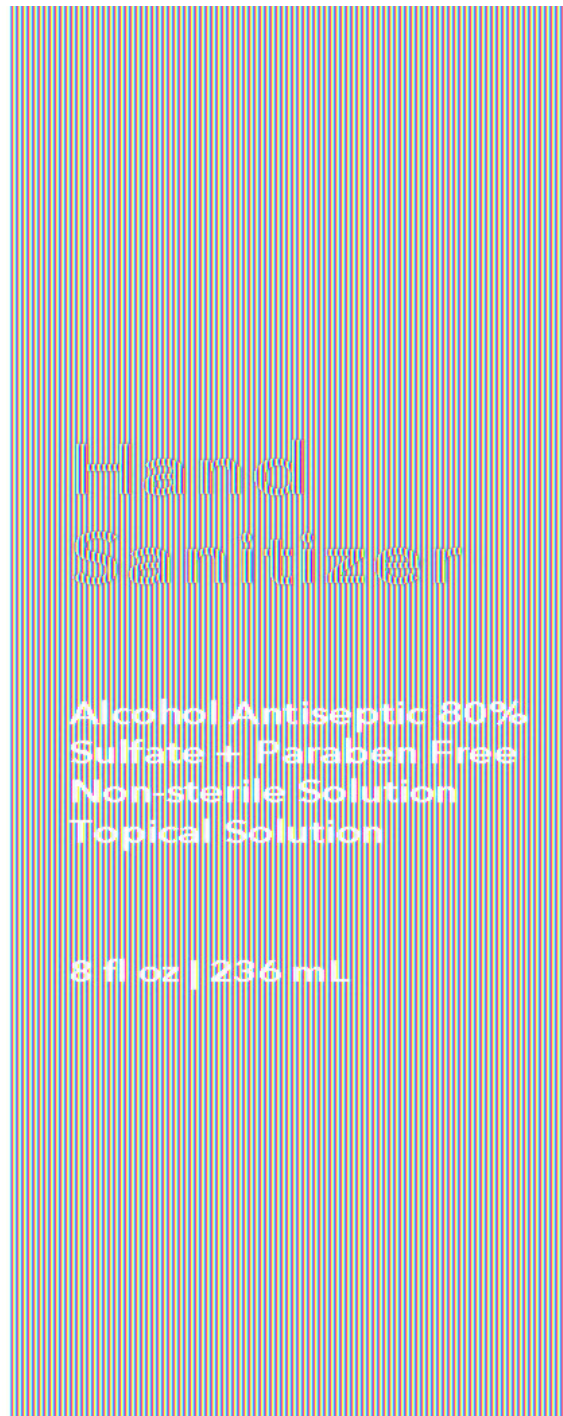
**Other information**

- 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**



NDC: 75540-946-0

<b>Drug Facts</b>
<b>Active Ingredient</b> Alcohol 80% w/v
Use Hand Sanitizer to potentially can cause d and water are not avail
<b>Warnings</b> For externa away from heat or flamm
Do not use • in childr • on open skin wound
When using this prod and mouth. In case of i thoroughly with water.
Stop use and ask a dc occurs. These may be s
Keep out of reach of i medical help or contac right away.
<b>Directions</b> • Place en cover all surfaces. Rub • Supervise children u using this product to a
<b>Other Information</b> • to 86°F) • Avoid freezi 40°C (104°F)
Inactive Ingredients: Purified Water USP.

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Vancou  
1-855-34-HY

237 mL NDC: 75540-946-08

<b>HYALOLEX HAND SANITIZER</b>			
alcohol liquid			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75540-946
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75540-946-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	03/30/2020		

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

**Registrant** - Priya Jambhekar (364601877)

### Establishment

Name	Address	ID/FEI	Business Operations
India Globalization Capital Inc		364601877	manufacture(75540-946)

Revised: 4/2020

India Globalization Capital Inc