#### HYALOLEX ANTISEPTIC HAND RUB- 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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Hyalolex Antiseptic Hand Rub 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

Healthcasre personnel hand rub to help reduce bacteria that potentially can casue disease

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

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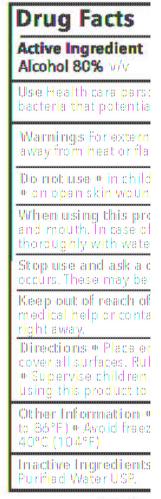


Amtiseptic Hand Rub

Alcohol Antiseptic 80% Sulfate + Paraben Free Non-sterile Solution Topical Solution

# 16 fl oz | 472 mL

Ν	D	C:	7	55	4.0	-9	41	
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Dist. by Vancou 1-855-34-H

437 mL NDC: 75540-941-16

HYALOLEX ANTISEPTIC HAND RUB
alcohol colution

Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:75540-941	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingredient Name			Basis of Strength	n Strength	

ALCOHOL

Inactive Ingredients	5			
	Ingredient Name			Strength
GLYCERIN (UNII: PDC6A	3C0OX)	1	1.45 mL in 100	) mL
HYDRO GEN PERO XIDE	(UNII: BBX060AN9V)	(	0.125 mL in 10	00 mL
WATER (UNII: 059QF0KC	DOR)			
Packaging				
	Package Description	Marketing	Start Date	Marketing End Da
# Item Code	<b>Package Description</b> 8 mL in 1 BOTTLE; Type 0: Not a Combination Product	-	Start Date	Marketing End Da
# Item Code	• •	-	Start Date	Marketing End Da
# Item Code	• •	-	Start Date	Marketing End Da
1 NDC:75540-941-16 473	B mL in 1 BOTTLE; Type 0: Not a Combination Product	-	Start Date	Marketing End Da
# Item Code	B mL in 1 BOTTLE; Type 0: Not a Combination Product	-	Start Date	Marketing End Da
Item Code   1 NDC:75540-941-16 473	B mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	Start Date	Marketing End Da Marketing End Da

Labeler - India Globalization Capital Inc (364601877)

Revised: 4/2020

India Globalization Capital Inc