

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.

Hyalolex 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 3% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

To help reduce germs on the skin.

Warnings

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

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.

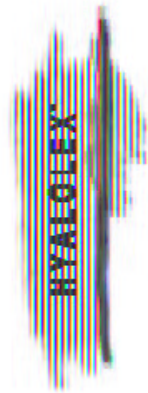
Other information

- Store between 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



Drug Facts

Active Ingredient
Ethyl Alcohol 73% v/v

Use to help reduce germs

Warnings
For external use only.

Flammable. Keep away from heat.

Do not use in or near the eyes. If eye contact occurs, rinse eyes thoroughly with water.

Stop use if irritation appears.

Keep out of reach of children.

Directions • Wet hands thoroughly, then rub hands together for at least 20 seconds. Rinse hands with water and dry. Do not use in or near the eyes. Do not use in children under 6 years in a supervised setting.

Other Information • Store at room temperature (68°F to 77°F) • May discolor over time.

Inactive Ingredients
Methyl Cellulose, Glycerin, Hydrogen Peroxide.

Man./Dist. by Halycon
Vancouver, BC
1-855-34-HYALO | hyalo.com

NDC: 75540-436-04

118 mL NDC: 75540-436-04

HYALOLEX HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75540-436
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	1.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

WATER (UNII: 059QF0KO0R)

23.37 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75540-436-04	118 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)

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India Globalization Capital, Inc.