

HYALOLEX HAND SANITIZER WITH LAVENDER AND ZINC- alcohol liquid

India Globalization Capital

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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antiseptic, Hand Sanitizer

Use

Warnings

For external use only. Flammable. Keep away from fire 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

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

Other information

- Store at 20-25C (68-77F)
- May discolor certain fabric

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

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.

Package Label - Principal Display Panel

Hylolex

Hand Sanitizer

Lavender + Zinc

Sulfate + Paraben Free

70% Ethyl Alcohol

Kills Germs



Hand Sanitizer Lavender + Zinc

Sulfate + Paraben Free
70% Ethyl Alcohol
Antimicrobial
Kills Germs

2 fl oz | 59 mL

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial

Use to help reduce germs on the skin.

Warnings
For external use only.

Flammable. Keep away from fire or flame.

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.

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 at 20°C to 25°C (68°F to 77°F) • May discolor certain fabrics

Inactive Ingredients Deionized Water, Aloe Vera, Glycerin, Hemp Oil, Carbomer, Xanthan Gum, Zinc Oxide, Lavender Oil.

Manufactured by Holi Hemp, LLC.
Vancouver, WA 98685
1-855-34-HYALO | hyalolex.com

59 mL NDC: 75540-528-02

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HYALOLEX HAND SANITIZER WITH LAVENDER AND ZINC

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75540-528
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HEMP (UNII: TD1MUT01Q7)	100 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	100 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	100 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z)	100 mL in 100 mL
WATER (UNII: 059QF0KO0R)	100 mL in 100 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	100 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	100 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75540-528-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2020	

Labeler - India Globalization Capital (364601877)

Revised: 1/2023

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