

HYALOLEX HAND SANITIZER WITH LEMON AND ZINC- alcohol solution

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.

Hyalolex Hand Sanitizer with Lemon and Zinc

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial Hand Sanitizer

Use

Hand Sanitizer 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 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 occurs

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 20C-25C (68F-77F)

- May discolor certain fabrics

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Hyalolex Hand Sanitizer with Lemon and Zinc
Safate and Paraben Free
70% Ethyl Alcohol
Antimicrobial
Kills Germs
Package Label - Principal Display Panel



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, Carbomer, Xanthan Gum, Zinc Oxide, Lemon Oil.	

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

NDC: 75540-536-02



Hand Sanitizer

Lemon + Zinc

Sulfate + Paraben Free
70% Ethyl Alcohol
Antimicrobial
Kills Germs

8 fl oz | 236 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, Carbomer, Xanthan Gum, Zinc Oxide, Lemon Oil.

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

NDC: 75540-536-08



Hand Sanitizer Lemon + Zinc

Sulfate + Paraben Free
70% Ethyl Alcohol
Antimicrobial
Kills Germs

16 fl oz | 472 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, Carbomer, Xanthan Gum, Zinc Oxide, Lemon Oil.

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

NDC: 75540-536-16



Hand Sanitizer

Lemon + Zinc

Sulfate + Paraben Free
70% Ethyl Alcohol
Antimicrobial
Kills Germs

128 fl oz | 1 gallon

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, Carbomer, Xanthan Gum, Zinc Oxide, Lemon Oil.

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

NDC: 75540-536-28



59 mL NDC: 75540-536-02
236 mL NDC: 75540-536-08
472 mL NDC: 75540-536-16
3785 mL NDC: 75540-536-28

HYALOLEX HAND SANITIZER WITH LEMON AND ZINC

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75540-536
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	2 mL in 100 mL
LEMON OIL (UNII: I9GRO824LL)	0.5 mL in 100 mL
ZINC ALUM (UNII: UGR874142R)	20 mg in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
CARBOMER 980 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL
WATER (UNII: 059QF0KO0R)	25 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75540-536-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:75540-536-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:75540-536-16	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
4	NDC:75540-536-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - India Globalization Capital (364601877)