

LOLES NATURALS HAND SANITIZER- alcohol gel
Diora Kimya Sanayi ve Ticaret Limited Sirketi

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.

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 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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.

Directions

- Put enough product in your palm to cover hands and rub hands together quickly until dry.
- Children under 6 years of age should be supervised when using.

Other information

- Store below 110 F (43 C)

Inactive ingredients

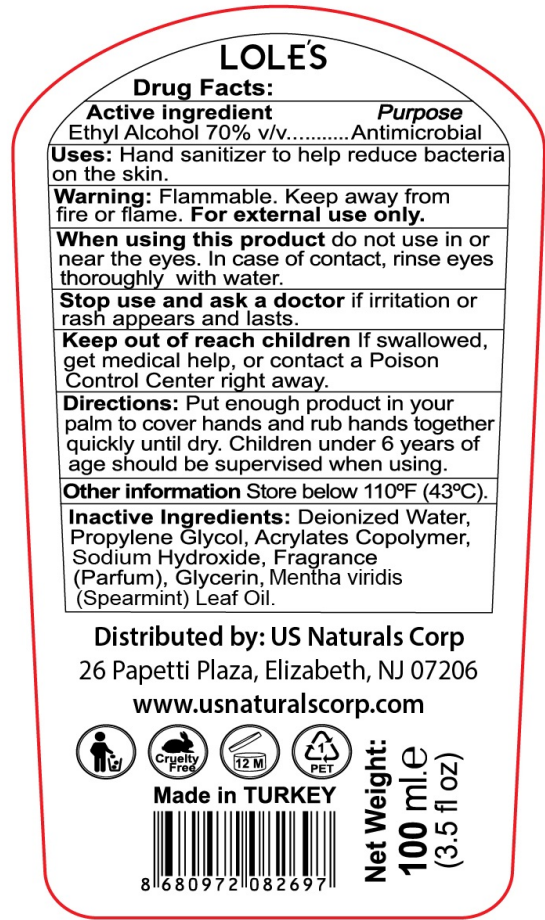
Deionized Water, Propylene Glycol, Acrylates Copolymer, Sodium Hydroxide, Fragrance (Parfum), Glycerin, Mentha viridis (Spearmint) Leaf Oil

Package Label - Principal Display Panel

74 mm



43 mm



100 mL NDC: 73485-001-01

250 mL NDC: 73485-001-02



LOLES NATURALS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73485-001
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
GLYCERIN (UNII: PDC6A3C00X)	1.5 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.2 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	5.75 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73485-001-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73485-001-01	100 mL in 1 BOTTLE, PLASTIC; 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	part333A	03/30/2020	

Labeler - Diora Kimya Sanayi ve Ticaret Limited Sirketi (533104358)

Registrant - US Naturals Corp (081035629)

Establishment

Name	Address	ID/FEI	Business Operations
Diora Kimya Sanayi ve Ticaret Limited Sirketi		533104358	manufacture(73485-001)

Revised: 1/2022

Diora Kimya Sanayi ve Ticaret Limited Sirketi