

GREEN WORLD HAND SKIN SANITISER- alcohol liquid LIDER KOZMETIK

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.

Green World Hand&Skin Sanitiser

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) (74.8%, weight/volume (w/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Benzalkonium Chloride 0.1 % (w/v)
- c. Glycerol
- 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 74.8% w/v - Benzalkonium Chloride 01% (w/v)

Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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. Keep away from heat or flame. Flammable liquid and vapor.

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, purified water USP

Package Label - Principal Display Panel

50 mL NDC:86966-002-02

green world

Effective at eliminating **99,9%** of many common harmful germs and bacteria

DERMATOLOGICALLY TESTED

HAND & SKIN SANITISER

Effective Protection

No Water - No Rinse
With moisturizers
Fragrance Free

74,8% ETHYL ALCOHOL

100 ml NDC CODE: 86966-002-03

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74,8% ETHYL ALCOHOL

Non-sterile Topical Solution

150 ml NDC CODE: 86966-002-04

Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 74.8% w/v	Antiseptic
Benzalkonium chloride 0.1% w/v	Antiseptic

Uses
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Warnings
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Do not use

- in children less than 2 months of age
- on open skin wounds

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 occurs. **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 briskly until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information
Store between 59-86 °F (15-30 °C). Avoid freezing and excessive heat above 104 °F (40 °C). May discolor certain fabrics or surface.

Inactive ingredients
Glycerin, Water

38554145-00

8 696630 145048

Lider kozmetik

Üretim: 0850 221 0506
Ruhat Sahibi-Üretici/Licence Owner-Manufacturer:
Lider Kozmetik San. ve Tic. A.Ş.
Dilovası Organize Sanayi Bölgesi 5.Kısım
D-50075 Saklı No:12 41454 Kocaeli-TURKEY
T: +90 (262) 754 78 54 F: +90 (262) 754 78 58

50 ML e

GH502

Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 74.8% w/v	Antiseptic
Benzalkonium chloride 0.1% w/v	Antiseptic

Uses
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
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www.liderkozmetik.com - info@liderkozmetik.com
Türk/Made in Turkey / صنع في تركيا

100 ML e

GH502

8 696630 145055

38554148-00

Drug Facts

Active Ingredients

Ethyl Alcohol 74.8% w/v
Benzalkonium chloride 0.1% w/v

Purpose

Antiseptic
Antiseptic

Uses

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. Keep away from heat or flame.
Flammable liquid and vapor.

Do not use

■ in children less than 2 months of age

■ on open skin wounds

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HAND & SKIN SANITISER

Effective Protection

No Water - No Rinse
With moisturizers
Fragrance Free



Non-sterile Topical Solution



Lider
kozmetik

Ücretsiz Danışma Hattı: 0850 221 0506
Ruhsat Sahibi / Üretici / Licence Owner / Manufacturer:
Lider Kozmetik San. ve Tic. A.Ş.
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GH502

ERC 150 ML e

385 51149-00



1000 ml NDC CODE: 86966-002-01

	Firma/Client LIDER KOZMETIK	Ebatlar/Dimensions 291.275x70 mm	Baskı Renkleri/Colours											
	Marka/Brand GREEN WORLD	Baskı Türü/Print Process ...												
	Proje/Project 1000 ml DEZENFEKTAN FDA	Kullanılan Program/Design Program Illustrator CC												
	Tarih/Date 09.12.2020	Hazırlayan/Prepared By Vildan HAMŞIOĞLU												
Notlar Notes:	PP OPAK ETİKET		Vernik Varnish		Baskı Yüzeyi Print Surface	Yüzey Uygulamaları Surface Applications								
														
														



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Inactive Ingredients
Glycerin, Water

Lider kozmetik

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Ruhsat Sahibi/Üretici/Licence Owner/Manufacturer:
Lider Kozmetik San. ve Tic. A.Ş.
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Türk/İngilizce/ Made in Turkey/ صنع في تركيا

38554160-01

8 696630 145208

ERC PBT 1L e GHS02

GREEN WORLD HAND SKIN SANITISER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86966-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZ ALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M)	ALCOHOL	74.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:86966-002-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
2	NDC:86966-002-02	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
3	NDC:86966-002-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	
4	NDC:86966-002-04	150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/01/2020	

Labeler - LIDER KOZMETIK (600762793)

Registrant - LIDER KOZMETIK (600762793)

Establishment

Name	Address	ID/FEI	Business Operations
LIDER KOZMETIK		600762793	manufacture(86966-002)

Revised: 1/2022

LIDER KOZMETIK