

## **GREEN WORLD HAND SKIN SANITISER- alcohol gel 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.*

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### **GREEN WORLD HAND&SKIN SANITISER GEL**

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) (70%, 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. Glycerol
- c. Triethanolamine
- d. Acrylates/C10-30 alkyl acrylate copolymer
- e. 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% 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. Flammable. 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**

- Put enough product in your palm to cover hands. Rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.



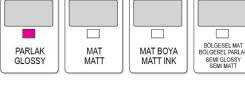
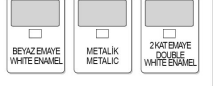

### **Other information**

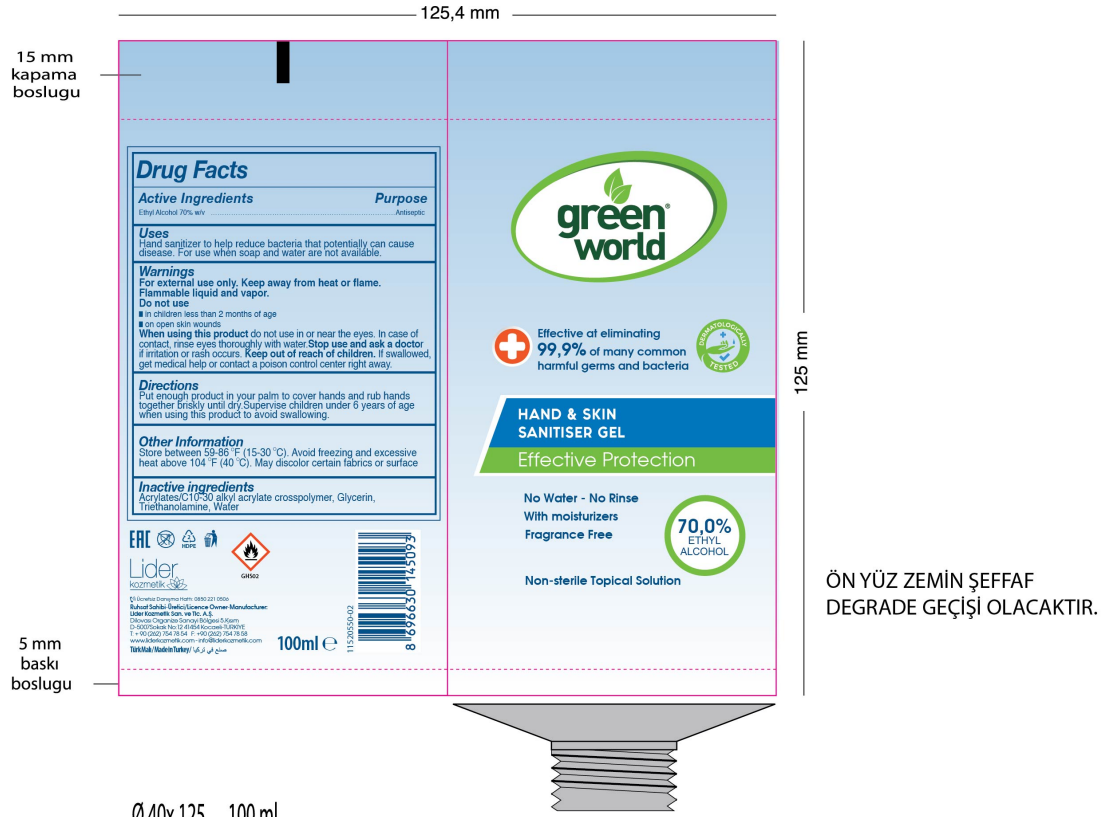
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surface.

### **Inactive ingredients**

glycerin, Triethanolamine, Acrylates/C10-30 alkyl acrylate copolymer, purified water USP

### **Package Label - Principal Display Panel**

	Firma/Client Lider Kozmetik	Ebatlar/Dimensions	Baskı Renkleri/Colours
	Marka/Brand GREEN WORLD	Baskı Türü/Print Process -	
Proje/Project 100 ML TÜP FDA	Tarih/Date 09.12.2020	Kullanılan Program/Design Programme Illustrator CC	Hazırlayan/Prepared By Vildan HAMŞIOĞLU
Notlar/Notes: BEYAZ TÜP BASKISI 11.06.2020 yazı metin revize edildi. FDA TÜP BASKI REVİZE 09.12.2020	Vernik/ Varnish	Baskı Yüzeyi/ Substrate	Yüzey Uygulamaları/ Background Application
			



Ø40x125 100 ml  
PLASTIK tüp baskı SABLONU

100 mL NDC:86966-001-01

## GREEN WORLD HAND SKIN SANITISER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86966-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 g in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
GLYCERIN (UNII: PDC6A3C0OX)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0K00R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86966-001-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	
<b>Marketing Information</b>				
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(86966-001)

Revised: 1/2022

LIDER KOZMETIK