## DERMOKIL- hand sanitizer gel EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş.

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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This is a hand sanitizer manufactured according to the FDA OTC monograph:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (71.5%, 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
- c. Isopropyl alcohol 2% (v/v)
- d. Water
- e. Sodium hydroxide 0.01% (v/v)

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 71.5% v/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

#### Do not use

- on children less than 2 months 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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**

Aloe barbadensis (aloe vera) leaf extract, carbomer, fragrance, glycerin, isopropyl alcohol, kaolin, sodium hydroxide, water

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

### **Drug Facts**

#### Active ingredient

Purpose

Ethyl alcohol 71.5%.....Antiseptic

**Use** for hand sanitizing to decrease bacteria on the skin

#### Warnings

Flammable, keep away from fire or flame

For external use only

Do not use on damaged, inflamed, or broken skin.

#### When using this product

- avoid contact with eyes
- in case of eye contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or redness develops and lasts for more than 72 hours

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

#### **Directions**

- wet hands thoroughly with product
- allow to dry without wiping

#### Other information

keep out of direct sunlight store in dry conditions

**Inactive ingredients** water, isopropyl alcohol, carbomer, fragrance, glycerin, aloe vera (aloe barbadensis), leaf extract, kaolin, sodium hydroxide

hands and skin without the use of water.

#### BEST IF USED BY 06/2022 Licensed manufacturer:

EZEL Kozmetik İthalat ve İhracat San. Tic. A.Ş

Made in Turkey Turkey

Merkez Ofis/Head Office Ahmet Turan Gazi OSB 8.Cadde No:2 SIVAS / TURKEY TEL: +90 (346) 218 13 17 Fax: 0 (346) 218 13 59 www.dermokil.com.tr - info@dermokil.com.tr

Distributed in the United States by: SupplySideUSA, Inc



# dermoki

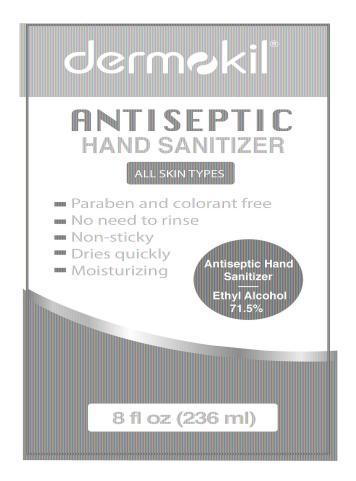
### ANTISEPT HAND SANITIZE

**ALL SKIN TYPES** 

- Paraben and colorant free
- No need to rinse
- Non-sticky
- Dries quickly
- **M**oisturizing

Antiseptic H Sanitizer **Ethyl Alcol** 

10 fl oz (295 ml)



### **Drug Facts**

#### Active ingredient

Ethyl alcohol 71.5%.....

Use for hand sanitizing to decre

#### **Warnings**

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#### Directions

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#### Other information

keep out of direct sunlight

Inactive ingredients water carbomer, fragrance, glycerin, alou leaf extract, kaolin, sodium hydroxi

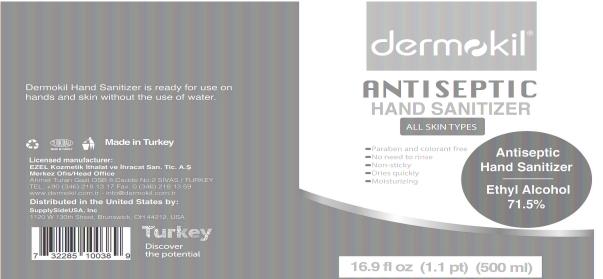
Licensed manufacturer:

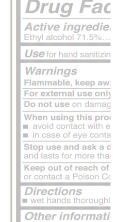
EZEL Kozmetik İthalat ve İhracat San. Tic. A.Ş

Abayat Turan Gazi OSB 8 Cadda Naz SIVAS, TURKEY

Distributed in the United States by:
SupplySideUsA, Inc
1120 W 130th Street, Brunswick, OH 44212, USA

Made





Inactive ingredie



### **ANTISEPTIC** HAND SANITIZER

**ALL SKIN TYPES** 

- Paraben and colorant free
- No need to rinse
- Non-sticky
- Dries quickly

Dermokil Hand Sanitizer is ready for use on hands and skin without the use of water. Licensed manufacturer:

EZEL Kozmetik İthalat ve İhracat San. Tic. A.Ş Merkez Ofis/Head Office

Ahmet Turan Gazi OSB 8.Cadde No:2 SİVAS / TURKEY TEL: +90 (346) 218 13 17 Fax: 0 (346) 218 13 59 www.dermokil.com.tr - info@dermokil.com.tr Distributed in the United States by:

SupplySideUSA, Inc 1120 W 130th Street, Brunswick, OH 44212, USA

**Antiseptic** Hand Sanitizer

**Ethyl Alcohol** 71.5%

### **Drug Facts**

Active ingredient Ethyl alcohol 71.5%.....

Purpose ....Antiseptic

 $Use \ \ \text{for hand sanitizing to decrease bacteria on the skin}$ 

#### Warnings

Flammable, keep away from fire or flame

For external use only

Do not use on damaged, inflamed, or broken skin

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Stop use and ask a doctor if

irritation or redness develops and lasts for more than 72 hours

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

#### Directions

- wet hands thoroughly with product
- allow to dry without wiping

#### Other information

■ keep out of direct sunlight

♣ore in cool, dry conditions

Inactive ingredients fragrance, glycerin, aloe vera kaolin, sodium hydroxide

water, isopropyl alcohol, carbomer, (aloe barbadensis), leaf extract,



1 Gallon (3.78 Liters)

3785 mL NDC: 75801-786-37

#### **DERMOKIL**

hand sanitizer gel

Product	Inform	ation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:75801-786

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71.5 mL in 100 mL

## Inactive Ingredients Ingredient Name Strength

ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)

SO DIUM HYDRO XIDE (UNII: 55X04QC32I)

0.01 mL in 100 mL

ISOPROPYL ALCOHOL (UNII: ND2M416302) 2 mL in 100 mL

GLYCERIN (UNII: PDC6A3C0OX)

CARBOMER 940 (UNII: 4Q93RCW27E)

WATER (UNII:  $059\,\mathrm{QF0\,KO0\,R}$ )

KAOLIN (UNII: 24H4NWX5CO)

#### Packaging

	rackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75801-786- 37	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75801-786- 50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75801-786- 29	295 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75801-786- 23	236 mL in 1 BOTTLE, PUMP; 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 - EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş. (566224588)

 $\pmb{Registrant -} \ \, \text{EZEL KOZMETIK IT H. VE IHR. T IC. VE SAN. A.S.} \ \, (566224588)$ 

#### **Establishment**

Name	Address	ID/FEI	Business Operations
EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş.		566224588	manufacture(75801-786)

Revised: 8/2020

EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş.