

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.

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.

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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

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

BEST IF USED BY 06/2022

Made in Turkey

Turkey



7 32285 10040 2

dermokil

ANTISEPTIC HAND SANITIZER

ALL SKIN TYPES

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

Antiseptic H
Sanitizer
Ethyl Alcohol
71.5%

10 fl oz (295 ml)

dermekil®

**ANTISEPTIC
HAND SANITIZER**

ALL SKIN TYPES

- Paraben and colorant free
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- Non-sticky
- Dries quickly
- Moisturizing

Antiseptic Hand
Sanitizer
Ethyl Alcohol
71.5%

8 fl oz (236 ml)

Drug Facts

Active ingredient

Ethyl alcohol 71.5%.....

Use for hand sanitizing to decre

Warnings

Flammable, keep away from f

For external use only

Do not use on damaged, inflan

When using this product

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Stop use and ask a doctor if ir
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Keep out of reach of children. I
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Directions

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- allow to dry without wiping

Other information

- keep out of direct sunlight

Inactive ingredients wate
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leaf extract, kaolin, sodium hydroxi

Licensed manufacturer: BE

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Turkey
 Discover the potential

dermokil®

**ANTISEPTIC
 HAND SANITIZER**

ALL SKIN TYPES

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

**Antiseptic
 Hand Sanitizer**
**Ethyl Alcohol
 71.5%**

16.9 fl oz (1.1 pt) (500 ml)

Drug Fac

Active ingredie
 Ethyl alcohol 71.5%...

Use for hand sanitizin

Warnings

Flammable, keep aw:
 For external use only
 Do not use on damag

When using this pro
 ■ avoid contact with e
 ■ in case of eye conta

Stop use and ask a d
 and lasts for more tha

Keep out of reach of
 or contact a Poison Cc

Directions

■ wet hands thoroughl

Other informati
 ■ keep out of direct su

Inactive ingredie
 glycerin, aloe vera (aloe

dermokil®

**ANTISEPTIC
 HAND SANITIZER**

ALL SKIN TYPES

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- No need to rinse
- Non-sticky
- Dries quickly

**Antiseptic
 Hand Sanitizer**
**Ethyl Alcohol
 71.5%**

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Made in Turkey
 

1 Gallon (3.78 Liters)

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 71.5%.....	Antiseptic

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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 cool, dry conditions

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

DERMOKIL

hand sanitizer gel

Product Information

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
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	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)

Registrant - EZEL KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş. (566224588)

Establishment

Name	Address	ID/FEI	Business Operations
EZEL KOZMETİK İTH. VE İHR. TIC. VE SAN. A.Ş.		566224588	manufacture(75801-786)

Revised: 8/2020

EZEL KOZMETİK İTH. VE İHR. TIC. VE SAN. A.Ş.