

**CLENSIL- alcohol 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 OTC Monograph published in April 2019.

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)

- 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. Glycerine (inactive)
- c. Water (inactive)
- d. Isopropyl alcohol (2% volume/volume (v/v)) (inactive)
- e. Sodium hydroxide (0.01% (v/v)) (inactive)

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**

For hand sanitizing to decrease bacteria on the skin

**Warnings**

Flammable. Keep away from fire or flame

For external use only

**Do not use**

Do not use on damaged, inflamed or broken skin

Avoid contact with eyes. In case of eye contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash develops and lasts for more than 72 hrs

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

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## Directions

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

## Other information

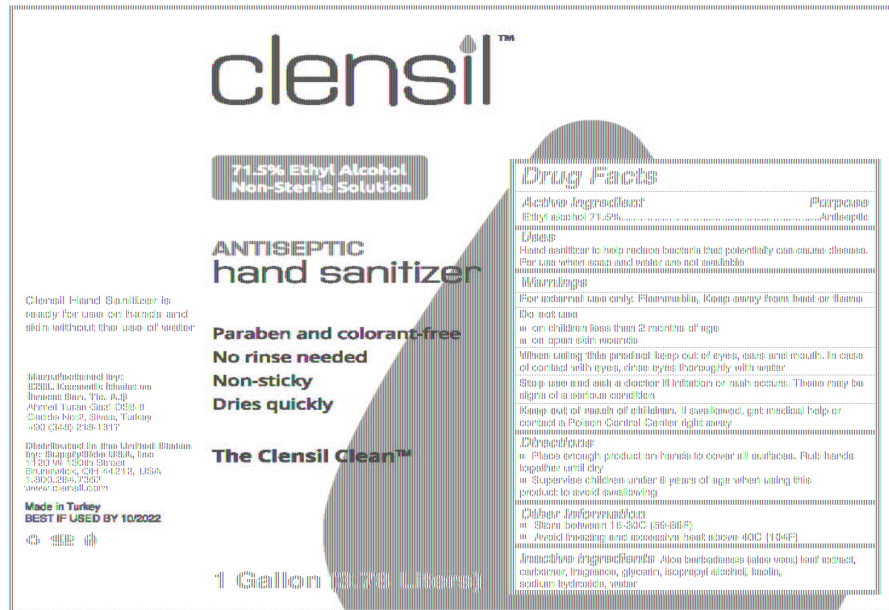
- keep out of direct sunlight
- Store in cool, dry conditions

## Inactive ingredients

glycerin, water, isopropyl alcohol, sodium hydroxide

## Package Label - Principal Display Panel





3785mL BOTTLE NDC: 75801-999-37

## CLENSIL

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75801-999
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF POLYSACCHARIDES</b> (UNII: W21O437517)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	0.01 mL in 100 mL
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	2 mL in 100 mL

**CARBOMER 940** (UNII: 4Q93RCW27E)

**KAOLIN** (UNII: 24H4NWX5CO)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75801-999-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2020	
2	NDC:75801-999-37	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

**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 KOZMETIK ITH. VE IHR. TIC. VE SAN. A.Ş.		566224588	manufacture(75801-999)

Revised: 6/2023

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