

IMMORTAL NYC HAND SANITIZER- alcohol gel
EF KOZMETİK KİMYA SANAYİ VE TİCARET LİMİTED SİRKETİ

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.

IMMORTAL NYC HAND SANITIZER

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%, 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 (1% v/v).
- c. Triethanolamine (0.3% v/v).
- d. Aloe Barbadensis Leaf Extract (0.01% v/v).
- e. Carbomer (0.3% v/v).
- f. 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% 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

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

When using this product keep out of eyes. 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 and rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store below 110 F (43 C).
- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surface.

Inactive ingredients

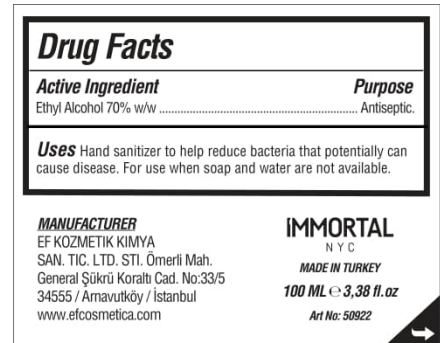
Aloe Barbadosis Extract, Carbomer, Glycerin, Triethanolamine, Water

Package Label - Principal Display Panel

100 mL NDC: 86822-001-01



13,3 cm



6,2 cm

IMMORTAL NYC HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86822-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.39 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.01 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86822-001-01	100 mL in 1 BOTTLE; 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 - EF KOZMETIK KIMYA SANAYI VE TICARET LIMITED SIRKETI (356062336)

Registrant - EF KOZMETIK KIMYA SANAYI VE TICARET LIMITED SIRKETI (356062336)

Establishment

Name	Address	ID/FEI	Business Operations
EF KOZMETIK KIMYA SANAYI VE TICARET LIMITED SIRKETI		356062336	manufacture(86822-001)

Revised: 6/2020

EF KOZMETIK KIMYA SANAYI VE TICARET LIMITED SIRKETI