

EJK HAND SANITIZER- alcohol gel
E.J.K. QUIMICOS SA. DE C.V.

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.

EJK Hand Sanitizer, Alcohol 70%

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, 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

Water, Glycerin, Hydroxyethyl cellulose, Triethanolamine, Benzalkonium Chloride, Hydrogen

Peroxide.

Package Label - Principal Display Panel

1000 mL NDC: 79157-001-01

E.J.K QUÍMICOS S.A. DE C.V.

HAND SANITIZER
GEL

Hand antiseptic

264.2 GAL
(1000 L)

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antiseptic

Use (s) Hand sanitizer to help reduce bacteria that potentially can cause disease.

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

Inactive ingredients: Water, Glycerin, Hydroxyethyl cellulose, Triethanolamine, Benzalkonium Chloride, Hydrogen Peroxide.

Manufactured by: EJK Quimicos S.A. de C.V.
Calle Buenos Aires Poniente #122, Colonia: Santa Cruz Tetela, Chiautempan.
Tlaxcala, México
C.P.90810

Product of México

EJK HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79157-002
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.075 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.025 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL

HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)

0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 157-002-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/06/2020	
2	NDC:79 157-002-02	200000 mL in 1 DRUM; Type 0: Not a Combination Product	07/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/06/2020	

Labeler - E.J.K. QUIMICOS SA. DE C.V. (812896292)

Registrant - E.J.K. QUIMICOS SA. DE C.V. (812896292)

Establishment

Name	Address	ID/FEI	Business Operations
E.J.K. QUIMICOS SA. DE C.V.		812896292	manufacture(79 157-002)

Revised: 7/2020

E.J.K. QUIMICOS SA. DE C.V.