# 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.

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## 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**

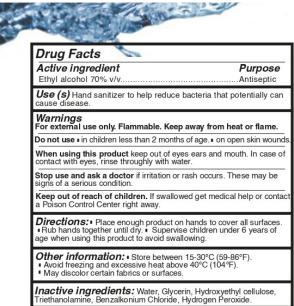
1000 mL NDC: 79157-001-01

E.J.K OUÍMICOS S.A. DE C.V.

HAND SANITIZER GEL

Hand antiseptic





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

ı	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	0.075 mL in 100 mL		
TROLAMINE (UNII: 903K93S3TK)	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		

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:79157-002- 01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/06/2020		
	2 NDC:79157-002- 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.