

EL BUENO- isopropyl alcohol gel
Fiesta Unión S. de R.L. 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.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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, trolamine, fragrance, polyacrylic acid, glycerin

Package Label - Principal Display Panel

**Alcohol Antiseptic
75% Topical Solution**

Hand Sanitizer

“EL BUENO”



**Antiseptic Hand Rub
Non-sterile Solution**

8.45 fl oz (250 mL)

Drug Facts	
Active ingredient(s)	Purpose
Isopropyl Alcohol 75% v/v	Antiseptic
Use(s)	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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.	
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Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15- 30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients water, glycerin, triethanolamine (trolamine), polyacrylic acid, fragrance	

Manufactured by: Inovaker Lab S.A. de C.V. Luis Quintanar Poniente 1105 Bellavista , Monterrey Nuevo León C.P México 64410
 Imported and Distributed by: FIESTA UNION LLC
 Brownsville TX 78526+1 (956) 509 9004
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 PRODUCT OF MEXICO



250 ml NDC: 75719-002-02

EL BUENO			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75719-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.5 mL in 100 mL	
	GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL	
	TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL	

WATER (UNI: 059QF0KO0R)	21.5 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNI: SXS9CO2TZK)	0.4 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75719-002-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

Labeler - Fiesta Unión S. de R.L. de C.V. (812828282)

Registrant - Fiesta Unión S. de R.L. de C.V. (812828282)

Establishment			
Name	Address	ID/FEI	Business Operations
Fiesta Union S de RL de CV		8 128 28 282	relabel(75719-002)

Establishment			
Name	Address	ID/FEI	Business Operations
INOVAKER LAB S.A. DE C.V.		951577122	manufacture(75719-002)

Revised: 5/2020

Fiesta Unión S. de R.L. de C.V.