

**HAND SANITIZER- alcohol gel**  
**Fuego Envasado SA de CV**

*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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**Active Ingredient(s)**

Alcohol 80% 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**

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



**PICO**

**Hand Sanitizing Gel**

advanced  
**80%**  
formula

kills 99.9% of  
bacteria & germs

59 mL (2 fl oz)

NPN #80100043

**P** SG-59

**Drug Facts**

**Active Ingredient:**  
Ethyl Alcohol 80%

**Purpose:**  
Antiseptic

**Use:** Hand sanitizer to help reduce bacteria on the skin.

**Warnings:** Flammable. Keep away from fire or flame. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Stop use and ask a doctor if irritation appears and lasts. For external use only. Keep out of eyes. In case of contact with eyes, rinse with water. Do not inhale or ingest.

**Other Information:** Store below 110°F (43°C). May discolor certain fabrics or furniture.

**Inactive Ingredients:** Sterile Distilled Water, Glycerin, Hydrogen Peroxide, Carbomec, Aminomethyl Propanol.

Distributed by: Pico Inc.  
180 John St, Toronto, ON, M5T 1X5, CAN  
www.picohospitality.com  
Made in Mexico

Manufactured by Fuego  
Envasado S.A. de C.V.  
Lot # 20051101  
MFG: 11/05/2020  
EXP: 11/05/2023





59 mL NDC: 76800-102-01

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76800-102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	800 mL in 1000 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	14.5 mL in 1000 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.83 mL in 1000 mL
WATER (UNII: 059QF0K00R)	179.15 mL in 1000 mL
CARBOMER 934 (UNII: Z135WT9208)	2.52 mL in 1000 mL
AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE (UNII: QCD5R22RNT)	3 mL in 1000 mL

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76800-102-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	05/22/2020	

**Labeler** - Fuego Envasado SA de CV (812932655)

**Registrant** - Fuego Envasado SA de CV (812932655)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fuego Envasado, S.A. de C.V.		812932655	manufacture(76800-102)

Revised: 4/2020

Fuego Envasado SA de CV