

## **HAND SANITIZER- alcohol gel**

### **PICO INC.**

*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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### **PICO Hand Sanitizer 80%**

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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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 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, Aminomethyl Propanol, Carbomer

### **Package Label - Principal Display Panel**

# PIC3

## Hand Sanitizing Gel

advanced  
**80%**  
formula

kills 99.9% of  
bacteria & germs

59 mL (2 fl oz)

NPN #80100043

 SG-59

<b>Drug Facts</b>	
<b>Active Ingredient:</b> Ethyl Alcohol 80% Ethanol 99.55% technical grade	<b>Purpose:</b> Antiseptic
<b>Use:</b> Hand sanitizer to help reduce bacteria on the skin, Adults only.	
<b>Warnings:</b> Flammable. Keep away from fire or flame. If swallowed, get medical help right away. Report any incident to <a href="http://Canada.ca/drug-device-reporting">Canada.ca/drug-device-reporting</a> . Do not use on broken or damaged skin. 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. Do not use if you are pregnant or breastfeeding. <b>Questions:</b> Call 1-866-234-2345 to report any adverse reaction.	
<b>Other Information:</b> Store below 110°F (43°C). May discolor certain fabrics or furniture.	
<b>Inactive Ingredients:</b> Sterile Distilled Water, Glycerin, Hydrogen Peroxide, Carbomer, Aminomethyl Propanol,	
Distributed by: Pico Inc, 180 John St, Toronto, ON, M5T 1X5, Canada <a href="http://www.picohospitality.com">www.picohospitality.com</a> Made in Mexico	Manufactured by Fuego Envasado S.A, de C.V.
Lot # 20051101 MFG: 11/05/2020 EXP: 11/05/2023	 8 8 2 6 0 5 9 9 8 8 7 2

59 mL NDC: 78082-000-01

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78082-000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	47.2 mL in 59 mL

### Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.17 mL in 59 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.85 mL in 59 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.074 mL in 59 mL
WATER (UNII: 059QF0KOOR)	10.36 mL in 59 mL

**CARBOMER 940** (UNII: 4Q93RCW27E)

0.34 mL in 59 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78082-000-01	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

**Labeler** - PICO INC. (203063060)

**Registrant** - PICO INC. (203063060)

### Establishment

Name	Address	ID/FEI	Business Operations
Fuego Envasado SA de CV		812932655	manufacture(78082-000)

Revised: 12/2021

PICO INC.