

**HAND SANITIZER- alcohol gel**  
**Healthy People Labs, 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.*

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**Hand Sanitizer**

This is a hand sanitizer manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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 (2% v/v).
- c. Carbopol (0.35% v/v).
- d. Triethanolamine (.1% v/v).
- e. Sterile distilled water or boiled cold water.

**Active Ingredient(s)**

Ethyl 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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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**

Purified water USP, Glycerine, Carbopol, Triethanolamine, and stabilizers.

**Package Label - Principal Display Panel**

1000 mL NDC: 78190-001-01



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Lot and expiration date. see packaging

**México**

MADE IN MEXICO by:  
 Healthy People Labs,  
 S. de R.L. de C.V.  
 Prol. Av. Alvaro Obregon 961  
 Col. Los Hoyos,  
 Irapuato, Gto. 36512

Distributed by:  
 Healthy People Co.  
 13105 Ramona Blvd. Ste F  
 Irwindale, CA 91706

NDC Code 77609-001-01



**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78 190-001
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.35 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:78190-001-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
<b>Marketing Information</b>				
<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	03/30/2020		

**Labeler** - Healthy People Labs, S. de R.L. de C.V. (951578183)

**Establishment**

Name	Address	ID/FEI	Business Operations
Healthy People Labs, S. de R.L. de C.V.		951578183	manufacture(78190-001)

Revised: 5/2020

Healthy People Labs, S. de R.L. de C.V.