

**HAND SANITIZER- alcohol gel**  
**ANTISEPTICOS DE MEXICO 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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**URIGEL 1000ML/1LTR 80% ALCOHOL GEL**

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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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

glycerin, hydrogen peroxide, purified water USP

## URIGEL 1000ML 80% ALCOHOL SANITIZER GEL

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 80%	Antiseptic
<b>Use</b>	
For hand washing to decrease bacteria on the skin.	
<b>Warnings</b>	
For external use only.	
Flammable, keep away from fire and flame.	
<b>Do not use</b> in the eyes.	
Stop use and ask a doctor if:	
• irritation and redness develop.	
• condition persists for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Other information</b>	
• Store between 59-86°F (15-30°C)	
• Avoid freezing and excessive heat above 104°F (40°C)	
<b>Inactive ingredients</b>	
Glycerin, hydrogen peroxide, water, paraffin, carbopol 940	
<b>NOT TESTED ON ANIMALS</b>	
Distributed in USA by:	
Urigel, Inc.	
1800 W. Beverly Blvd., Ste. 101	
Montebello, CA 90640	
1-800-255-3924	
Product of Mexico	
Distributed in Mexico by:	
Antisépticos de México, S.A. DE C.V.	
Blvd. Clio 10219, Col. Lomas del Mirador,	
C.P. 37358, León, Guanajuato, México	
Tel.: 477-103 55 47	
LOT AND EXP. DATE ARE PRINTED ON THE BOTTLE	



**ANTISEPTIC  
HAND SANITIZER**  
80% Ethyl Alcohol  
Non-Sterile Topical Solution

*Neutra*



**33.81 fl oz (1.05 qt) (1 L)**

1000 mL NDC: 76554-100-05

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76554-100
<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	80 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76554-100-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

**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	03/30/2020	

**Labeler** - ANTISEPTICOS DE MEXICO SA DE CV (951576637)**Registrant** - ANTISEPTICOS DE MEXICO SA DE CV (951576637)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ANTISEPTICOS DE MEXICO SA DE CV		951576637	manufacture(76554-100)

Revised: 1/2021

ANTISEPTICOS DE MEXICO SA DE CV