# URIGEL 80% HAND SANITIZER GEL 3ML PACKET- alcohol liquid Antisépticos de México, S.A. 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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#### URIGEL 3ML 80% ALCHOL SANITIZER GEL

# **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, water USP.

Package Label - Principal Display Panel 3ML 80% Alcohol Sanitizer Gel



3 mL NDC: 76554-003-01

# **URIGEL 80% HAND SANITIZER GEL 3ML PACKET**

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76554-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6 A3C0 OX)		

### HYDROGEN PERO XIDE (UNII: BBX060AN9V)

WATER (UNII: 059QF0KO0R)

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I	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:76554-003-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	09/05/2020	

# **Marketing Information**

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/05/2020	

# Labeler - Antisépticos de México, S.A. de C.V. (951576637)

**Registrant** - Antisépticos de México, S.A. de C.V. (951576637)

Establishment				
Name	Address	ID/FEI	Business Operations	
Antisépticos de México, S.A. de C.V.		951576637	manufacture(76554-003)	

Revised: 1/2021 Antisépticos de México, S.A. de C.V.