URIGEL 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.

URIGEL 80% ALCOHOL SANITIZER 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.

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.

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)

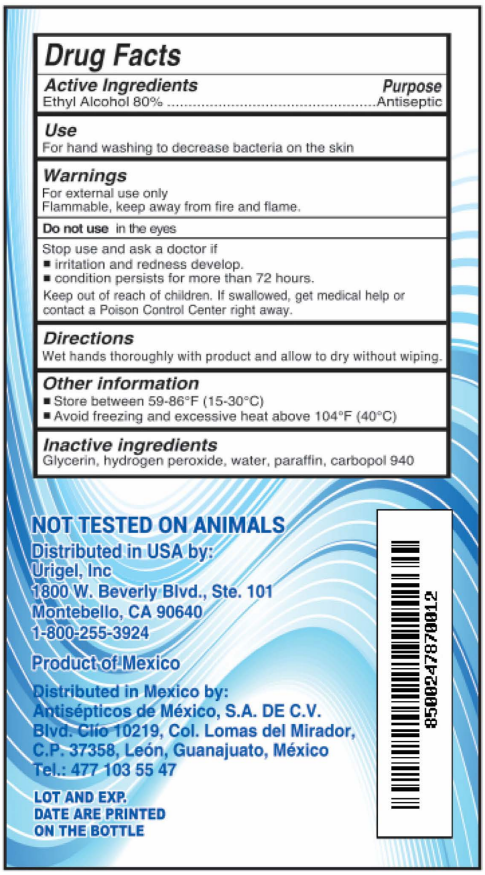
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

URIGEL 3ML 80% HAND SANITIZER GEL

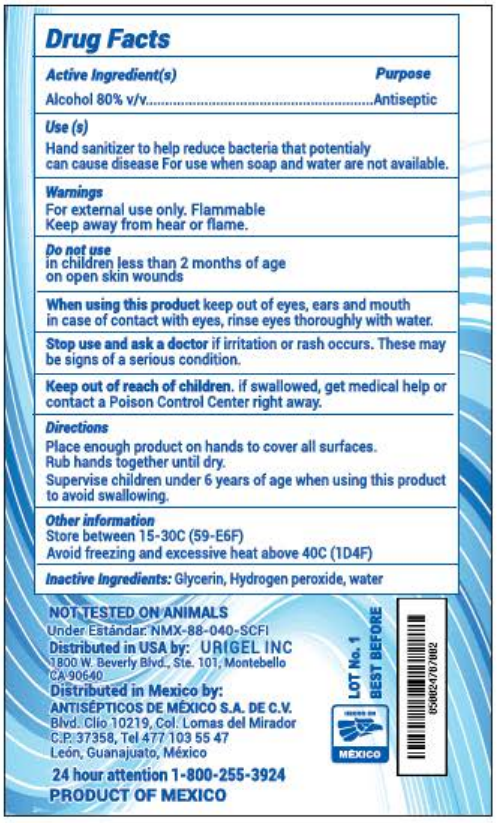
3 mL NDC: 76554-007-01

URIGEL 60ML 80% HAND SANITIZER GEL



60ML NDC: 76554-007-02

URIGEL 250ML 80% HAND SANITIZER GEL



Drug Facts

Active Ingredient(s) — **Purpose**

Alcohol 80% v/v..... Antiseptic

Use (s)

Hand sanitizer to help reduce bacteria that potentialy can cause disease For use when soap and water are not available.

Warnings

For external use only. Flammable
Keep away from hear 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.

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-E6F)
Avoid freezing and excessive heat above 40C (1D4F)

Inactive Ingredients: Glycerin, Hydrogen peroxide, water

NOT TESTED ON ANIMALS
Under Estándar: NMX-88-040-SCFI
Distributed in USA by: URIGEL INC
1800 W. Beverly Blvd., Ste. 101, Montebello CA 90640
Distributed in Mexico by:
ANTISÉPTICOS DE MÉXICO S.A. DE C.V.
Blvd. Clio 10219, Col. Lomas del Mirador
C.P. 37358, Tel 477 103 55 47
León, Guanajuato, México
24 hour attention 1-800-255-3924
PRODUCT OF MEXICO

LOT No. 1
BEST BEFORE

MÉXICO

250ML NDC: 76554-007-03

URIGEL 500ML 80% HAND SANITIZER GEL

Drug Facts

Active Ingredients — **Purpose**
Ethyl Alcohol 80% ..... Antiseptic

Use
For hand washing to decrease bacteria on the skin

Warnings
For external use only
Flammable, keep away from fire and flame.

Do not use 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.

Directions
Wet hands thoroughly with product and allow to dry without wiping.

Other information
- Store between 59-86°F (15-30°C)
- Avoid freezing and excessive heat above 104°F (40°C)

Inactive ingredients
Glycerin, hydrogen peroxide, water, paraffin, carbopol 940

NOT TESTED ON ANIMALS

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

8580247870836

250ML NDC: 76554-007-03

URIGEL 1000ML/1LTR 80% HAND SANITIZER GEL

1000ML/1GAL NDC: 76554-007-05

URIGEL 3.75ML/1GAL 80% HAND SANITIZER GEL

URIGEL Inc

ANTISEPTIC HAND SANITIZER

80% Ethyl Alcohol

Neutro

Non-Sterile Topical Solution

FIGHTS URIGEL BACTERIA

126.8 fl oz (3.96 qt) (3.75 L)

Drug Facts

Active ingredient — **Purpose**
Ethyl Alcohol 80% ..... Antiseptic

Use
For hand washing to decrease bacteria on the skin

Warnings
For external use only.
Flammable, keep away from fire and flame.

Do not use 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.

Directions
Wet hands thoroughly with product and allow to dry without wiping.

Other information
- Store between 59-86°F (15-30°C)
- Avoid freezing and excessive heat above 104°F (40°C)

Inactive ingredients
Glycerin, hydrogen peroxide, water.

NOT TESTED ON ANIMALS

Distributed in USA by:
Urigel, Inc.
1800 W. Beverly Blvd., Ste 101
Montebello, CA 90640

Product of Mexico

Distributed in Mexico by:
Antisépticos de México S.A. De C.V.
Blvd. Clío 10219, Col. Lomas del Mirador, C.P. 37358
León, Guanajuato, México
Tel.: 477 103 55 47

Lot No:
Best Before:

850024787005

3.75ML/1GAL NDC: 76554-007-10

URIGEL HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76554-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76554-007-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76554-007-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76554-007-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76554-007-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76554-007-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:76554-007-10	3750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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

Name	Address	ID/FEI	Business Operations

ANTISEPTICOS DE MEXICO SA DE CV		951576637	manufacture(76554-007)