

PROTECT CARE HAND SANITIZER - USA- ethyl alcohol gel

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.

Protect Care 70% USA Made

Active Ingredient(s)

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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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

Water(aqua), Glycerin, Carbomer, Triethanolamine

Package Label - Principal Display Panel 250 mL

250 ml NDC: 76554-003-01



Protect Care
"We make sanitizer products for you"

Alcohol Antiseptic 70%

Topical Solution
Hand Sanitizer Gel Non-sterile Solution

8.4 fl. oz. (250 mL)

Drug Facts	
Active Ingredient	Purpose
Alcohol 70% v/v.....	Antiseptic
Use (s)	
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	
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Directions	
- Place enough product on hands to cover all surfaces. - Rub hands together until dry. - Supervise children under 6 years if 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, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.	

Manufactured by: Antisépticos de México S.A. de C.V. Blvd. Clio #1029, León. Guanajuato. Z.P. 37358. México.
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Ph.: +52 477-842-26-54
PRODUCT OF MEXICO

Package Label - Principal display panel 500mL



Protect Care

"We make sanitizer products for you"

Alcohol Antiseptic 70%

**Topical Solution
Hand Sanitizer Gel Non-sterile Solution**

16.9 fl. oz. (500 mL)

Drug Facts	
Active Ingredient	Purpose
Alcohol 70% v/v.....	Antiseptic
Use (s)	
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	
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Directions	
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Inactive ingredients	
Glycerin, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.	

MANUFACTURED FOR:
HERBROCH TRADE LLC
9331 WESTRIDGE BLVD.
APT. 3406
MCKINNEY TX. 75072-1461
(972) 838-8881
PRODUCT OF MEXICO

500 mL NDC: 76554-030-02

PACKAGE LABEL- Principal Display Panel 1000mL



Protect Care

"We make sanitizer products for you"

Alcohol Antiseptic 70%

**Topical Solution
Hand Sanitizer Gel Non-sterile Solution**

33.81 fl. oz. (1000 mL)

Drug Facts	
Active Ingredient	Purpose
Alcohol 70% v/v.....	Antiseptic
Use (s)	
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	
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Directions	
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Inactive ingredients	
Glycerin, polyacrylic acid (Carbomer), triethanolamine (Trolamine), Water.	

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PRODUCT OF MEXICO

1000 mL NDC: 76554-030-03

PROTECT CARE HAND SANITIZER - USA

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76554-030
Route of Administration	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
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76554-030-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
2	NDC:76554-030-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
3	NDC:76554-030-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

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(76554-030)

Revised: 11/2020

Antisépticos de México, S.A. de C.V.