

HAND SANITIZER- alcohol gel
Rodríguez Fierro, Marco Antonio

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.

Hand Sanitizer

Active Ingredient(s)

Alcohol 75% 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, carbomer 940, trolamine, purified water

Package Label - Principal Display Panel



Alcohol Antiseptic
75%
Topical Solution
GEL

Hand Sanitizer

Ethyl Alcohol

8.8 FL OZ (250mL)

250 mL NDC: 78368-577-17

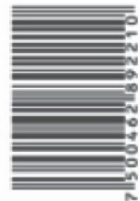
Package Label - Principal Display Panel

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
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Other Information ■ Store between 16-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Glycerin, Carbomer 940, Trolamine, Purified water.	

PRODUCT OF MEXICO

Imported by:
Dist. de Prod. Alim. el Paisita
4712 N 12Th St Suite 47
McAllen TX. 78504
Phone 956-438-5436

Manufactured by:
Rodríguez Fierro, Marco Antonio
Ave. Las Americas 409 Col. Leon XIII
Guadalupe, N.L. México C.P. 67120
Ph. +52(81) 2667 9693
RFC : ROFM 690527 Cu1
distribuidoranaturalgold.com





Alcohol Antiseptic
75%
Topical Solution
GEL

Hand Sanitizer

Ethyl Alcohol

33.81 FL OZ (1000 mL)

1000 mL NDC: 78368-577-18

Package Label - Principal Display Panel

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
Warnings For external use only. Flammable, Keep away from heat or flame	
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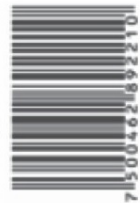
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SINCE



2010

NATURAL GOLD

Alcohol Antiseptic
75%
Topical Solution
GEL

Hand Sanitizer

Ethyl Alcohol

127.98 FL OZ (3785 mL)

3785 mL NDC: 78368-577-19

Package Label - Principal Display Panel

Drugs Facts

Active Ingredient

Purpose

Ethyl alcohol 75% v/v.....Antiseptic

Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water

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.

Directions

- Place enough product on hands to cover all surface. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information ■ Store between 16-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Carbomer 940, Trolamine, Purified water.

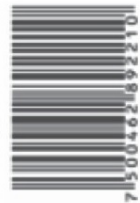
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SINCE



2010

NATURAL GOLD

Alcohol Antiseptic
75%
Topical Solution
GEL

Hand Sanitizer

Ethyl Alcohol

676.28 FL OZ (20000 mL)

20000 mL NDC: 78368-577-20

Package Label - Principal Display Panel

Package Label - Principal Display Panel

Drugs Facts	
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Ethyl alcohol 75% v/v.....	Antiseptic
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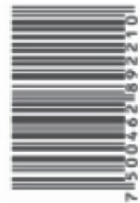
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Alcohol Antiseptic 75% Topical Solution GEL

Hand Sanitizer

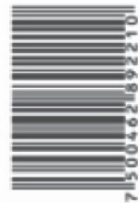
Ethyl Alcohol

6762.8 FL OZ (200000 mL)

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
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200000 mL NDC: 78368-577-21

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78368-577
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	

CARBOMER 940 (UNII: 4Q93RCW27E)	0.75 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78368-577-17	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78368-577-18	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78368-577-19	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78368-577-20	20000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78368-577-21	200000 mL in 1 DRUM; 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 - Rodríguez Fierro, Marco Antonio (951578245)

Registrant - Mario Hidalgo (080666336)

Establishment

Name	Address	ID/FEI	Business Operations
Rodríguez Fierro, Marco Antonio		951578245	manufacture(78368-577)

Revised: 6/2020

Rodríguez Fierro, Marco Antonio