

## **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.*

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### **Hand Sanitizer**

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 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.

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, carbomer 940, trolamine, purified water USP

**Package Label - Principal Display Panel**



**Alcohol Antiseptic**  
**75%**  
*Topical Solution*  
**GEL**

**Hand Sanitizer**

**Ethil Alcohol**

**8.8 FL OZ (250mL)**

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
<b>Warnings</b> For external use only. Flammable, Keep away from heat or flame	
<b>Do not use</b> ■ In children less than 2 months of age ■ On open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children</b> if swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ 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	
<b>Other Information</b> ■ Store between 16-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Glycerin, Carbomer 940, Trolamine, Purified water.	

**MADE IN 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



Package Label - Principal Display Panel



Alcohol Antiseptic  
75%  
Topical Solution  
GEL

Hand Sanitizer

Ethil Alcohol

33.81 FL OZ (1000 mL)

1000 mL 78368-567

Package Label - Principal Display Panel

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
<b>Warnings</b> For external use only.	
Flammable, Keep away from heat or flame	
<b>Do not use</b>	
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<b>Other Information</b> ■ Store between 16-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
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SINCE



2010

**NATURAL GOLD**

**Alcohol Antiseptic**  
**75%**  
*Topical Solution*  
**GEL**

**Hand Sanitizer**

**Ethil Alcohol**

**127.98 FL OZ (3785 mL)**

3785 mL NDC: 78368-567-14

**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**

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- 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.

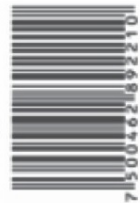
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SINCE



2010

**NATURAL GOLD**

**Alcohol Antiseptic**  
**75%**  
*Topical Solution*  
**GEL**

**Hand Sanitizer**

**Ethil Alcohol**

**676.28 FL OZ (20000 mL)**

20000 mL NDC: 78368-567-15

**Package Label - Principal Display Panel**

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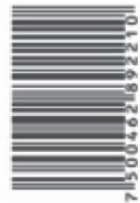
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**Alcohol Antiseptic**  
**75%**  
*Topical Solution*  
**GEL**

**Hand Sanitizer**

**Ethil Alcohol**

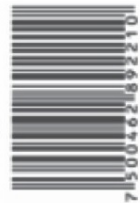
**6762.8 FL OZ (200000 mL)**

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
<b>Warnings</b> For external use only. Flammable, Keep away from heat or flame	
<b>Do not use</b> ■ In children less than 2 months of age ■ On open skin wounds	
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<b>Other Information</b> ■ Store between 16-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Glycerin, Carbomer 940, Trolamine, Purified water.	

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200000 mL NDC: 78368-567-16

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78368-567
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78368-567-12	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78368-567-13	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78368-567-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78368-567-15	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78368-567-16	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(78368-567)

Revised: 5/2020

Rodríguez Fierro, Marco Antonio