

**HAND SANITIZER- alcohol gel**  
**HARMONIC NATURE S DE RL MI**

*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, Trilomine, purified water

**Package Label - Principal Display Panel**



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

**Hand Sanitizer**

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<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 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> 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:**  
Harmonic Nature S. de R.L. MI.  
Lacandon #205 Fracc. Azteca  
Guadalupe, N.L. México C.P. 67150  
Ph. +52(81) 2029 6703  
www.hnatur.com



**33.81 FL OZ (1000mL)**

1000 mL NDC: 76949-234-01

Package Label - Principal Display Panel



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

**Hand Sanitizer**

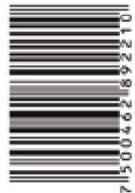
**8.45 FL OZ (250mL)**

<b>Drugs Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 75% v/v.....	Antiseptic
<b>Uses</b> ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<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 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b>	
Glycerin, Carbomer 940, Trolamine, Purified water.	

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<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76949-234
<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: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	0.75 g in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.25 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76949-234-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
2	NDC:76949-234-02	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - HARMONIC NATURE S DE RL MI (951576951)

**Registrant** - Mario Hidalgo (080666336)

### Establishment

Name	Address	ID/FEI	Business Operations
HARMONIC NATURE S DE RL		951576951	manufacture(76949-234)

Revised: 4/2020

HARMONIC NATURE S DE RL MI