

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.

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.

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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

Package Label - Principal Display Panel



Alcohol Antiseptic
75 %
Topical Solution

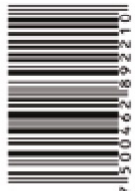
Hand Sanitizer

| | |
|--|----------------|
| Drugs Facts | |
| Active Ingredient | Purpose |
| Ethyl alcohol 75% v/v..... | Antiseptic |
| Uses ■ Health care personnel hand rub to help reduce bacteria that potentially can cause disease. | |
| 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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| Other Information ■ Store between 15-30C (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:
 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



8.45 FL OZ (250mL)

250 mL NDC: 76949-235-01

Package label Principal display panel

1000 mL NDC: 76949-235-02



Alcohol Antiseptic 75 % Topical Solution

Hand Sanitizer

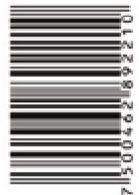
33.81 FL OZ (1000mL)

| | |
|--|----------------|
| Drugs Facts | |
| Active Ingredient | Purpose |
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|--|--|---------------------------|-----------------|
| HAND SANITIZER | | | |
| alcohol gel | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76949-235 |
| 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 |

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76949-235-01 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:76949-235-02 | 1000 mL in 1 BOTTLE, PLASTIC; 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 - HARMONIC NATURE S DE RL MI (951576951)

Registrant - Mario Hidalgo (080666336)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| HARMONIC NATURE S DE RL MI | | 951576951 | manufacture(76949-235) |

Revised: 5/2020

HARMONIC NATURE S DE RL MI