

HAND SANITIZER- ethyl alcohol solution
LABORATORIOS ANDIFAR

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

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. Isopropyl Alcohol (75%, 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)

ETHYL ALCOHOL 70%

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, GLYCERIN CARBOMER TRIETHANOLAMINE

Package Label - Principal Display Panel

VIVA PURE

ANTIBACTERIAL

1 Gallon (128 fl. oz.)

| Drug Facts | |
|---|------------|
| Active ingredient | Purpose |
| Ethyl alcohol 70% | Antiseptic |
| Uses ■ In solution rubbing on the skin that could cause disease ■ recommended for repeated use | |
| Warnings For external use only: hands Flammable, keep away from fire or flame. When Using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. ■ do not inhale or ingest. Stop use and ask a doctor if ■ irritation and redness develop or condition persists for more than 72 hours. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions ■ wet hands thoroughly with product and allow to dry without wiping. ■ for children under 6, use only under adult supervision and avoid contact with broken skin. | |
| Other information ■ do not store above 105 °F ■ may discolor some fabrics ■ harmful to wood finishes and plastics | |
| Inactive ingredients water, glycerin, carbomer, triethanolamine | |
| Questions? 1-305-216-4327 | |

Lot.: Exp.:



Sole Distributor:
 CM Trading, LLC,
 12905 SW 42 Street, Suite 210
 Miami, Florida 33175

Made in Honduras by:
 LABORATORIOS
Andifar

*Effective at eliminating 99.99% of many common harmful germs & bacteria in as little as 15 seconds.

VIVA PURE

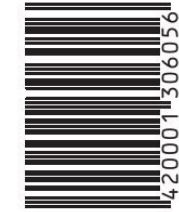
ANTIBACTERIAL

118 mL (4 fl. oz.)

Lot.: Exp.:

| Drug Facts | Purpose |
|--|----------------------------------|
| Active ingredient | Ethyl alcohol 70%.....Antiseptic |
| Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use | |
| Warnings For external use only: hands Flammable, keep away from fire or flame. When Using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest. Stop use and ask a doctor if ■ irritation and redness develop or condition persists for more than 72 hours. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants | |
| Other information ■ do not store above 105 °F ■ may discolor some fabrics ■ harmful to wood finishes and plastics | |
| Inactive ingredients Water, glycerin, carbomer, triethanolamine | |
| Questions? 1-305-216-4327 | |

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118 ML 78441-001-01

HAND SANITIZER

ethyl alcohol solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78441-001 |
| 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) | 0.1095 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 2.5 mL in 100 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.21 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 27.19 mL in 100 mL |

Product Characteristics

| | | | |
|-----------------|--|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78441-001-01 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:78441-001-02 | 3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |

VIVA PURE

ANTIBACTERIAL

118 mL (4 fl. oz.)

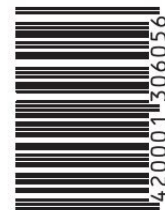
Lot.: Exp.:

| | |
|---|---|
| Drug Facts | Purpose |
| Active Ingredient | Ethyl alcohol 70% Antiseptic |
| Uses | to decrease bacteria on the skin that could cause disease |
| Warnings | recommended for repeated use |
| For external use only: hands | |
| Flammable, keep away from fire or flame. | |
| When Using this product | keep out of eyes. In case of contact with eyes, flush thoroughly with water. avoid contact with broken skin. do not inhale or ingest. |
| Stop use and ask a doctor if | irritation and redness develop or condition persists for more than 72 hours. |
| Keep out of reach of children. | If swallowed, get medical help or contact a Poison Control Center right away. |
| Directions | wet hands thoroughly with product and allow to dry without wiping for children under 6, use only under adult supervision |
| Other Information | do not store above 105 °F may discolor some fabrics harmful to wood finishes and plastics |
| Inactive Ingredients | Water, glycerin, carbomer, triethanolamine |
| Questions? | 1-305-216-4327 |

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Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - LABORATORIOS ANDIFAR (816366021)

Registrant - LABORATORIOS ANDIFAR (816366021)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| LABORATORIOS ANDIFAR | | 816366021 | manufacture(78441-001) |

Revised: 6/2020

LABORATORIOS ANDIFAR