HAND SANITIZER- is opropyl alcohol gel MILLENIA PRODUCTIONS, LLC

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 24oz

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)

Isopropyl 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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

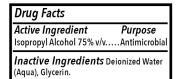
Uses: To decrease bacteria on the skin that could cause disease.

Recommended for repeated use.

For External Use Only. For Professional Use Only. Keep out of reach of children. Para uso externo. Para uso profesional solamente. Mantener fuera del alcance do los niños. Pour usage externe. Réservé à un usage professionnel. Tenir hors de portée des enfants. Solo per uso esterno. Solo per uso professionale tenere lontano dalla portata dei bambini.

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 and condition persists for more than 72 hours. If swallowed, get medical help or contact a Poison Control Center right away.

Flammable: Keep away from fire or flame.





MANUFACTURED BY LA PALM SPA PRODUCTS®
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316-425-2500
MADE IN THE USA.

APPROX **24oz ⊕** (709.76ML)

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.

Instrucciones: Moje bien las manos con el producto y deje secar sin limpiar. Para niños de 6 años, use solo bajo la supervisión de un adulto. No recomendado para bebés.

Indicazioni: bagnare accuratamente le mani con il prodotto e lasciare asciugare senza strofinare. Per i bambini di 6 anni, usare solo sotto la supervisione di un adulto. Non raccomandato per i bambini.

Mode d'emploi: Mouiller soigneusement les mains avec le produit et laisser sécher sans essuyer. Pour les enfants de 6 ans, utilisez uniquement sous la surveillance d'un adulte. Non recommandé pour les nourrissons.

Meets the FDA hand wash criteria.



709.76 ml ml NDC: 75692-709-01

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75692-709

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| Route | Λŧ | Δ | mini | CTPO | tion |
| | | | | | |

TOPICAL

Active Ingredient/Active Moiety

| ı | Active ingredient/Active wrotety | | | | |
|---|--|----------------------|--------------------|--|--|
| | Ingredient Name | Basis of Strength | Strength | | |
| | ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL | | |

| Inactive Ingredients | | | | |
|--|--------------------|--|--|--|
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | 1.45 mL in 100 mL | | | |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL | | | |
| WATER (UNII: 0590E0KOOR) | | | | |

| ı | Packaging | | | | |
|---|------------------------|--|------------|-----------------------|--|
| | # Item Code | Item Code Package Description | | Marketing End Date | |
| | 1 NDC:75692-709- 01 | 709.76 mL in 1 BOTTLE; 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 | | |
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Labeler - MILLENIA PRODUCTIONS, LLC (105112507)

Registrant - MILLENIA PRODUCTIONS, LLC (105112507)

| Establishment | | | | |
|---------------------------|---------|-----------|--|--|
| Name | Address | ID/FEI | Business Operations | |
| MILLENIA PRODUCTIONS, LLC | | 105112507 | manufacture(75692-709), label(75692-709) | |

Revised: 4/2020 MILLENIA PRODUCTIONS, LLC