

**HAND SANITIZER- isopropyl alcohol gel**  
**MILLENNIA 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.*

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**Hand sanitizer 32 oz**

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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 de los niños. Pour usage externe. Réserve 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.

#### Drug Facts

Active Ingredient	Purpose
Isopropyl Alcohol 75% v/v.....	Antimicrobial

#### Inactive Ingredients

Deionized Water (Aqua), Glycerin



MANUFACTURED BY  
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MADE IN THE USA.

APPROX **32 oz.** (946.35ML)

**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.**



# HAND SANITIZER

isopropyl alcohol gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75692-946
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

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: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75692-946-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

**Labeler** - MILLENIA PRODUCTIONS, LLC: (105112507)

**Registrant** - MILLENIA PRODUCTIONS, LLC: (105112507)

## Establishment

Name	Address	ID/FEI	Business Operations
MILLENIA PRODUCTIONS, LLC		105112507	manufacture(75692-946) , label(75692-946)

Revised: 4/2020

MILLENIA PRODUCTIONS, LLC: