

HAND SANITIZER- isopropyl alcohol liquid

MBS Medical Technologies

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.

75% Isopropyl Alcohol 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)

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.

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, hydrogen peroxide, purified water

Package Label - Principal Display Panel

Drug Facts (continued)
 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 allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

Other information ■ do not store above 110°F (43°C) ■ may discolor some fabrics ■ harmful to wood finishes and plastics

Inactive ingredient water, glycerol, hydrogen peroxide

Questions or comments? Call 1-888-482-4201 Monday-Friday 9AM-5PM PST

Manufactured by: MBS Medical Technologies, Inc. 6750 N. Desert Blvd., El Paso, TX 79912 MADE IN THE USA mbsmedtech.com

MBS Medical Technologies
SimpliSterile
Antiseptic Hand Sanitizer
 Help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

16 FL OZ (475 mL)

Drug Facts

| Active Ingredient | Purpose |
|---------------------------|------------|
| Isopropyl Alcohol 75% v/v | 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 or redness develops ■ condition persists for more than 72 hours

UPC CODE

HAND SANITIZER

isopropyl alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79590-000 |
| 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 |
|--------------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79590-000-00 | 475 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 09/17/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 09/17/2020 | |

Labeler - MBS Medical Technologies (117581535)**Registrant** - MBS Medical Technologies (117581535)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| MBS Medical Technologies | | 117581535 | manufacture(79590-000) |

Revised: 9/2020

MBS Medical Technologies