

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION- alcohol solution
Amarini Sourcing

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 rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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 Rub

Use

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.

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 USP

Isopropyl Alcohol Antiseptic 75% Topical Solution**Isopropyl Alcohol Antiseptic 75%
Topical Solution****Hand Sanitizer
Non-sterile Solution**

12 fl oz (341 mL)

Amarini Sourcing LLC
(603) 413-3583

This product was made in strict accordance with the guidelines stipulated in the March 27, 2020 revision of FDA document
“Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry”

| | |
|--|------------------------------|
| Drug Facts | |
| Active ingredient[s] Isopropyl alcohol 75% v/v | Purpose Antiseptic |
| Use[s] 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 | |
| <ul style="list-style-type: none"> • 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. | |
| Directions | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients glycerin, hydrogen peroxide, purified water USP | |

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

alcohol solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77374-111 |
| 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 L in 100 L |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 L in 100 L |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 L in 100 L |
| WATER (UNII: 059QF0KO0R) | 18.425 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:77374-111-11 | 0.341 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/11/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/11/2020 | |

Labeler - Amarini Sourcing (044064910)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Amarini Sourcing | | 044064910 | manufacture(77374-111) |

Revised: 5/2020

Amarini Sourcing