

ISOPROPYL ALCOHOL- isopropyl alcohol gel
Marine Essence Biosciences Corporation of USA

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.

Isopropyl Alcohol Hand Sanitizer

Active Ingredient[s]

Isopropyl alcohol 75% v/v
.....Antiseptic

Hand sanitizer to help reduce bacteria that potentially can cause disease.

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.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

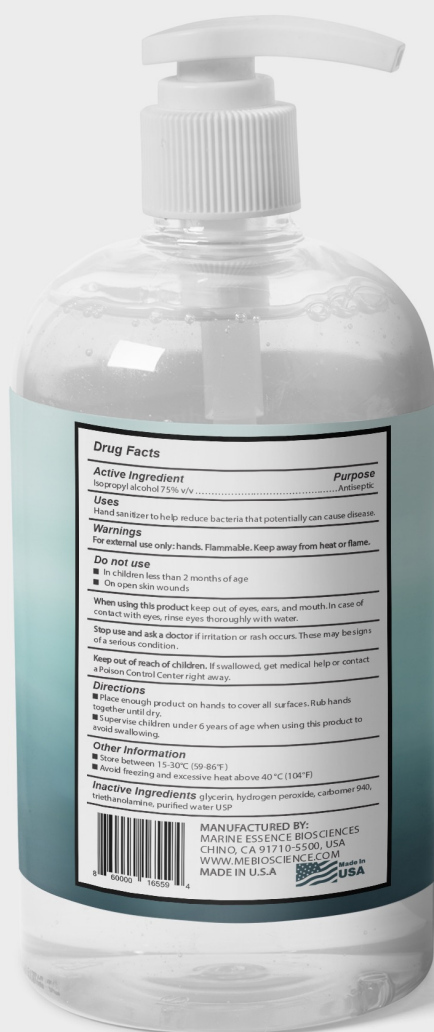
glycerin, hydrogen peroxide, carbomer 940, triethanolamine, purified water USP

For external use only: hands. Flammable. Keep away from heat or flame.

Topical - Administration to a particular spot on the outer surface of the body.

Gel form

To help reduce bacteria on the hands that can potentially cause disease.



ISOPROPYL ALCOHOL

isopropyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73764-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - | ISOPROPYL | 75.8 mL |

| UNII:ND2M416302) | | ALCOHOL | in 100 mL | |
|--------------------------------------|--|---|----------------------|--------------------|
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73764-001-01 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/23/2020 | |
| 2 | NDC:73764-001-02 | 236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/23/2020 | |
| 3 | NDC:73764-001-03 | 177 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/23/2020 | |
| 4 | NDC:73764-001-04 | 473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/23/2020 | |
| 5 | NDC:73764-001-05 | 250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/01/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 03/23/2020 | | |

Labeler - Marine Essence Biosciences Corporation of USA (116587566)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---|
| Marine Essence Biosciences Corporation of USA | | 116587566 | manufacture(73764-001) , pack(73764-001) , label(73764-001) |

Revised: 6/2020

Marine Essence Biosciences Corporation of USA