

HAND SANITIZER- alcohol solution

Biominales Pharma

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

DRUG FACTS

Active ingredient

Ethyl alcohol 80% v/v

Purpose

Antiseptic

Inactive ingredients

Glycerin, Purified Water, Hydrogen Peroxide.

Use (s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when water and soap 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 or 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 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

Distributed by:

MPP Dist. LLC.

sales@mppint.com

PRINCIPAL DISPLAY PANEL - 3.785 L Container Label

Alcohol Antiseptic 80% Topical Solution

MPP

INSTANT
HAND
SANITIZER

1 gallon
(3.785 L)

NDC: 77110-110-01

Distributed by:
MPP Dist. LLC.
sales@mppint.com

Kills 99.9% of Germs

Alcohol Antiseptic 80% Topical Solution



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INSTANT **HAND** 
SANITIZER

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(3.785 L)

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alcohol solution

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77110-110 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M) | Alcohol | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------|
| Glycerin (UNII: PDC6A3C0OX) | |
| Water (UNII: 059QF0K00R) | |
| Hydrogen Peroxide (UNII: BBX060AN9V) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:77110-110-01 | 3785 mL in 1 CONTAINER; Type 0: Not a Combination Product | 07/15/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 07/15/2020 | |

Labeler - Biominerales Pharma (117489663)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Biominerales Pharma | | 117489663 | MANUFACTURE(77110-110) |

Revised: 7/2020

Biominerales Pharma