ECOLOGIC HAND SANITIZER- ethyl alcohol gel MERCATOR

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.

Ecologic 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.

Active Ingredient(s)

Ethyl Alcohol 70% 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.

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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

Deionized water, Acrylates/C10-30 alkyl acrylate crosspolymer, Triethanolamine, EDTA.

Package Label - Principal Display Panel



296 mL NDC: 77851-100-15

ECOLOGIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77851-100

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Active Ingredient/Active Moiety

| ı | Ingredient Name | Basis of Strength | Strength |
|---|--|-------------------|-----------------|
| ı | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

| Inactive Ingredients |
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| nactive ingredients | | |
|-------------------------------------|-------------------|--|
| Ingredient Name | Strength | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | 0.1 mL in 100 mL | |
| EDETIC ACID (UNII: 9G34HU7RV0) | 0.15 mL in 100 mL | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.75 mL in 100 mL | |
| WATER (UNII: 059QF0KO0R) | 29 mL in 100 mL | |

Packaging

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|---|---|----------------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | NDC:77851-100- 15 | 296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/27/2020 | | |

Marketing Information

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|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 04/27/2020 | |
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Labeler - MERCATOR (140445987)

Revised: 5/2020 MERCATOR