

CLEAN SEPT ALCOHOL ANTISEPTIC 70% HAND SANITIZER- ethyl alcohol liquid
BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E
EXPORTACAO LTDA

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.

NO CHANGES NOTIFICATION

Drug Facts Panel - Active Ingredients

Denatured Ethyl Alcohol 70% w/w. Purpose: Antiseptic.

Drug Facts Panel - Purpose

Purpose: Antiseptic

Drug Facts Panel - Use

Use: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Drug Facts Panel - 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.

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.

Drug Facts Panel - 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.

Drug Facts Panel - Other Information

Store between 15-30 °C (59-86 °F)

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

Drug Facts Panel - Inactive Ingredients

Water.

Package Label - Principal Display Panel

5000 ml, NDC 79916-002-01

Clean SEPT



Alcohol Antiseptic 70% Hand Sanitizer

Drug Facts

Active ingredients

Denatured Ethyl Alcohol 70% w/w.....

Purpose

Antiseptic

Uses

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.

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° - 30°C (59° - 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Water.

Questions or reporting of adverse events?

Contact weekdays from 9AM or 5PM at 1-786-272-5677

Manufactured by:

Be Factory Laboratories Industria Comercio Importacao e Exportacao Ltda
Av. Forte do Leme 205, Parque Sao Lourenco, Sao Paulo, 08340-010, Brazil



1.3 gal / 5 L

MADE IN BRAZIL



7 898584 623165
LOT / EXPIRATION DATE: Printed on the packaging

CLEAN SEPT ALCOHOL ANTISEPTIC 70% HAND SANITIZER

ethyl alcohol liquid

| Product Information | | | | |
|--|------------------|---|----------------------|--------------------|
| Product Type | | HUMAN OTC DRUG | Item Code (Source) | |
| Route of Administration | | TOPICAL | NDC:79916-002 | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | | ALCOHOL | 70 mL in 100 mL |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| WATER (UNII: 059QF0K00R) | | | 30 mL in 100 mL | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:79916-002-01 | 5000 mL in 1 JUG; Type 0: Not a Combination Product | 08/06/2020 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part333A | 08/06/2020 | |

Labeler - BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E EXPORTACAO LTDA (900786538)

| Establishment | | | |
|---|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E EXPORTACAO LTDA | | 900786538 | manufacture(79916-002) , pack(79916-002) , label(79916-002) |