ECOSOL HAND SANITIZER- benzalkonium chloride liquid Ecosolutions, S. de R.L. de C.V.

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

Active Ingredient(s)

Benzalkonium chloride 0.13% 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

water, ethyl alcohol, lauryl glucoside, n-alkyl-n-dimethyl ammonium chloride, grapefruit seed extract.

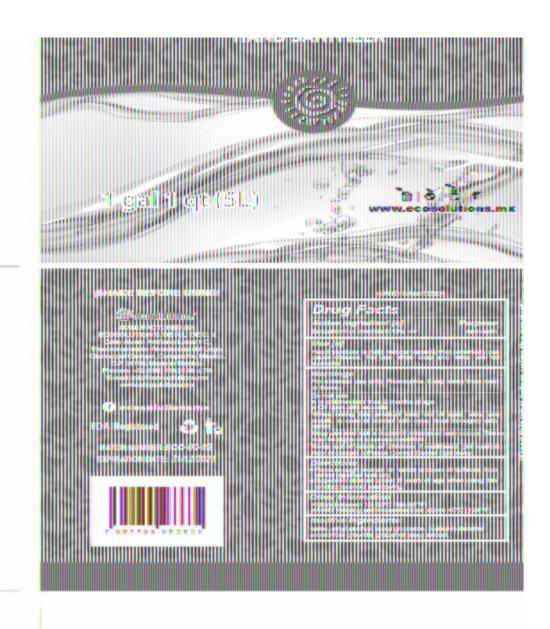
PDP

1000 mL NDC: 77993-005-01



5000 mL NDC: 77993-005-02







HAND SAN TIZER



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MANNIFACTURED BY:
ECOSOLUTIONS DE FIL DE C. V.
Calle Alvaro Avineno Losari C.
Fraccionamiento Pseudoresi del Liego
Dioled del Carmen, Campache Mexico
C. Carmen, Carme





DA Registered DA REGISTER BATCH NUMBER: 200-00-02 EXPIRATION DATE: 21/12/2021



HAND SANTIZER Drug Facts

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200000 mL NDC: 77993-005-04







ECOSOL HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77993-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6 JUD5X6 Y) BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - CHLO RIDE in 100 mL

| Inactive Ingredients | | | | | | | | | |
|---|--------------------|--|--|--|--|--|--|--|--|
| Ingredient Name | Strength | | | | | | | | |
| 3-CHLORO-2-HYDROXYPROPYLCOCOALKYLDIMETHYLAMMONIUM CHLORIDE (UNII: 0V8LAK7MX8) | 0.03 mL in 100 mL | | | | | | | | |
| LAURYL GLUCO SIDE (UNII: 76 LN7P7UCU) | 0.45 mL in 100 mL | | | | | | | | |
| WATER (UNII: 059QF0KO0R) | 98.89 mL in 100 mL | | | | | | | | |
| GRAPEFRUIT SEED OIL (UNII: 598 D944HOL) | 0.03 mL in 100 mL | | | | | | | | |
| METHYL ALCOHOL (UNII: Y4S76JWI15) | 0.47 mL in 100 mL | | | | | | | | |

| P | Packaging | | | | | | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|--|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | | | | | |
| 1 | NDC:77993-005- 01 | 1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | | | | | | | | |
| 2 | NDC:77993-005- 02 | 5000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | | | | | | | | |
| 3 | NDC:77993-005- 03 | 20000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | | | | | | | |
| 4 | NDC:77993-005- 04 | 200000 mL in 1 CONTAINER; Type 0: Not a Combination Product | 03/30/2020 | | | | | | | | |
| | | | | | | | | | | | |

| Marketing Information | | | | | | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|--|--|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | | | | | | |
| OTC monograph not final | part333A | 03/30/2020 | | | | | | | | | |
| | | | | | | | | | | | |

Labeler - Ecosolutions, S. de R.L. de C.V. (814399275)

Registrant - Ecosolutions, S. de R.L. de C.V. (814399275)

| Establishment | | | |
|----------------------------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| Ecosolutions, S. de R.L. de C.V. | | 814399275 | manufacture(77993-005), pack(77993-005), label(77993-005) |

Revised: 9/2020 Ecosolutions, S. de R.L. de C.V.