

HAND SANITIZER- benzethonium chloride gel
RIMPORTS INC.

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.

Active Ingredient:

Benzethonium Chloride 0.105%

Purpose

Antiseptic

Stop use and ask a doctor if redness appears and persists for more than 72 hours.

KEEP OUT OF REACH OF CHILDREN. If swallowed, contact medical help or poison control.

Directions Spray on palm and rub your hands together until absorbed.

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Betaine, Fragrance, Citrus Aurantium Dulcis (Orange) Peel Oil, Zingiber Officinale (Ginger) Root Oil,, Phenoxyethanol, Diazolidinyl Urea, Palmitamidopropyltrimonium Chloride, Sodium Citrate, Disodium EDTA.

Other Information

May damage fabrics and surfaces.

Uses

For waterless hand washing to decrease bacteria on skin. Recommended for repeated use.

WARNINGS:

For external use only.

When using this product, Avoid face, eyes or sensitive areas. If contact occurs flush thoroughly with water.

| Drug Facts | | Drug Facts (continued) | |
|---|------------------------------|---|--|
| Active Ingredient Benzethonium Chloride 0.105% Hand Sanitizer | Purpose Antiseptic | Directions Spray on palm and rub your hands together until absorbed. | |
| Uses For waterless hand washing to decrease bacteria on skin. Recommended for repeated use. | | Inactive Ingredients Water, PEG-40 Hydrogenated Castor Oil, Betaine, Fragrance, Citrus Aurantium Dulcis (Orange) Peel Oil, Zingiber Officinale (Ginger) Root Oil, Phenoxylethanol, Diazolidinyl Urea, Palmitamidopropyltrimonium Chloride, Sodium Citrate, Disodium EDTA. | |
| WARNINGS: For external use only. When using this product, Avoid face, eyes, or sensitive areas. If contact occurs flush thoroughly with water. | | Other Information May damage fabrics and surfaces. Designed in USA. Assembled in China with US fragrance. | |
| Stop use and ask a doctor. If redness appears and persists for more than 72 hours. | | Distributed by: Rimports Inc. 201 East Bay Blvd. Provo, UT 84606 | Questions? (801) 437-4302 8AM to 4PM MST |
| KEEP OUT OF REACH OF CHILDREN If swallowed, contact medical help or poison control. | | | |

HAND SANITIZER

benzethonium chloride gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72131-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|-------------------|
| BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | BENZETHONIUM CHLORIDE | 0.105 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| BETAINE (UNII: 3SCV180C9W) | |
| CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T) | |
| ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414) | |
| WATER (UNII: 059QF0KO0R) | |

PALMITAMIDO PROPYLTRIMONIUM CHLORIDE (UNII: N2U96D202F)

SODIUM CITRATE (UNII: 1Q73Q2JULR)

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72131-003-01 | 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/06/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/06/2018 | |

Labeler - RIMPORTS INC. (361320844)

Revised: 3/2018

RIMPORTS INC.