

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%	Purpose Antiseptic Hand Sanitizer	Directions Spray on palm and rub your hands together until absorbed.	Inactive Ingredients Water, PEG-40 Hydrogenated Castor Oil, Betaine, Fragrance, Lavandula Angustifolia (Lavender) Oil, Ormenis Multicaulis Oil, Phenoxyethanol, Diazolidinyl Urea, Palmitamidopropyltrimonium Chloride, Sodium Citrate, Disodium EDTA.
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. Stop use and ask a doctor. If redness appears and persists for more than 72 hours.	Other Information May damage fabrics and surfaces. Designed in USA. Assembled in China with US fragrance.	Distributed by: Rimports Inc. 201 East Bay Blvd. Provo, UT 84606 V03 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:72131-005
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)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
WATER (UNII: 059QF0K00R)	

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:72131-005-01	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.