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 Limon (Lemon) Peel Oil, Citrus Grandis (Grapefruit) Peel 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.



HAND SANITIZER

benzethonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72131-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.105 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
BETAINE (UNII: 3SCV180C9W)		
CITRUS LIMON FRUIT OIL (UNII: 0 HNC1J1YED)		
GRAPEFRUIT PEEL (UNII: 3582N05Q44)		
WATER (UNII: 059QF0KO0R)		

PALMITAMIDO PRO PYLTRIMO NIUM CHLO RIDE (UNII: N2U96D202F)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Packaging			
# Item Cod	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72131-00	4- 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.