

HAND SANITIZER- benzethonium chloride gel

Biolab International Incorporated

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 0.095%

Purpose

Antiseptic

Keep it out of children.

Directions: Place a small amount of product in your hand, and rub hands together until dry.

Inactive Ingredients: Water(EAU), Betaine Anhydrous, PEG-40 Hydrogenated Castor Oil, Phenoxyethanol, Diazolidinyl Urea, Palmitamidopropyltrimonium Chloride, Propylene Glycol, Fragrance(Parfum), Sodium Citric Acid, Disodium EDTA.

Storage: Avoid direct sunlight.

Uses

Decrease bacteria on hands.

Warnings For external use only.

In case of contact with eyes, rinse immediately with plenty of water. Discontinue use if rash or irritation occurs and consult a doctor.



HAND SANITIZER

benzethonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72264-003	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)		BENZETHONIUM CHLORIDE	0.095 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
BETAINE (UNII: 3SCV180C9W)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
PALMITAMIDOPROPYLTRIMONIUM CHLORIDE (UNII: N2U96D202F)				
DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)				
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:72264-003-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/18/2018	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/18/2018	

Labeler - Biolab International Incorporated (200167919)