BODY PRESCRIPTIONS ANTIBACTERIAL HAND WASH MINT AND TEA TREEbenzalkonium chloride solution ENCHANTE ACCESSORIES 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.

G0ABHW05

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

■ For hand washing to decrease bacteria on hands

WARNINGS

For external use only - hands

When Using this Product

Keep out of eyes. In case of contact with eyes, flush thoroughly with water

Stop use and ask a doctor if skin irritation develops.

keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

Directions

Apply a small amount to hands. Lather for at least 20 seconds then rinse with warm water

Avoid contact with eyes

Not recommended for infants

Other Information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients

Water, Cocamidopropyl Betaine, PEG-150 Distearate, Cocamide MEA, Benzyl Alcohol, Fragrance, Phenoxyethanol, Sodium Hydroxide, Mentha Arvensis Extract, Melaleuca Alternifolia (Tea Tree) Extract, Benzoic Acid, Blue 1,





244*75mm



BODY PRESCRIPTIONS ANTIBACTERIAL HAND WASH MINT AND TEATREE

benzalkonium chloride solution

 Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:50563-235

 Route of Administration
 TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6JUD5X6Y)
BENZALKONIUM
CHLORIDE
0.13 g
in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)				
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
WATER (UNII: 059QF0KO0R)				
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				
MENTHA ARVENSIS WHOLE (UNII: 46477RRB3O)				
MELALEUCA ALTERNIFOLIA WHOLE (UNII: 976 KV4FXYF)				
BENZOIC ACID (UNII: 8 S KN0 B 0 MIM)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:50563-235-01	500~mL in $1~BOTTLE;$ Type 0: Not a Combination Product	06/30/2020					
Marketing Information								
]	Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
07	TC monograph not fi	nal part333A	06/30/2020					

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment							
Name	Address	ID/FEI	Business Operations				
Xiamen Chengda Industrial Co., Ltd		540042034	manufacture(50563-235)				

Revised: 6/2020 ENCHANTE ACCESSORIES INC.