

BODY PRESCRIPTIONS COCONUT ANTIBACTERIAL FOAMING HAND- benzalkonium chloride soap

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.

G0ABHW08

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

- For hand washing to decrease bacteria on the skin

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 then rinse with warm water

Avoid contact with eyes

Wash hands for 20 seconds

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, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Yellow

5, Red 4



147 golden

247x76mm



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benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-238
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
DISODIUM HEDTA (UNII: KME849MC7A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-238-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-238)

Revised: 8/2020

ENCHANTE ACCESSORIES INC.