BODY PRESCRIPTIONS ROSE INFUSED WITH VITAMIN E 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.

50563-266/JAS21F06

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

■ For hand washing to decrease bacteria on the skin

WARNINGS

For external use only

When suing 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 accidenta ingestion, seek professional assistance or contact a Poison Control Center immdiately.

Directions

Apply a small amount to hands, lather for seconds, then rinse with warm water.

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, Tocopheryl Acetate, Yellow 5, Red 33



224*50mm





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benzalkonium chloride soap

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-266	
Route of Administration	TOPICAL			

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			
DISO DIUM HEDTA (UNII: KME849 MC7A)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:50563-266-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/23/2020		

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment				
Name	Address	ID/FEI	Business Operations	
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-266)	

Revised: 9/2020 ENCHANTE ACCESSORIES INC.