SEA MINERALS ANTIBACTERIAL- benzalkonium chloride solution Manna Kadar Beauty 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.

Sea Minerals Antibacterial Hand Soap

Active Ingredient(s)

Benzalkonium Chloride 0.1%

Purpose

Antiseptic

Uses

For handwashing to decrease bacteria on the skin.

Warnings

For external use only.

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask a doctor if

irritation or redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply product onto your wet hands, lather and rinse with water.

Other information

• Store at 15° to 30°C (59° to 86°F). Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

Acrylic Acid /Acrylamidomethyl Propane Sulfonic Acid Copolymer, Cocamidopropyl Betaine, CI 17200, Citral, DMDM Hydantoin, Disodium EDTA, D-Limonene, Linalool, Parfum (Fragrance), Sea Water, Sodium Laureth Sulfate, Sodium Chloride.



SEA MINERALS ANTIBACTERIAL

benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78656-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
DMDM HYDANTO IN (UNII: BYR0546 TOW)		
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)		
2-ACRYLAMIDO-2-METHYL-1-PRO PANESULFO NIC ACID (UNII: 490 HQE5KI5)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)		
WATER (UNII: 059QF0KO0R)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
CITRAL (UNII: T7EU0O9VPP)		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78656-002- 50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	
2	NDC:78656-002- 51	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	
3	NDC:78656-002- 26	260 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	
4	NDC:78656-002- 27	260 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - Manna Kadar Beauty Inc. (078629402)

Establishment			
Name	Address	ID/FEI	Business Operations
XIAMEN ROSEMARY BIOTECHNOLOGY CO.,LTD		543263460	manufacture(78656-002)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dongyang Mukang Pharmaceutical Factory		554531139	manufacture(78656-002)	

Revised: 11/2020 Manna Kadar Beauty Inc.