SEA MINERALS HAND SANITIZER- ethyl alcohol 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 Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 70%

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, CI 17200, Citral, D-Limonene, Linalool, Parfum (Fragrance), Sea Water.

Package Label - Principal Display Panel



SEA MINERALS HAND SANITIZER

ethyl alcohol solution

ı	Product Information	roduct Information					
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78656-001			
ı	Route of Administration	TOPICAL					

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
WATER (UNII: 059QF0KO0R)				
CITRAL (UNII: T7EU0O9VPP)				
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)				
LIMO NENE, (+)- (UNII: GFD7C86Q1W)				
LINALOOL, (+/-)- (UNII: D81QY6188E)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:78656-001- 50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020		
2	NDC:78656-001- 51	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020		
3	NDC:78656-001- 26	260 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020		

4	Product	06/15/2020		
Marketing Information				
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fi	nal part333A	06/15/2020		

Labeler - Manna Kadar Beauty Inc. (078629402)

Establishment				
Name	Address	ID/FEI	Business Operations	
XIAMEN ROSEMARY BIOTECHNOLOGY CO.,LTD		543263460	manufacture (78656-001)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Dongyang Mukang Pharmaceutical Factory		554531139	manufacture (78656-001)	

Revised: 11/2020 Manna Kadar Beauty Inc.