MANOLIA ANTIBACTERIAL HANDSOAP- benzalkonium chloride liquid TELLINI 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.

MANOLIA ANTIBACTERIAL HAND SOAP WITH MOISTURIZERS

USE

For hand washing to decrease bacteria on the skin. Recommended for repeated use

WARNINGS

For external use only

When using the product; avoid contact with eyes, In case of eye contact, flush with water.

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

DIRECTIONS

Pump into hands and wet as needed. Lather vigorously for at least 15 seconds. Wash skin, rinse thoroughly and dry.

Active Ingredient(s)

Benzalkonium Chloride 0.1% Purpose Antiseptic

Inactive Ingredients

Aqua, Sodium Laureth Sulfate, Sodium Chloride, Cocamide DEA, Cocamidopropyl Betain, Styrene/acrylates copolymer, Parfum, Glycerin, Polyquternium-7, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Citcic Acid, Benzophenone-4, Cl42090, Cl 19140

Keep out of reach of children

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

Purpose

Antiseptic

Package Label - Principal Display Panel



400 ML Ndc: 80887-005-01

MANOLIA ANTIBACTERIAL HANDSOAP

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80887-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
COCAMIDE (UNII: 3YXD33R71G)	1 g in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1 g in 100 mL	
ETIDRO NATE TETRASO DIUM (UNII: CZZ9 T1T1X4)	1 g in 100 mL	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	1 g in 100 mL	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	1 g in 100 mL	
BENZOPHENO NE-5 (UNII: 853Z42ZYAS)	1 g in 100 mL	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	1 g in 100 mL	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	1 g in 100 mL	
WATER (UNII: 059QF0KO0R)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	1 g in 100 mL	

METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	1 g in 100 mL
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	1 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1 g in 100 mL
CHLORINE (UNII: 4R7X1O2820)	1 g in 100 mL

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

Packaging

Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:80887-005-01 400 mL in 1 BOTTLE; Type 0: Not a Combination Product 10/01/2020



	Marketing Inform			
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333E	10/01/2020	
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Labeler - TELLINI INC. (117014846)

Registrant - TELLINI INC. (117014846)

Establishment

Name	Address	ID/FEI	Business Operations
BSK GRUP KIMYA SANAYI VE TICARET LIMITED SIRKETI		595676471	manufacture(80887-005)

Revised: 10/2020 TELLINI INC.