HOME FORMATION ANTIBACTERIAL SHEA BUTTER- benzalkonium chloride liquid
PATCOS COSMETICS (INDIA) PRIVATE LIMITED

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.

Active ingredient

Benzalkonium Chloride (0.13%)

Purpose

Antibacterial

Warnings

For external use only.
When using this product avoid contact with eyes . In case of eyes contact, flush with water.

Stop use and ask a doctor if irritation and redness develops.

Keep out of reach of children if swallowed, get medical help or contact a Poison control center right away.

Uses

For hand washing to decrease bacteria on the skin.

Directions

• Pump into hands.
• Lather vigorously for at least 15 seconds.
• Rinse and dry thoroughly.

Inactive ingredient

Water, Sodium Laureth Sulphate,Sodium Laureth sulfate & Glycol Distearate & Cocamide MEA & Laureth - 10, Cocamido Propyl Betaine,
Cocomonoethanolamide, Sodium Chloride, Glycerine,Perfume, PEG 150 Distearate, Bronopol, Disodium EDTA,Phenoxyethanol, Benzophenone 3, Citric Acid, CI. No. 17200, FD and C Yellow 5,CI. No. 19140 , D and C Red 33.

CMYK
W 1.625 in x H 4.25 in

HOME FORMATION ANTIBACTERIAL SHEA BUTTER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68121-005
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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
BRONOPOL (UNII: 6PU1E16C9W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOPHENONE (UNII: 701M4TTV9O)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
LAURETH-10 (UNII: BD7AST04GA)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68121-005-01	333 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/03/2021	

Labeler - PATCOS COSMETICS (INDIA) PRIVATE LIMITED (916169451)

Revised: 2/2021 PATCOS COSMETICS (INDIA) PRIVATE LIMITED