

**HOME FORMATION ANTIBACTERIA -BERRY- 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

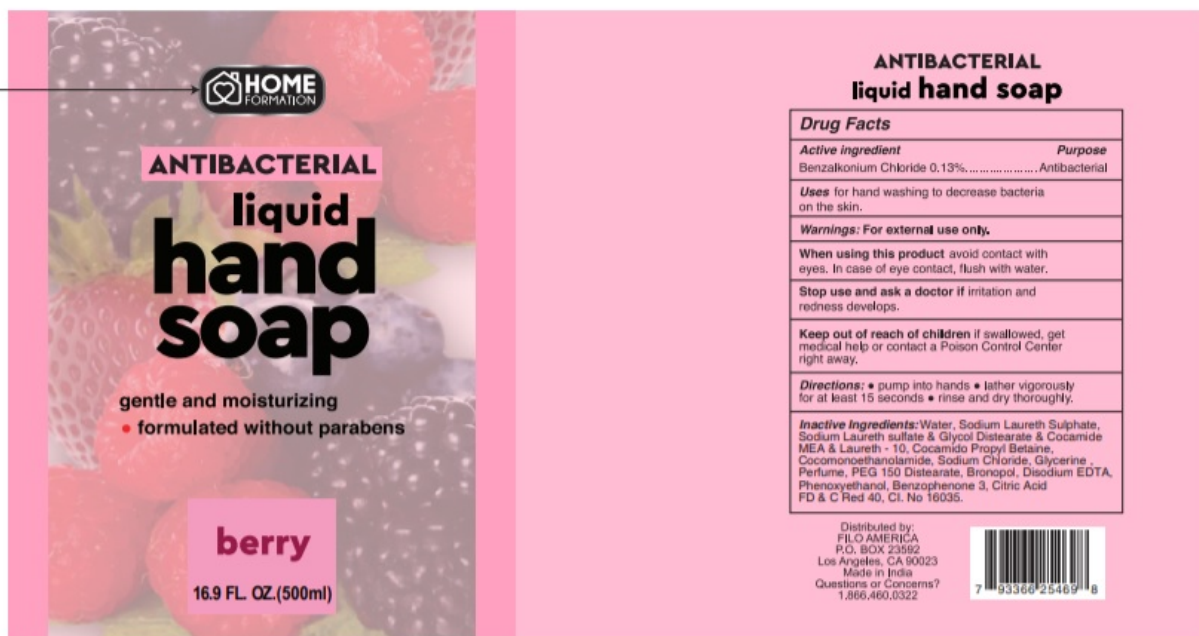
Inactive ingredient

Water, Sodium Laureth Sulphate, Sodium Laureth sulfate & Glycol Distearate & Cocamide MEA & Laureth - 10, Cocamido Propyl Betaine, Cocomonooethanolamide, Sodium Chloride, Glycerine, Perfume, PEG 150 Distearate, Bronopol, Disodium EDTA, Phenoxyethanol, Benzophenone 3, Citric Acid, FD & C Red 40, CI. No 16035.

Label

160 x 100mm

Silver Foil



C:0 M:48 Y:3 K:0

HOME FORMATION ANTIBACTERIA -BERRY

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68121-007
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)	
COCAMIDO PROPYL BETAINE (UNII: 5OCF3011KX)	
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
LAURETH-10 (UNII: BD7AST04GA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68121-007-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/29/2021	

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

Establishment			
Name	Address	ID/FEI	Business Operations
PATCOS COSMETICS (INDIA) PRIVATE LIMITED		675973979	manufacture(68121-007)

Revised: 2/2021

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