

CRISP CLEAN ANTIBACTERIAL HAND- benzalkonium chloride soap
Apollo Health and Beauty Care 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.

Drug Facts

Active ingredients

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Uses

For hand washing to decrease bacteria on the skin.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor

if irritation or redness develops and lasts for more than 72 hours.

Keep out of reach of children.

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

Directions

- Apply onto dry hands.
- Lather and rinse thoroughly with water.

Other information

Store at room temperature.

Inactive ingredients

Water (Aqua), Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Red 40 (CI 16035), Yellow 5 (CI 19140), Red 33 (CI 17200).

Label Copy



CRISP CLEAN ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISO THIAZOLINONE (UNII: 229D0E1QFA)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-109-07	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/29/2017	

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-109)

Revised: 3/2017

Apollo Health and Beauty Care Inc.