CRISP PEAR ANTIBACTERIAL FOAMING 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. In case of contact, 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), Cocamidopropyl Betaine, Polysorbate 20, Fragrance (Parfum), Glycerin, Decyl Glucoside, Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Polyquaternium-7, Xanthan Gum, Tetrasodium EDTA, Sodium Citrate, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Green 3 (CI 42053), Yellow 10 (Ci 47005).

Label Copy



CRISP PEAR ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-112
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)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
GLYCERIN (UNII: PDC6A3C0OX)			
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			

POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63148-112- 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(63148-112)		

Revised: 3/2017 Apollo Health and Beauty Care Inc.