FRESH WATER 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 immediately.

Directions

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

Other information

Store at room termpature

Inactive ingredients

Water (Aqua), Cocamdiopropyl Betaine, Polysorbate 20, Fragrance (Parfum), Glycerin, Decyl Glucoside, Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Polyquaternium-7, Xanthan Gum, Propylene Glycol, Tetrasodium EDTA, Sodium Citrate, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Ext. Violet 2 (CI 60730).

Label Copy

FRESH WATER ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63148-110
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: 5OCF3O11KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	

XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-110-07	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(63148-110)

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