

P.O.V. 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 ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Uses

helps eliminate bacteria on hands.

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.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

Pump onto wet hands, rub into a rich foamy lather and rinse clean.

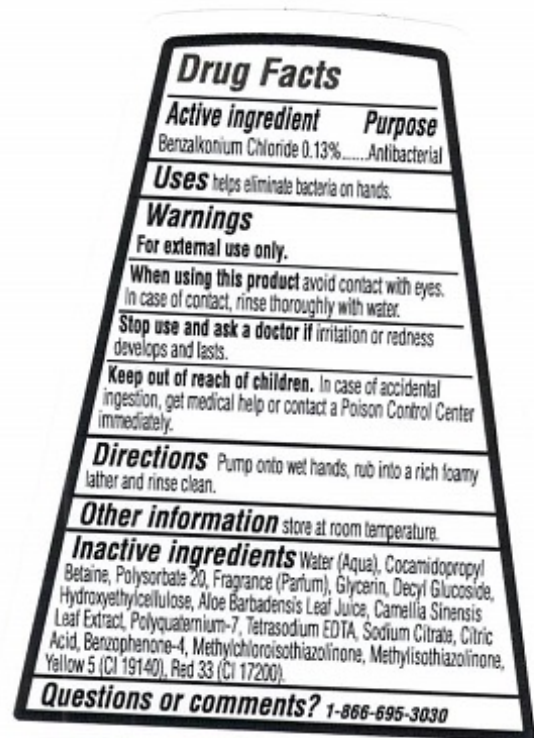
Other information

store at room temperature.

Inactive ingredients

Water (Aqua), Cocamidopropyl Betaine, Polysorbate 20, Fragrance (Parfum), Glycerin, Decyl Glucoside, Hydroxyethylcellulose, Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Polyquatarnium-7, Tetrasodium EDTA, Sodium Citrate, Citric Acid, Benzophenone-4, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (CI 19140), Red 33 (CI 17200).

Label Copy



Distributed by:
 Apollo Health & Beauty Care Inc.
 1 Apollo Place, Toronto, ON M3J 0H2
 06-22787

P.O.V. ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-197
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)	
HYDROXYETHYL CELLULOSE (5000 CPS AT 1%) (UNII: X70SE62ZAR)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SULISOBENZONE (UNII: 1W6L629B4K)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
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:63148-197-08	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/10/2017	

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(63148-197)

Revised: 11/2017

Apollo Health and Beauty Care Inc.