TOPCARE ANTIBACTERIAL FOAMING HAND COMPLETE- benzalkonium chloride liquid
TopCo Associates LLC

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 and redness develops or 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 hands. Work into a rich foamy lather, rinse thoroughly and dry.

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, Polyquaternium-7, Tetrasodium EDTA, Sodium Citrate, Citric Acid, Benzophenone-4, Methylchloroisothiazolinone, Methylisothiazolinone, Red 4 (CI 14700), Yellow 5 (CI 19140).

Label Copy

TOPCARE ANTIBACTERIAL FOAMING HAND COMPLETE

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-124
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 RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-124-07	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/31/2017	

Labeler - TopCo Associates LLC (006935977)

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(36800-124)

Revised: 4/2017 TopCo Associates LLC