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 USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION AND REDNESS DEVELOP AND LAST

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

PUMP ONTO DRY 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, GLYCERIN, FRAGRANCE (PARFUM), SODIUM CITRATE, XANTHAN GUM, POLYQUATERNIUM-7, DECYL GLUCOSIDE, TETRASODIUM EDTA, CITRIC ACID, CAMELLIA SINENSIS LEAF EXTRACT, ALOE BARBADENSIS LEAF JUICE, 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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	

DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
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:36800-124-08	222 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/28/2014	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(36800-124)

Revised: 7/2014 TOPCO ASSOCIATES LLC