# TOPCARE ANTIBACTERIAL FOAMING HAND FRESH PEAR- 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.

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### 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

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, YELLOW 10 (CI 47005), GREEN 3 (CI 42053)

### LABEL COPY



# TOPCARE ANTIBACTERIAL FOAMING HAND FRESH PEAR

benzalkonium chloride liquid

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)		
POLYSORBATE 20 (UNII: 7T1F30 V5YH)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
XANTHAN GUM (UNII: TTV12P4NEE)		
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)		

DECYL GLUCO SIDE (UNII: Z17H97EA6 Y)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:36800-109-08	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(36800-109)	

Revised: 7/2014 TOPCO ASSOCIATES LLC