AWAKEN BY QUALITY CHOICE FOAMING HAND WASH SPRING SHOWERS-
benzalkonium chloride soap
Chain Drug MArketing Association 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 bacterial on hands.

Warnings

For external use only.

When using this product

avoid contact with eyes. If contact occurs, 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 dry hands. Work into a rich foamy lather, rinse thoroughly and dry.

Other information

Store at room temperature.

Inactive ingredients

Water (Aqua), Cocamidopropyl Betaine, Glycerin, Decyl Glucoside, Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Fragrance (Parfum), Polyquaternium-7, Xanthan Gum, Tetrasodium EDTA, Polysorbate 20, Sodium Citrate, Propylene Glycol, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue1 (CI 42090), Ext. Violet 2 (CI 60730).

Questions or comments?

1-248-449-9300

Label Copy

AWAKEN BY QUALITY CHOICE FOAMING HAND WASH SPRING SHOWERS

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-115
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)	
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)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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:63868-115-07	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/18/2016	

Labeler - Chain Drug MArketing Association Inc (011920774)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(63868-115)

Revised: 8/2016 Chain Drug MArketing Association Inc