

GIANT EAGLE REFRESHING CITRUS REFILL- benzalkonium chloride liquid

Apollo Health and Beauty Care

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 the 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

Use to refill a pump bottle. From the pump bottle, apply a small amount to hands. Lather into a rich foam and rinse clean.

Other information

Store at room temperature

Inactive ingredients

Water (Aqua), Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Yellow 5 (CI 19140).

Label Copy



GIANT EAGLE REFRESHING CITRUS REFILL

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-724
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: 059QF0K00R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
COCO MONOETHANOLAMIDE (UNII: C80684146D)
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
EDETATE SODIUM (UNII: MP1J8420LU)
SODIUM SULFATE (UNII: 0YPR65R21J)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-724-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/27/2016	

Labeler - Apollo Health and Beauty Care (201901209)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(63148-724)