

GIANT EAGLE RED BERRY FOAMING- benzalkonium chloride liquid
Apollo Health and Beauty Care 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 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 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

- apply onto dry hands
- lather and rinse thoroughly

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, Polyquatarnium-7, Tetrasodium EDTA, Sodium Citrate, Citric Acid, Benzophenone-4, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (CI 19140), Red 33 (CI 17200).

Label Copy



GIANT EAGLE RED BERRY FOAMING

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-108
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: 5OCF3011KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ALOE VERA LEAF (UNII: ZY81Z83HOX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 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 YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-108-08	222 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/09/2017	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-108)

Revised: 5/2017

Apollo Health and Beauty Care Inc.