

AMERFRESH ANTIBACTERIAL- benzethonium chloride soap
Yangzhou Tracey Daily Chemical Plastic Co., Ltd.

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.

73343 004 AMERFRESH Antibacterial SOAP (0.1% Benzethonium chloride)

Drug Facts

Active Ingredient

Benzethonium Chloride 0.1%

Purpose

Antibacterial

Uses

For washing to decrease bacteria on skin.

Warnings

For External Use Only.

When using this product avoid contact with eyes. In case of eye contact, flush with water.

Do not use this product on infants under 6.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet bar with water
- Lather vigorously and wash skin
- Rinse and dry thoroughly

Inactive Ingredients

Soap (Sodium Palmate and/or Sodiun Tallowate. Sodium Cocoate and/or Sodium Palm Kernelate) Water, Palm Acid, Glycerin, Sodium Chloride, Coconut Acid, Fragrance, Tetrasodium EDTA, Citric Acid Anhydrous.

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S-3-UN-AB
200PCS
N.W.: 15.6KGS
G.W.: 16 KGS
MEAS'T:
32 × 15 × 27.5

FOR INSTITUTIONAL USE
AMERFRESH SOAP
ANTIBACTERIAL
NO.S-3-UN-AB UNWRAP
200PER CASE
MADE IN CHINA

AMERFRESH ANTIBACTERIAL

benzethonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73343-004
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PALMATE (UNII: S0A6004K3Z)	
COCONUT ACID (UNII: 40U37V505D)	
PALM ACID (UNII: B6G0Y5Z616)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73343-004-01	1 in 1 CASE	08/15/2020	
1		85 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/15/2020	

Labeler - Yangzhou Tracey Daily Chemical Plastic Co., Ltd. (560398069)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Tracey Daily Chemical Plastic Co Ltd		560398069	manufacture(73343-004)

Revised: 8/2020

Yangzhou Tracey Daily Chemical Plastic Co., Ltd.