CAREONE CITRUS FRESH ANTIBACTERIAL HAND- benzalkonium chloride soap American Sales Company

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 wet hands.
- lather and rinse thoroughly.

Other information

store at room temperature.

Inactive ingredients

Water (Aqua), Cetrimonium Chloride, Lauramidopropylamine Oxide, Glycerin, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Citrus Nobilis (Mandarin Orange) Peel Extract, Camellia Sinensis Leaf Extract, Zingiber Officinale (Ginger) Root Extract, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (CI 19140), Yellow 6 (CI 15985).

Label copy





CAREONE CITRUS FRESH ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-303

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
(BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURAMIDO PRO PYLAMINE O XIDE (UNII: 16 KX160 QTV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	

TANGERINE PEEL (UNII: JU3D414057)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GINGER (UNII: C5529G5JPQ)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
SODIUM SULFATE (UNII: 0 YPR65R21J)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-303-	333 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/18/2019	

Labeler - American Sales Company (809183973)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(41520-303)

Revised: 7/2019 American Sales Company