ANTIBACTERIAL 2X- benzalkonium chloride liquid
Brands International Corporation

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.

Benzalkonium Chloride - 0.13%

Purpose: Antibacterial

Direction
- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse

For external use only

When using this product
- do not get it into eyes. If contact occurs, rinse eye thoroughly with water

Stop use and ask a doctor if irritation or redness develops

Keep out of reach of children

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

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow# 5 (Cl 19140), Red# 4 (Cl 14700)

Uses for handwashing or decrease bacteria to the skin

ANTIBACTERIAL 2X

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50157-016
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)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:50157-016-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/08/2016	

Labeler - Brands International Corporation (243748238)

Registrant - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(50157-016)

Revised: 8/2021 Brands International Corporation