ANTIBACTERIAL- benzalkonium chloride liquid
Sante Manufacturing 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.

Benzalkonium Chloride - 0.13%

Purpose - Antibacterial

Uses for handwashing or decrease bacteria to the skin

Stop use and ask a doctor If irritation or redness develops

Warning for external use only

When using this product

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water

Keep out of reach of children

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

Direction

- Wet hands
- apply palmful to hands
- scrub thoroughly
- rinse

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

ANTIBACTERIAL

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71020-002
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**
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71020-002-16	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 - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Sante Manufacturing Inc		242048747	manufacture(71020-002)