ANTIBACTERIAL- 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

Uses for handwashing or decrease bacteria to the skin

Warning For external use only

Stop use and ask a doctor if irritation or redness develops

When using the product
- Do not get into eyes. If contact occurs rinse eye thoroughly with water

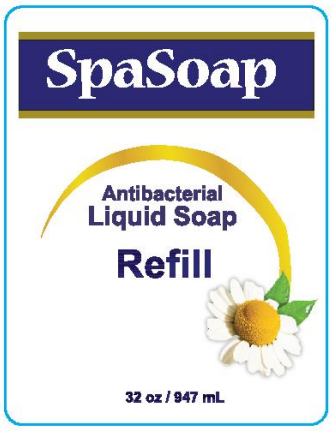
Keep out of reach of children

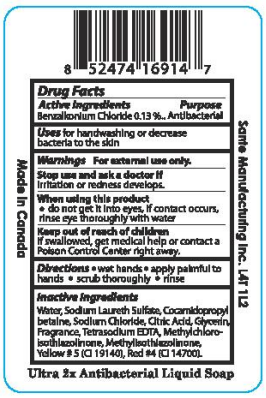
If swallowed, get medical help or contact a Poison Control Center right away

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

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

Spa Soap Antibacterial Liquid Soap





ANTIBACTERIAL

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50157-003
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**
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	

DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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:50157-003-32	947 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 Manufcaturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(50157-003)

Revised: 5/2021 Brands International Corporation