

## ANTIBACTERIAL 2X- 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.*

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Benzalkonium Chloride - 0.13%

Purpose: Antibacterial

Direction

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

For external use only

Stop use and ask a doctor if irritation or redness develops

When using this product

- do not get it 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

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

Uses for handwashing or decrease bacteria to the skin





**SpaSoap 500 mL (16.9 oz liq.)  
Antibacterial Liquid Soap 2X  
Savon Liquide Antibactérien 2X**

**Directions:** Wet hands and apply soap. Wash vigorously and rinse. If product comes in contact with eyes, rinse with water.

**Mode d'emploi :** Mouiller les mains et appliquez du savon. Laver vigoureusement et rincer. Si le produit entre en contact avec les yeux, rincer à l'eau.

**Active Ingredient/Ingrédient tensioactif :**  
0.13% Benzalkonium Chloride

**Ingredient/Ingrédient :** Aqua, Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Tetrasodium EDTA, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Glycerine, FD&C Red #4, FD&C Yellow #5.

Sante Manufacturing Inc.  
L4T 1L2  
Fabriqué au Canada

## ANTIBACTERIAL 2X

benzalkonium chloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71020-016
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DITETRACYCLINE TETRASODIUM EDETATE</b> (UNII: WX0A0IT7K5)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:71020-016-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/2018	
2	NDC:71020-016-20	600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/30/2018	

**Labeler** - Sante Manufacturing Inc (242048747)

**Registrant** - Sante Manufacturing Inc (242048747)

## Establishment

Name	Address	ID/FEI	Business Operations
Sante Manufacturing Inc		204348627	manufacture(71020-016)

## Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(71020-016)

Revised: 1/2022

Sante Manufacturing Inc