

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, 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.

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Sante Manufacturing Inc.
L4T 1L2
Fabriqué au Canada

| 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)

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

Revised: 8/2021

Brands International Corporation