ANTIBACTERIAL AQUA CLEAR 2X ULTRA- 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

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

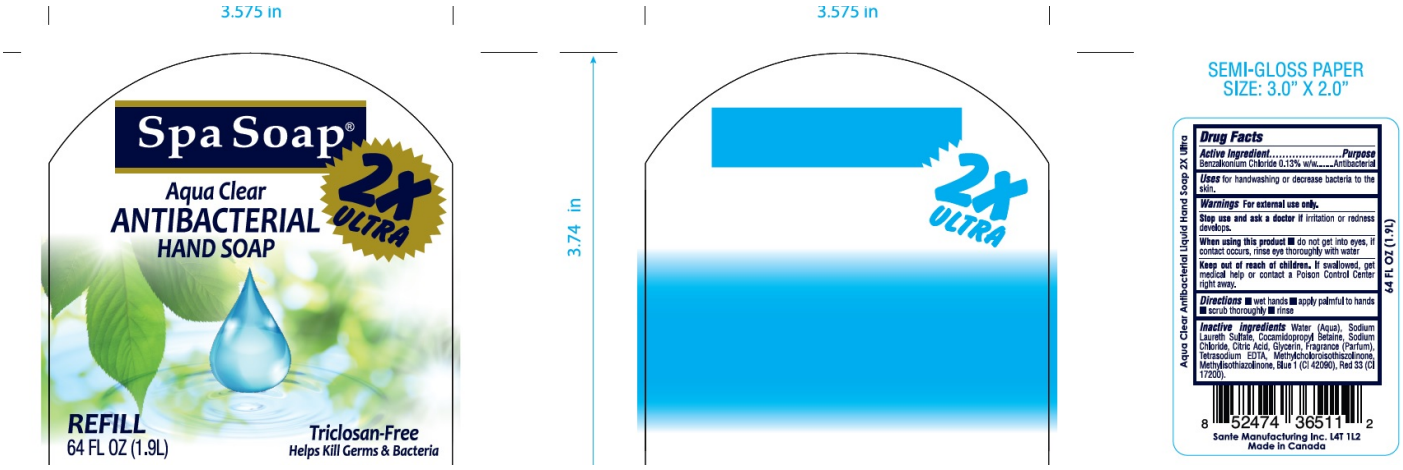
When using this product
- do not get it into eyes. If contact occurs, rinse eye thoroughly with water

Keep out of reach of children

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

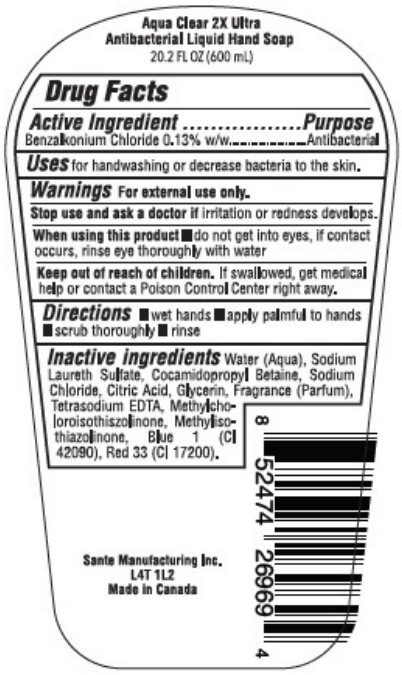
Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1, Red# 4 (CI 14700)

Uses for handwashing or decrease bacteria to the skin



CLEAR FILM
SIZE: 4.15" X 2.4561"

LABEL SIZE: 4.15" X 2.4561"
WHITE BOPP
BACK LABEL



ANTIBACTERIAL AQUA CLEAR 2X ULTRA

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71020-030
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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 BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71020-030-64	1900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2016	
2	NDC:71020-030-30	600 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)

Registrant - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Sante Manufacturing Inc		204348627	manufacture(71020-030)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(71020-030)

Revised: 1/2022 Sante Manufacturing Inc