ANTIBACTERIAL 2X- triclosan 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.

Active Ingredient - Triclosan 0.115%

Purpose - Antibacterial

Uses - for handwashing to decrease bacteria on the skin

Warning For external use only

Stop use and ask a doctor if irritation or redness develops

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

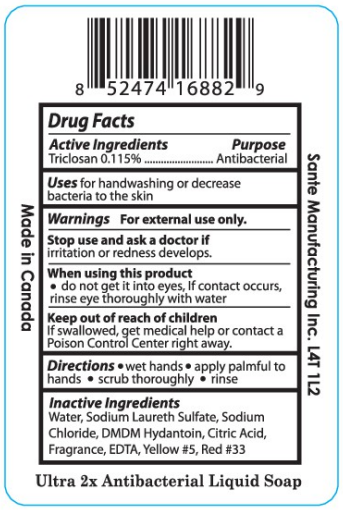
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

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

Water, Sodium Laureth Sulfate, Sodium Chloride, DMDM Hydantoin, Citric Acid, Fragrance, EDTA, Yellow # 5, Red# 33

Clear Area shown as light blue



ANTIBACTERIAL 2X

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71020-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.15 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETIC ACID (UNII: 9G34HU7RV0)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71020-009-64	1900 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/19/2016	

Labeler - Sante Manufacturing Inc (242048747)

Establishment

Name	Address	ID/FEI	Business Operations
Sante Manufacturing Inc		242048747	manufacture(71020-009)

Revised: 10/2016 Sante Manufacturing Inc