

ANTIBACTERIAL- 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 or decrease bacteria to the skin

Warnings 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



Drug Facts		Antibacterial Liquid Soap
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Directions • wet hands • apply palmful to hands • scrub thoroughly • rinse		
Inactive Ingredients		
Water, Sodium Laureth Sulfate, Sodium Chloride, DMDM Hydantoin, Citric Acid, Fragrance, EDTA, Yellow #5, Red #33		Sante Manufacturing Inc. L4T 1L2 Made in Canada

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71020-006
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETIC ACID (UNII: 9G34HU7RV0)	
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:71020-006-16	500 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(71020-006)

Revised: 10/2016

Sante Manufacturing Inc