

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 Ingredients - Triclosan 0.115%

Purpose - Antibacterial

Uses for handwashing or decrease bacteria to the skin

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

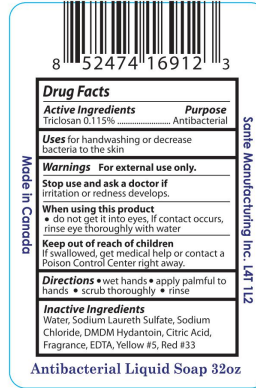
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away

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

Warning For external use only



ANTIBACTERIAL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71020-007
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)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETTIC ACID (UNII: 9G34HU7RV0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71020-007-32	947 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(71020-007)

Revised: 10/2016

Sante Manufacturing Inc