

SPATHERAPY - triclosan lotion
Xiamen Olivee Daily Use Chemical Co., Ltd.

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.

Drug Facts

Inactive Ingredients - Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, DMDM Hydantoin, Benalkonium Chloride, Fragrance, Xanthan Gum, Disodium EDTA, Citric Acid. May contain: CI 14700, CI 17200, CI 19140, CI 42090

Active Ingredient

Triclosan 0,3 %

Purpose

Antibacterial

Use - handwashing to decrease bacteria on skin

Directions - wet hands, work into rich lather - rinse well

Warnings

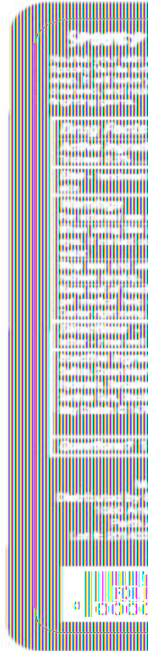
For external use only

When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation and redness develop

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

Questions? 1-800-FDA-1088



SPATHERAPY

triclosan lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 136-0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM50 39 Y5X) (TRICLOSAN - UNII:4NM50 39 Y5X)	TRICLOSAN	.79 g in 293 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6 A3C0 OX)	

DMDM HYDANTOIN (UNII: BYR0546TOW)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56136-010-01	293 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/27/2014	

Labeler - Xiamen Olivee Daily Use Chemical Co., Ltd. (526021375)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Olivee Daily Use Chemical Co., Ltd.		526021375	manufacture(56136-010)

Revised: 4/2014

Xiamen Olivee Daily Use Chemical Co., Ltd.