SPATHERAPY - benzalkonium chloride 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 Clhoride, Fragrance,

Xanthan Gum, Disodium EDTA,

Citiric Acid. May contain: CI 14700, CI 17200, CI 19140, Ci 42090

Active Ingredient

Benzalkonium Chloride 0,2 %

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,

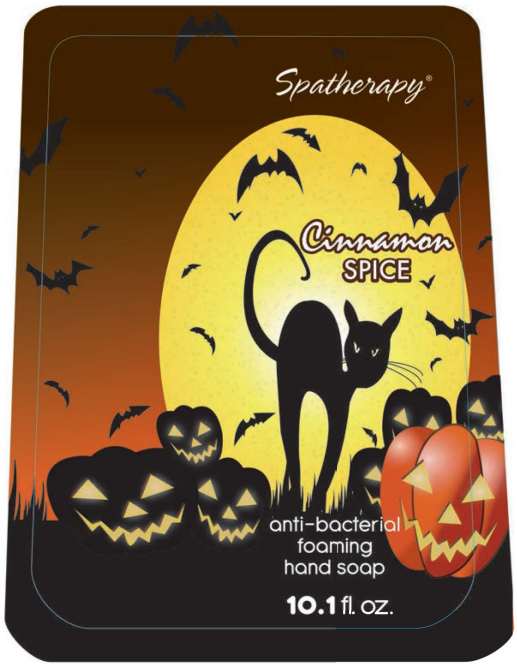
rinse thoroughly with water.

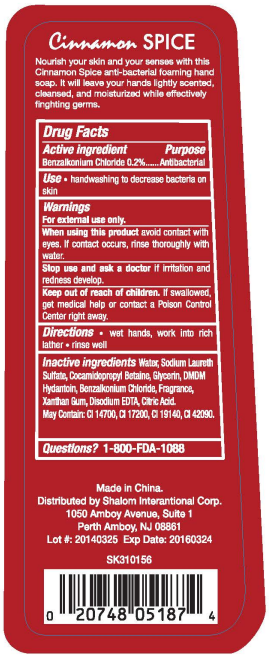
Stop use and ask a doctor if irritation and redness develop

EKeep out of reach of children. If swallowed, get medical help

or contact a Poison Control Center right away.

Questions? 1-800-FDA-1088





SPATHERAPY

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56136-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	.56 g in 293 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

GLYCERIN (UNII: PDC6A3C0OX)	
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: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56136-008-01	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(56136-008)

Revised: 4/2014 Xiamen Olivee Daily Use Chemical Co., Ltd.