

SPATHERAPHY - alcohol 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, Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Triethonamine, Fragrance, PEG-40 Hydrogenated
Castor Oil, May contain:

D C Red 33, FD C Red 4, FD C Yellow 5, FD C Blue 1

Active Ingredient

Alcohol Denat 62 % w/w

Purpose

Antibacterial

Use

- To decrease bacteria on the skin and clean hands
- Recommended for repeated use

Warnings

For external use only

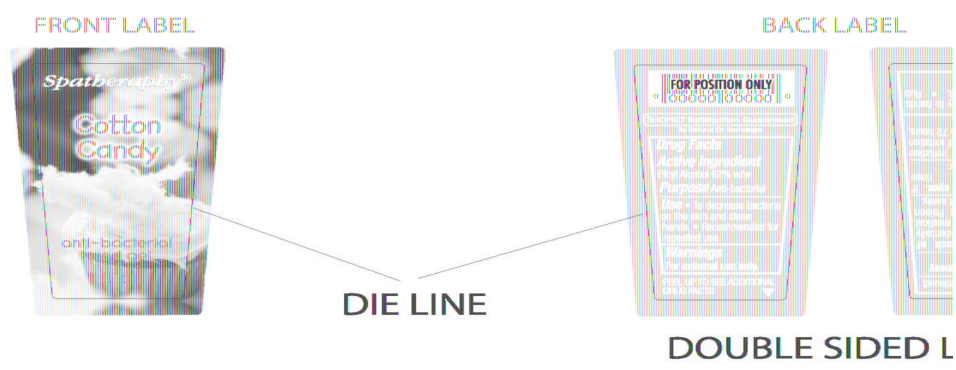
Keep out of reach of children.

If accidentally swallowed, get medical help or
contact a Poison Control Center right away.

Discontinue use if irritation or redness develop. If irritation persists
for more than 72 hours, consult a doctor.

Do not get into eye. If contact occurs, rinse thoroughly with water.

Directions - Apply to hands until thoroughly wet - Rub
vigorously until dry.



SPATHERAPY

alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 136-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	18.6 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YT)	

CASTOR OIL (UNII: D5340Y2I9G)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
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:56136-007-01	30 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/01/2013	

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(56136-007)

Revised: 9/2013

Xiamen Olivee Daily Use Chemical Co., Ltd.