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,

Triethonalamine, 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.

Romatic Fragrances

Passion Bliss: (honeysuckle & jasmine)

FRONT LABEL



BACK LABEL



TRI-FOLD LABEL REMOVABLE LABEL

SPATHERAPHY

alcohol lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56136-004
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: 903K93S3TK)				
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)				

CASTOR OIL (UNII: D5340 Y219 G)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
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:56136-004-01	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 (56 136 - 004)	

Revised: 9/2013 Xiamen Olivee Daily Use Chemical Co., Ltd.