

**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.*

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**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.

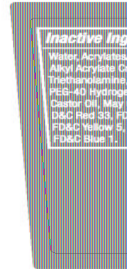
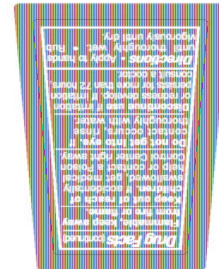
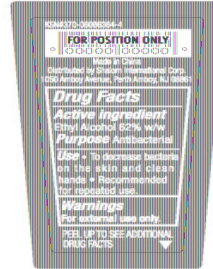
# Romatic Fragrances

Vanilla Kiss:  
(warm vanilla & musk)

FRONT LABEL



BACK LABEL



TRI-FOLD LABEL  
REMOVABLE LABEL

## SPATHERAPY

alcohol lotion

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:56 136-003 |
| Route of Administration | TOPICAL        |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | 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)                                       |          |

|   |  |
|---|--|
| <b>CASTOR OIL</b> (UNII: D5340Y2I9G)            |  |
| <b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)    |  |
| <b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)    |  |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)   |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:56136-003-01 | 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(56136-003) |

Revised: 9/2013

Xiamen Olivee Daily Use Chemical Co., Ltd.