

**ANTI-BACTERIAL HAND CLEANSER- ethyl alcohol liquid**  
**Tri-Coastal Design Company Inc.**

*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**

**Active Ingredient**

Ethyl Alcohol 62%

**Purpose**

Antiseptic

**Uses**

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use

**Warnings**

- For external use only
- Flammable, keep away from fire and flame
- Does not contain grain alcohol; do not drink, if taken internally will produce serious gastric disturbances

**When using this product**

- Avoid the eyes and mucous membranes
- In the case of eyes or mucous membrane contact; rinse area thoroughly with water Use only as directed

**Stop use and ask a doctor if**

- Condition worsens
- Redness or irritation develops
- If condition persists for more than 3 days

**Keep out of reach of children**

If swallowed contact a doctor or Poison Control Center immediately.

**Directions**

- Rub dime sized amount between hands until dry
- Supervise children in the use of this product
- in the case of eye contact, rinse eyes thoroughly with water

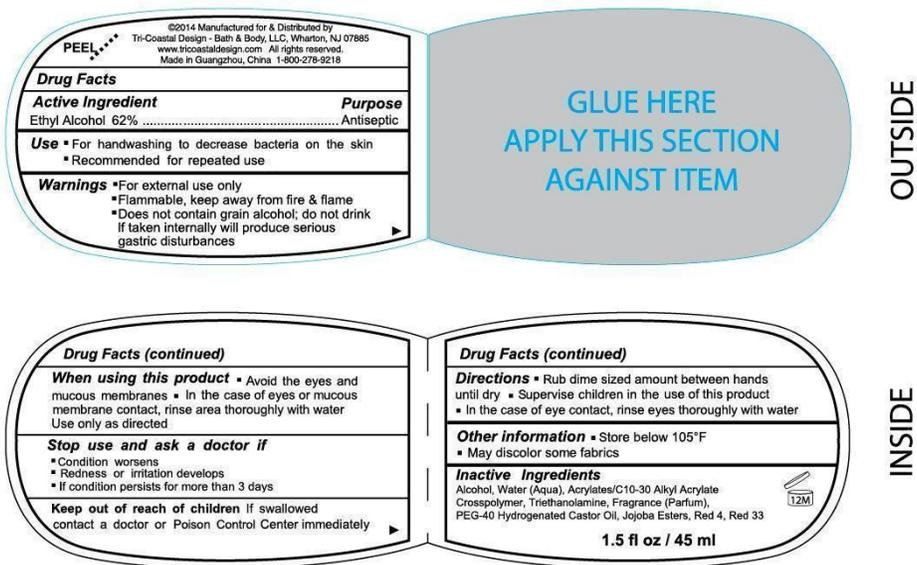
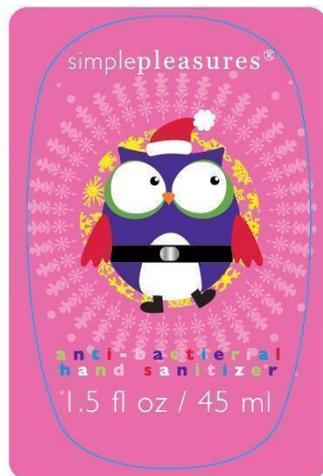
**Other information**

- Store below 105F
- May discolor some fabrics

## Inactive Ingredients

Water (Aqua), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Fragrance (Parfum), PEG-40 Hydrogenated Castor Oil, Jojoba Esters, Red 4, Red 33

## Package Label



## ANTI-BACTERIAL HAND CLEANSER

ethyl alcohol liquid

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49852-301 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 62 g in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R)                                    |          |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) |          |
| TROLAMINE (UNII: 9O3K93S3TK)                                |          |
| POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)      |          |
| HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)     |          |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX)                           |          |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)                           |          |

**Packaging**

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49852-301-30 | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2014           |                    |
| 2 | NDC:49852-301-45 | 45 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2014           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 09/01/2014           |                    |

**Labeler** - Tri-Coastal Design Company Inc. (609734900)**Establishment**

| Name                              | Address | ID/FEI    | Business Operations    |
|-----------------------------------|---------|-----------|------------------------|
| Ganzhou Olivee Cosmetic Co., Ltd. |         | 543008195 | manufacture(49852-301) |

Revised: 1/2018

Tri-Coastal Design Company Inc.