

**PACIFIC ANTI-BACTERIAL HAND CLEANSE STRAWBERRY ESSENCE- triclosan gel
Filo America**

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.

Active Ingredient

Purpose

Triclosan 0.15%.....Antibacterial

Uses

for handwashing to eliminate bacteria and germs on the skin.

Keep away from children, except if under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

Wet hand, apply palmful to hands, scrub thoroughly, Rinse.

Warnings

For external use only.

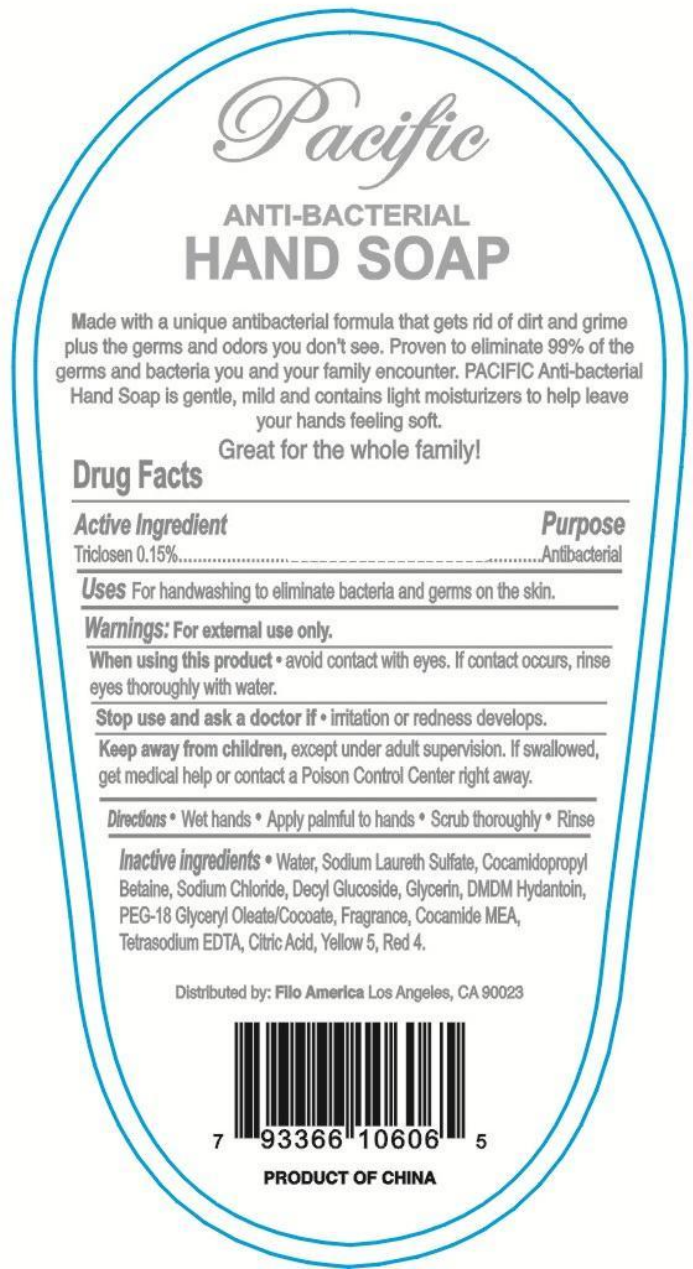
When using this product, avoid contact with eyes, if contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor, if irritation or redness develops

Wet hand, apply palmful to hands, scrub thoroughly, Rinse.

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisoithiazolinone, methylisoithiazolinone, sodium hydroxide, water, cocamide MEA, PEG-18 glyceryl



PACIFIC ANTI-BACTERIAL HAND CLEANSE STRAWBERRY ESSENCE

triclosan gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50438-104 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X) | TRICLOSAN | 1.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| PEG-150 DISTEARATE (UNII: 6F36Q0I0AC) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:50438-104-01 | 500 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 08/08/2013 | |

Labeler - Filo America (943873703)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Ningbo Pulisi Daily Chemical Products Co., Ltd. | | 529047265 | manufacture(50438-104) |

Revised: 8/2013

Filo America