ROYAL ANTIBACTERIAL PASSION PLUM HAND CLEANSE- triclos an 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

 \Box Uses

for handwashing to decrease bacteria on the skin.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

□ Warnings

For external use only.

Avoid getting into eyes. If this happens, rinse thoroughly with water.

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

Inactive Ingredients

camphor, carbomer, ethyl alcohol, fd&c blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water, cocamide MEA, PEG-18 glycaryl





Drug Facts

Active Ingredient

Purpose

Triclosan 0.15%.....

.Antibacterial

Uses For handwashing to decrease bacteria on the skin.

Warnings: for external use only.

Avoid getting into Eyes. If this happens, rinse thoroughly with water.

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: • Wet hands • Apply to hands • Scrub thoroughly • Rinse.

Inactive Ingredients: Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, Sodium Chloride, Glyceryl Cocoate, Fragrance, Polyquaternium-7, Cocamide MEA, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, FD&C Blue 1, FD&C Red 33.

*This product is not manufactured or distributed by Colgate-Palmolive Company, distributor of Softsoap® Brand Aquarium Series Antibacterial Soap.



Distributed by: FILO AMERICA P.O. Box 23592 Los Angeles, CA 90023 Made in China Questions or Concerns? 1.866.460.0322

ROYAL ANTIBACTERIAL PASSION PLUM HAND CLEANSE

triclosan gel

Product Information

Product Type HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:50438-107

Route of Administration

TOPICAL

DEA Schedule

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------------|-------------------|----------------|
| TRICLOSAN (TRICLOSAN) | TRICLOSAN | 1.5 mg in 1 mL |

Inactive Ingredients

| 8 ** ** | | |
|--------------------------------|----------|--|
| Ingredient Name | Strength | |
| WATER | | |
| SODIUM C14-16 OLEFIN SULFONATE | | |
| SO DIUM LAURETH SULFATE | | |
| COCO DIETHANOLAMIDE | | |

| SODIUM CHLORIDE | |
|---------------------------------|--|
| PEG-150 DISTEARATE | |
| CITRIC ACID MONOHYDRATE | |
| GLYCERIN | |
| EDETATE DISO DIUM | |
| .ALPHATO COPHEROL ACETATE | |
| METHYLCHLORO ISO THIAZO LINO NE | |
| FD&C YELLOW NO. 5 | |
| METHYLISOTHIAZOLINONE | |

| Packaging | | | | |
|--------------------|---------------------|-----------------------------|--------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:50438-107-01 | 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 | 09/17/2013 | |
| | | | |

Labeler - Filo America (943873703)

| Establishment | | | |
|---|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| Ningbo Pulisi Daily Chemical Products Co., Ltd. | | 529047265 | manufacture(50438-107) |

Revised: 9/2013 Filo America