MOISTURIZING ANTI-BACTERIAL HAND SOAP - triclosan 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.

Drug Facts

Active Ingredient

 $Triclosan\,0.1\%$

Purpose

Antiseptic

Uses

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

Warnings For external use only

When using this product

- avoid the eyes and mucous membranes
- in the case of eyes or mucous membrane contact; rinse area thoroughly with water

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

- Wet hands, work into a lather. Rinse well
- supervise children in the use of this product
- in the case of eye contact, rinse eyes thoroughly with water

Other information

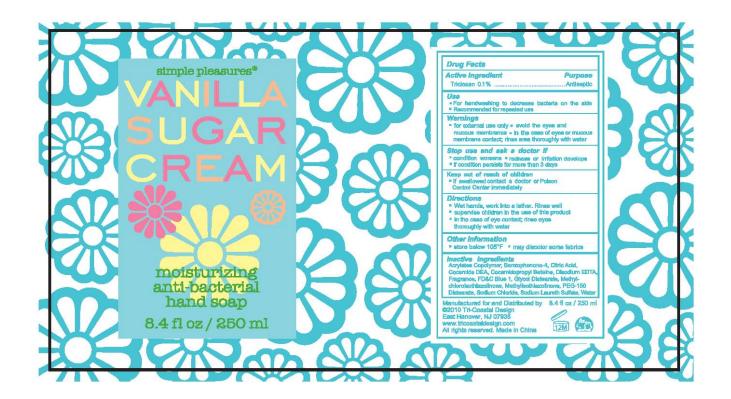
- store below 105F
- may discolor some fabrics

Inactive Ingredients

Acrylates Copolymer, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, FDC Blue 1, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Chloride, Sodium Laureth Sulfate, Water

Package Label

Package Label



MOISTURIZING ANTI-BACTERIAL HAND SOAP

triclosan liquid

| Product Information | | | | | | | | |
|----------------------------------|----------------------------|-----------------------|------------------|------------------|--|--|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) NI | | NDC:49852-004 | | | | |
| Route of Administration | TOPICAL | | | | | | | |
| | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | |
| Ingredient Name | | | Basis of Strengt | h Strength | | | | |
| TRICLOSAN (UNII: 4NM5039Y5X) (TR | ICLOSAN - UNII:4NM5039Y5X) | | TRICLOSAN | 0.1 mL in 100 mL | | | | |
| Inactive Ingredients | | | | | | | | |
| - | | | | Strength | | | | |

| BENZOPHENONE (UNII: 7 | 01M4TTV9O) | | | | | |
|---|---|-------------|---|------|--------------------|--|
| CITRIC ACID MONOHYD | RATE (UNII: 2968PHW8QP) | | | | | |
| COCAMIDOPROPYL BE | F AINE (UNII: 50CF3O11KX) | | | | | |
| EDETATE DISODIUM (UN | III: 7FLD91C86K) | | | | | |
| FD&C BLUE NO.1 (UNII: | H3R47K3TBD) | | | | | |
| METHYLISOTHIAZOLIN | ONE (UNII: 229 D0 E1QFA) | | | | | |
| SODIUM CHLORIDE (UN | I: 451W47IQ8X) | | | | | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | | | | | | |
| WATER (UNII: 059QF0KO | 0 R) | | | | | |
| Packaging | | | | | | |
| # Item Code | Package Description | Marketii | ıg Start Date | Ma | rketing End Date | |
| 1 NDC:49852-004-08 | 250 mL in 1 BOTTLE, PUMP | | | | | |
| Marketing Infor | mation | | | | | |
| 8 | Application Number or Monograph Citation | | Marketing Start Date | | | |
| Marketing Category | Application Number or Monogra | ph Citation | Marketing Start | Date | Marketing End Date | |
| 0 | Application Number or Monogra part333 | ph Citation | Marketing Start 0 2/0 1/20 10 | Date | Marketing End Date | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|----------------------------|
| Guangzhou St Eva Fine Chemical Co Ltd | | 528039793 | manufacture |

Revised: 1/2010

Tri-Coastal Design Company Inc.