# SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND- triclos an soap 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 0.3%

### 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 eye or mucous membrane contact; rinse area thoroughly with water

#### Stop use and ask a doctor if

- condition worsens
- redness or irritation develops
- 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

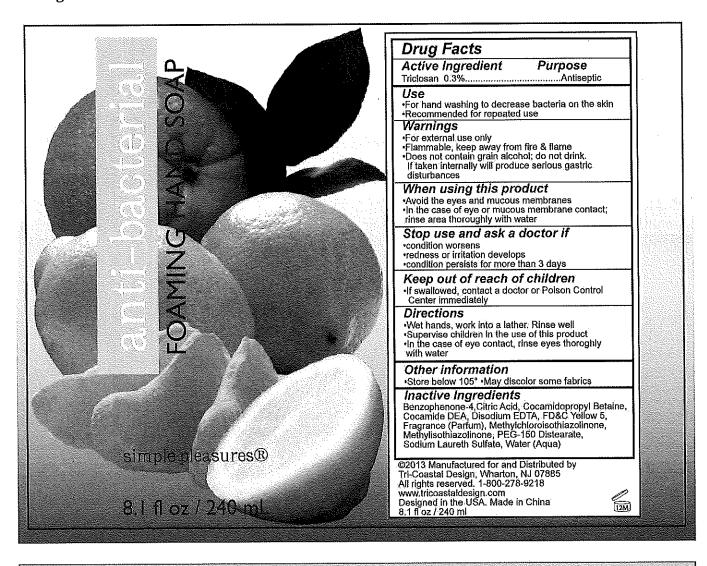
#### Other information

- Store below 105F
- May discolor some fabrics

### **Inactive Ingredients**

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Cocamide DEA, Disodium EDTA, FDC Yellow 5, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Laureth Sulfate, Water (Aqua)

# Package Label



#### SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND triclosan soap **Product Information** NDC:49852-176 HUMAN OTC DRUG Item Code (Source) Product Type TOPICAL Route of Administration Active Ingredient/Active Moiety **Basis of Strength** Strength Ingredient Name TRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X) TRICLOSAN 0.3 g in 100 mL

# **Inactive Ingredients** Ingredient Name Strength BENZOPHENONE (UNII: 701M4TTV9O) CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP) COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX) CO CO DIETHANO LAMIDE (UNII: 92005F972D) EDETATE DISO DIUM (UNII: 7FLD91C86K) FD&C YELLOW NO. 5 (UNII: I753WB2F1M) METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) PEG-150 DISTEARATE (UNII: 6F36Q0I0AC) SODIUM LAURETH SULFATE (UNII: BPV390UAP0) WATER (UNII: 059QF0KO0R) **Packaging** Marketing Start Date **Marketing End Date** Package Description Item Code 240 mL in 1 BOTTLE, PUMP 1 NDC:49852-176-08 **Marketing Information**

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

Establishment Name	Address	s ID/FEI Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793 manufacture(49852-176)

Application Number or Monograph Citation

Revised: 10/2012

Marketing Category

OTC monograph not final part333A

Tri-Coastal Design Company Inc.

Marketing End Date

Marketing Start Date

10/21/2012