# SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND- triclosan 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

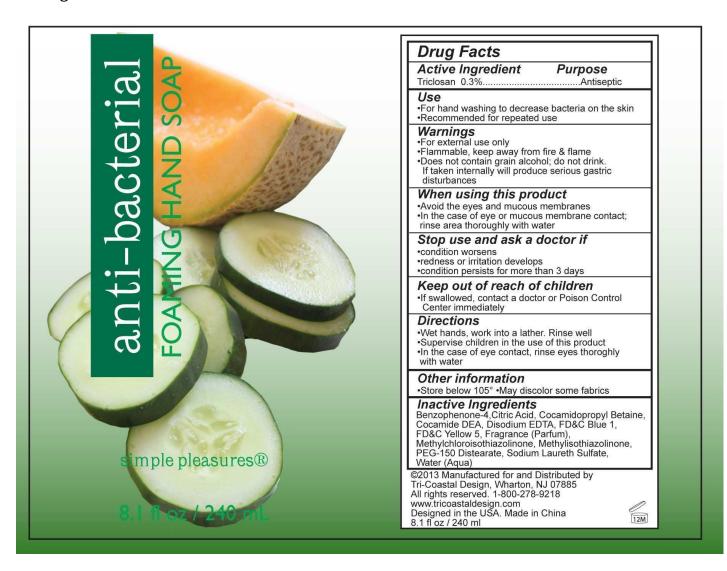
#### Other information

- Store below 105F
- May discolor some fabrics

# **Inactive Ingredients**

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Cocamide DEA, Disodium EDTA, FDC Blue 1, 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				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-173	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZOPHENONE (UNII: 701M4TTV9O)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3O 11KX)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)		
METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)		
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)		
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)		
WATER (UNII: 059QF0KO0R)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:49852-173-08	240 mL in 1 BOTTLE, PUMP			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/21/2012		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture(49852-173)	

Revised: 10/2012 Tri-Coastal Design Company Inc.