

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

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 disturbance

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, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, FDC Blue 1, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Laureth Sulfate, Water (Aqua)

Package Label

anti-bacterial
FOAMING HAND SOAP

simple pleasures®

8.1 fl oz / 240 mL

Drug Facts	
Active Ingredient	Purpose
Triclosan 0.3%	Antiseptic
Use	
<ul style="list-style-type: none"> •For hand washing to decrease bacteria on the skin •Recommended for repeated use 	
Warnings	
<ul style="list-style-type: none"> •For external use only •Flammable, keep away from fire & flame •Does not contain grain alcohol; do not drink. •If taken internally will produce serious gastric disturbances 	
When using this product	
<ul style="list-style-type: none"> •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	
<ul style="list-style-type: none"> •condition worsens •redness or irritation develops •condition persists for more than 3 days 	
Keep out of reach of children	
<ul style="list-style-type: none"> •If swallowed, contact a doctor or Poison Control Center immediately 	
Directions	
<ul style="list-style-type: none"> •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	
<ul style="list-style-type: none"> •Store below 105° •May discolor some fabrics 	
Inactive Ingredients	
Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Cocamide DEA, Disodium EDTA, FD&C Blue 1, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Laureth Sulfate, Water (Aqua)	

©2013 Manufactured for and Distributed by Tri-Coastal Design, Wharton, NJ 07885
All rights reserved. 1-800-278-9218
www.tricoastaldesign.com
Designed in the USA. Made in China
8.1 fl oz / 240 ml

SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-171
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 MONOHYDRATE (UNII: 2968PHW8QP)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
COCO DIETHANOLAMIDE (UNII: 92005F972D)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-171-08	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(49852-171)

Revised: 10/2012

Tri-Coastal Design Company Inc.