

**ANTI-BACTERIAL FOAMING - 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 0.1%

**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**

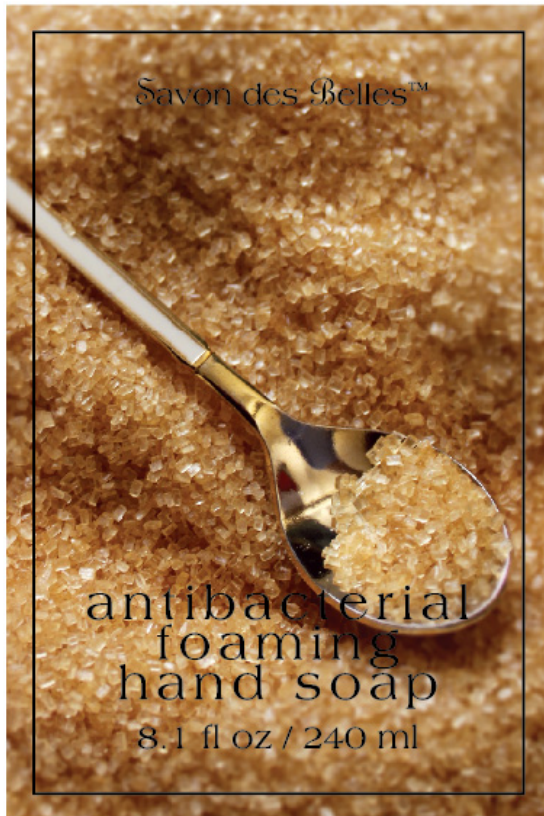
- store below 105F
- may discolor some fabrics

**Inactive Ingredients**

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

**Package Label**

Package Label



<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Triclosan 0.1%.....	Antiseptic
<b>Use</b>	
<input type="checkbox"/> For handwashing to decrease bacteria on the skin <input type="checkbox"/> Recommended for repeated use	
<b>Warnings</b>	
<input type="checkbox"/> For external use only	
<b>When using this product</b>	
<input type="checkbox"/> avoid the eyes and mucous membranes <input type="checkbox"/> in the case of eyes or mucous membrane contact; rinse area thoroughly with water	
<b>Stop use and ask a doctor if</b>	
<input type="checkbox"/> condition worsens <input type="checkbox"/> redness or irritation develops <input type="checkbox"/> if condition persists for more than 3 days	
<b>Keep out of reach of children</b>	
<input type="checkbox"/> If swallowed contact a doctor or Poison Control Center immediately	
<b>Directions</b>	
<input type="checkbox"/> Wet hands, work into a lather. Rinse well <input type="checkbox"/> supervise children in the use of this product <input type="checkbox"/> In the case of eye contact; rinse eyes thoroughly with water	
<b>Other information</b>	
<input type="checkbox"/> store below 105°F <input type="checkbox"/> may discolor some fabrics	
<b>Inactive Ingredients</b>	
Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, FD&C Yellow 5, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Laureth Sulfate, Water	
Manufactured for and Distributed by ©2011 Tri-Coastal Design Wharton, NJ 07885 www.tricoastaldesign.com 1-800-278-9218 All rights reserved. Designed in USA. Made in China 8.1 fl oz / 240 ml	

**ANTI-BACTERIAL FOAMING**

triclosan soap

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49852-016
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.1 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
BENZOPHENONE (UNII: 701M4TTV9O)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
CO CAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (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**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-016-08	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	08/15/2011	

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

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

Revised: 8/2011

Tri-Coastal Design Company Inc.