

**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.*

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**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 Yellow 5, FDC Blue 1, Fragrance, Methylchloroithiazolinone, Methylisothiazolinone, Sodium Chloride, Sodium Laureth Sulfate, Water

**Package Label**  
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<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Triclosan 0.1 %	Antiseptic
<b>Use</b>	
<ul style="list-style-type: none"> <li>For handwashing to decrease bacteria on the skin</li> <li>Recommended for repeated use</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>for external use only - avoid the eyes and mucous membranes - In the case of eye or mucous membrane contact; rinse area thoroughly with water</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>condition worsens</li> <li>redness or irritation develops</li> <li>if condition persists for more than 3 days</li> </ul>	
<b>Keep out of reach of children</b>	
<ul style="list-style-type: none"> <li>If swallowed contact a doctor or Poison Control Center immediately</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Wet hands, work into a lather. Rinse well</li> <li>supervise children in the use of this product</li> <li>In the case of eye contact; rinse eyes thoroughly with water</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>store below 105°F</li> <li>may discolor some fabrics</li> </ul>	
<b>Inactive Ingredients</b>	
Acrylates Copolymer, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, Fragrance, FD&C Yellow 5, FD&C Blue 1, Glycol Distearate, Methylchloroithiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Chloride, Sodium Laureth Sulfate, Water	
Manufactured for and Distributed by 8.4 fl oz / 250 ml ©2010 Tri-Coastal Design East Hanover, NJ 07936 <a href="http://www.tricoastaldesign.com">www.tricoastaldesign.com</a> All rights reserved. Made in China	

**MOISTURIZING ANTI-BACTERIAL HAND SOAP**

triclosan liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49852-006
<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)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-006-08	250 mL in 1 BOTTLE, PUMP		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	02/01/2010	

**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.