MOISTURIZING ANTI-BACTERIAL HAND SOAP - triclos an 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.

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

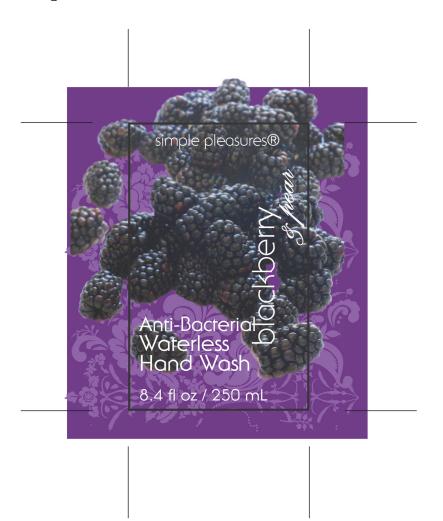
- store below 105F
- may discolor some fabrics

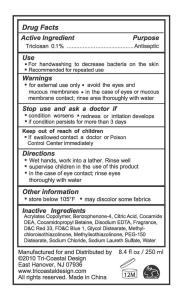
Inactive Ingredients

Acrylates Copolymer, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DC Red 33, FDC Blue 1, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Chloride, Sodium Laureth Sulfate, Water

Package Label

Package Label





MOISTURIZING ANTI-BACTERIAL HAND SOAP

TOPICAL

triclosan liquid

Route of Administration

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-162

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	0.1 mL in 100 mL
--	------------------

Inactive Ingredients		
Ingredient Name	Strength	
BENZOPHENONE (UNII: 701M4TTV9O)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)		
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)		
WATER (UNII: 059QF0KO0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49852-162-08	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.