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.

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 Red 40, DC Red 33, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Chloride, Sodium Laureth Sulfate, Water

Package Label

Package Label



MOISTURIZING ANTI-I triclosan liquid	BACTERIAL HAND	SOAP				
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code	Item Code (Source)		NDC:49852-170	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingree	dient Name		Basis of Strengtl	Streng	th	
TRICLOSAN (UNII: 4NM5039Y5X) (TR	ICLOSAN - 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: 50CF3011KX)						
EDETATE DISO DIUM (UNII: 7FLD91C86K)						
FD&C RED NO. 40 (UNII: WZB9127XOA)						
D&C RED NO.33 (UNII: 9DBA0SBB0L)						
METHYLISOTHIAZOLING	METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)					
SODIUM CHLORIDE (UNI	: 451W47IQ8X)					
SODIUM LAURETH SULF	ATE (UNII: BPV390UAP0)					
WATER (UNII: 059QF0KO0R)						
Packaging						
# Item Code	Package Description	Marketin	ng Start Date	Ma	rketing End Date	
1 NDC:49852-170-08	250 mL in 1 BOTTLE, PUMP					
Marketing Inform	nation					
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date	
OTC monograph not final	part333		0 2/0 1/20 10			

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.