## DERMACEN FOAMING ANTIMICROBIAL-T HAND - triclos an liquid Central Solutions 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 ingredients

Triclosan 0.375%

Purpose

Antimicrobial

Uses

An effective antimicrobial hand cleanser

Kills and inhibits bacterial growth on hands

Gentle cleansers leave hands clean and moisturized

Reduces the possibility of cross-contamination

Warnings

For External Use Only

When using this product

Avoid contact with eyes

Discontinue use if irritation occurs

Keep out of reach of children.

Directions

Use as you would any liquid hand soap.

Wet hands with water, then apply a small amount of product to palm.

Rub hands together vigorously for at least 15 seconds.

Rinse and dry thoroughly.

Inactive ingredients

Purified Water, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Lauramide DEA, Cocamide DEA, Cocamidopropyl Betaine, Sodium Cumene Sulfonate, Propylene Glycol, Citric Acid, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5, Red 4

DermaCen

Foaming Antimicrobial-T

Hand Soap

A foaming antimicrobial

hand soap to decrease bacteria on the skin

Net Contents 8.5 ounces

(251 ml)



triclosan liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62654-239	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.375 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH SULFATE (UNII: BPV390 UAPO)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
LAURIC DIETHANO LAMIDE (UNII: 12912VHG38)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3O11KX)		
SODIUM CUMENESULFO NATE (UNII: 5798 KA13PG)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62654-239-14	251 mL in 1 BOTTLE, PLASTIC		
2	NDC:62654-239-13	1000 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	0 1/0 1/20 0 7		

## Labeler - Central Solutions Inc (007118524)

Establishment				
Name	Address	ID/FEI	Business Operations	
Central Solutions Inc		007118524	manufacture	

Revised: 7/2011 Central Solutions Inc