# ANTIBACTERIAL FOAMING COMPLETE- triclosan liquid TOPCO ASSOCIATES LLC

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 0.46%

## Purpose

Antibacterial

#### Uses

Helps reduce bacteria on the skin.

## **Warnings**

For external use only.

## When using this product

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

#### Stop using this product and ask doctor

If irritation and redness develop.

#### Keep out of reach of children

In case of accidental ingestion, get medical help and contact a Poison Control Center immediately.

#### **Directions**

Pump onto dry hands, work into a lather and rinse thoroughly.

#### Other information

Store at room temperature.

### **Inactive Ingredients**

WATER, SODIUM XYLENESULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE, DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLPARABEN, PROPYLPARABEN, RED 4 (CI 14700), YELLOW 5 (CI 19140).

#### Front and back labels



### ANTIBACTERIAL FOAMING COMPLETE

triclosan liquid

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Prod	nct	Into	rma	tion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-169

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.46 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)				
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)				

COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SO DIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516 E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-169-08	222 mL in 1 BOTTLE, PUMP		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	11/0 1/20 11		

## Labeler - TOPCO ASSOCIATES LLC (006935977)

## Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture	

Revised: 11/2011 TOPCO ASSOCIATES LLC