ANTIBACTERIAL FOAMING - triclos an 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.

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 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

triclosan liquid

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-177

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: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	

SODIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CITRIC ACID MO NO HYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:36800-177-08	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	11/07/2011	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 11/2011 TOPCO ASSOCIATES LLC