ANTIBACTERIAL FOAMING CUCUMBER MELON- 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.

Drug Facts Box - Back Label

Active Ingredient

Triclosan 0.6%

Purpose

Antibacterial

Uses

Helps reduce bacteria on the skin.

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

if irritation and redness develop.

Keep out of reach of children

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

Directions

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

Other information

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Inactive ingredients

Water, Sodium Xylenesulfonate, Dipropylene Glycol, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Fragrance, Disodium Phosphate, Citric Acid, Blue 1 (CI 42090), Yellow 5 (CI 19140), Red 40 (CI 16035).



ANTIBACTERIAL FOAMING CUCUMBER MELON

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-067

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.6 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-067-08	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	09/02/2011	

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: 9/2011 Topco Associates llc