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 0.6 PERCENT

PURPOSE

ANTIBACTERIAL

USES

HELPS REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

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 DEVELOPS AND LASTS.

DIRECTIONS

PUMP ONTO DRY HANDS, WORK INTO A LATHER AND RINSE THOROUGHLY.

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, SODIUM XYLENESULFONATE, SODIUM LAURETH SULFATE, DIPROPYLENE GLYCOL, COCAMIDOPROPYL BETAINE, POLYSORBATE 20, FRAGRANCE, DISODIUM PHOSPHATE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 33 (CI 17200), YELLOW 5 (CI 19140).

FRONT AND BACK LABELS

	Drug Facts Active ingredient Purpose			
	Triclosan 0.6% Antibacterial Uses = Helps reduce bacteria on the skin.			
	Warnings For external use only.			
TopCare.	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.			
ANTIBACTERIAL	Keep out of reach of children I in case of accidental ingestion, get medical help or contact Poison Control Center immediately.			
foaming	Directions = Pump onto dry hands, work into a lather and rinse thoroughly.			
hand soap	Other information = Store at room temperature.			
nanu suap	Other information Store arrowing store arrowing the store arrowing the store arrowing the store arrowing the store of the			
	Methylchloroisothlazolinone, Methyllsottilazolinone, Neu So (of 1720), Yellow 5 (Cl 19140).			
gentle enough for every day	This TOPCARE's product is laboratory bated to guarantee its highest quality. Vour trait something is guaranteed			
BERRY BLAST	MADE IN CANADA DISTRIBUTED BY TOPCO ASSOCIATES LLC			
	7711 GROSS POINT ROAD			
7.5 FL OZ (222 mL)	SKOKIE, IL 6007 (Stored Anasta QUESTIONS? 1-888-423-0139 topcare@topco.com 01-16660			

ANTIBACTERIAL FOAMING triclosan liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source)	
Product Information	
Product Type HUMAN OTC DRUG Item Code (Source)	
	NDC:36800-076
Route of Administration TOPICAL	
Active Ingredient/Active Moiety	
Ingredient Name Basis of Stren	ngth Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)TRICLOSAN	0.6 mL in 100 mL
Inactive Ingredients	
Ingredient Name	Strength
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	
D&C RED NO.33 (UNII: 9DBA0SBB0L) FD&C YELLOW NO.5 (UNII: 1753WB2F1M)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)

METHYLCHLORO ISOTH	HAZOLINONE (UNII: DEL7T5QRPN)							
METHYLISOTHIAZOLIN	ONE (UNII: 229D0E1QFA)							
Packaging								
# Item Code	Package Description	Marketing Start Date Ma		larketing End Date				
1 NDC:36800-076-08	222 mL in 1 BOTTLE, PUMP							
Marketing Information								
0				. .				
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date			
OTC monograph not final	part333E		11/02/2011					

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: 11/2011

TOPCO ASSOCIATES LLC