PRICE CHOPPER PUMPKIN SPICE ANTIBACTERIAL FOAMING- triclos an liquid APOLLO HEALTH AND BEAUTY CARE

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

FOR WASHING TO DECREASE 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 OR REDNESS DEVELOPS AND LASTS MORE THAN 7 DAYS

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

APPLY TO DRY HANDS, WORK INTO A RICH FOAMY LATHER AND RINSE THOROUGHLY

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, POLYSORBATE 20, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-7, FRAGRANCE (PARFUM), PEG-7 GLYCERYL COCOATE, PEG-8, TETRASODIUM EDTA, BHT, BENZOPHENONE-4, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, ORANGE 4 (CI 15510), RED 40 (CI 16035)



Drug Facts

Active ingredient Purpose Triclosan 0.46%....... Antibacterial

Uses ■ For washing to decrease 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 or redness develops and lasts more than 7 days.

Keep out of reach of children. ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions ■ Apply to dry hands, work into a rich foamy lather and rinse thoroughly.

Other information
Store at room temperature.

Inactive ingredients: Water (Aqua), Sodium Laureth Sulfate, Polysorbate 20, Cocamidopropyl Betaine, Polyquaternium-7, Fragrance (Parfum), PEG-7 Glyceryl Cocoate, PEG-8, Tetrasodium EDTA, BHT, Benzophenone-4, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Orange 4 (Cl 15510), Red 40 (Cl 16035).

DISTRIBUTED BY PRICE CHOPPER, INC. SCHENECTADY, NY 12306 www.pricechopper.com

Made in Canada Manufactured By: Apollo Health and Beauty Care



06-19583

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-118	
Route of Administration	TOPICAL			

	Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength		
1	TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	4.6 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SO DIUM LAURETH SULFATE (UNII: BPV390 UAPO)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)			
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
EDETATE SO DIUM (UNII: MP1J8420 LU)			
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)			
SULISOBENZONE (UNII: 1W6L629B4K)			
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63148-118-08	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	06/05/2014		

Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations

20 19 0 120 9 manufacture (6 3 148 - 118)

Revised: 6/2014

APOLLO HEALTH AND BEAUTY CARE