ANTIBACTERIAL FOAMING - triclos an liquid MEIJER DISTRIBUTION INC

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 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, DIPROPYLENE GLYCOL, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, FRAGRANCE, DISODIUM PHOSPHATE, CITRIC ACID, RED 33 (CI 17200), YELLOW 5 (CI 19140).

front and back labels



ANTIBACTERIAL FOA	MING				
riclosan liquid					
-					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:41250-176	
Route of Administration	TOPICAL				
A T 11	• .				
Active Ingredient/Active Mo					
Ingredient Name			Basis of Strength	Strength	
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)			TRICLOSAN	0.6 mL in 100 mL	
Inactive Ingredients					
Inactive Ingredients	Ingredient Name			Strength	
	•			Strength	
SODIUM XYLENESULFONATE (UNI	I: G4LZF950UR)			Strength	
SODIUM XYLENESULFONATE (UNI DIPROPYLENE GLYCOL (UNII: E107	I: G4LZF950UR) /L85C40)			Strength	
SODIUM XYLENESULFONATE (UNI DIPROPYLENE GLYCOL (UNII: E107 AMMONIUM LAURYL SULFATE (UN	I: G4LZF950UR) 7L85C40) NII: Q7AO2R1M0B)			Strength	
SO DIUM XYLENESULFONATE (UNI DIPRO PYLENE GLYCOL (UNII: E107 AMMONIUM LAURYL SULFATE (UN CO CAMIDO PRO PYL BETAINE (UNI	I: G4LZF950UR) 7L85C40) NII: Q7AO2R1M0B) I: 5OCF3O11KX)			Strength	
Inactive Ingredients SODIUM XYLENESULFONATE (UNI DIPROPYLENE GLYCOL (UNII: E107 AMMONIUM LAURYL SULFATE (UN COCAMIDOPROPYL BETAINE (UNI SODIUM PHOSPHATE, DIBASIC, DII CITRIC ACID MONOHYDRATE (UNI	I: G4LZF950UR) 2L85C40) NII: Q7AO2R1M0B) I: 5OCF3O11KX) HYDRATE (UNII: 9425516E2T)			Strength	

FD&C YELLOW NO.5 (UNII: I753WB2F1M)								
WATER (UNII: 059QF0KO	0 R)							
Packaging								
# Item Code	Package Description	Marketin	g Start Date	Ma	arketing End Date			
1 NDC:41250-176-08	221 mL in 1 BOTTLE, PUMP							
Marketing Information								
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date			
OTC monograph not final	part333E		10/21/2011					

Labeler - MEIJER DIST RIBUTION INC (006959555)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 10/2011

MEIJER DISTRIBUTION INC