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.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IF IRRITATION AND REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

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

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, DIPROPYLENE GLYCOL, SODIUM XYLENESULFONATE, COCAMIDOPROPYL BETAINE, POLYSORBATE 20, FRAGRANCE, DISODIUM PHOSPHATE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 4 (CI 14700), YELLOW 5 (CI 19140).

front and back labels





ANTIBACTERIAL FOAMING

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-185

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
TRICLOSAN	(UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)	TRICLOSAN	0.6 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41250-185-08	221 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	10/21/2011	

Labeler - MEJJER 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