AURORA ANTIBACTERIAL COCONUT TROPICAL ISLAND- triclosan 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, FRARANCE (PARFUM), COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-7, PEG-8, PEG-7 GLYCERYL COCOATE, TETRASODIUM EDTA, BHT, BENZOPHENONE-4, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 4 (CI 14700), RED 33 (CI 17200), YELLOW 5 (CI 19140)

LABEL COPY

AURORA ANTIBACTERIAL COCONUT TROPICAL ISLAND

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63148-104
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63148-104-08	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	01/13/2015	

Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(63148-104)

Revised: 1/2015 APOLLO HEALTH AND BEAUTY CARE