ANTIBACTERIAL MANDARIN AND POMELO- triclosan liquid
AMERICAN SALES COMPANY

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 0.15%

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 WITH WATER.

STOP USE AND ASK A DOCTOR IF

IF IRRITATION OR 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 WET HANDS, WORK INTO A LATHER AND RINSE THOROUGHLY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, DECYL GLUCOSIDE, PEG-120 METHYL GLUCOSE DIOLEATE, POLYQUATERNIUM-7, CITRUS GRANDIS (POMELO) EXTRACT, CITRUS NOBILIS (MANDARIN) FRUIT EXTRACT, PEG-7 GLYCERYL COCOATE, FRAGRANCE (PARFUM), PEG-40 HYDROGENATED CASTOR OIL, TETRASODIUM EDTA, DMDM HYDANTOIN, CITRIC ACID, SODIUM CHLORIDE, YELLOW 5 (CI 19140), RED 4 (CI 14700), RED 33 (CI 17200).

ANTIBACTERIAL MANDARIN AND POMELO

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-293
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.15 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
PUMMELO (UNII: ET1TN5W71X)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-293-08	236 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	04/01/2011	

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 4/2011 AMERICAN SALES COMPANY