ANTIBACTERIAL MANDARIN- triclosan solution
TOPCO ASSOCIATES L LLC

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 BOX

ACTIVE INGREDIENT

TRICLOSAN 0.6%

PURPOSE

ANTIBACTERIAL

USES

FOR WASHING TO HELP DECREASE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

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

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

IRRITATION OR RASH DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

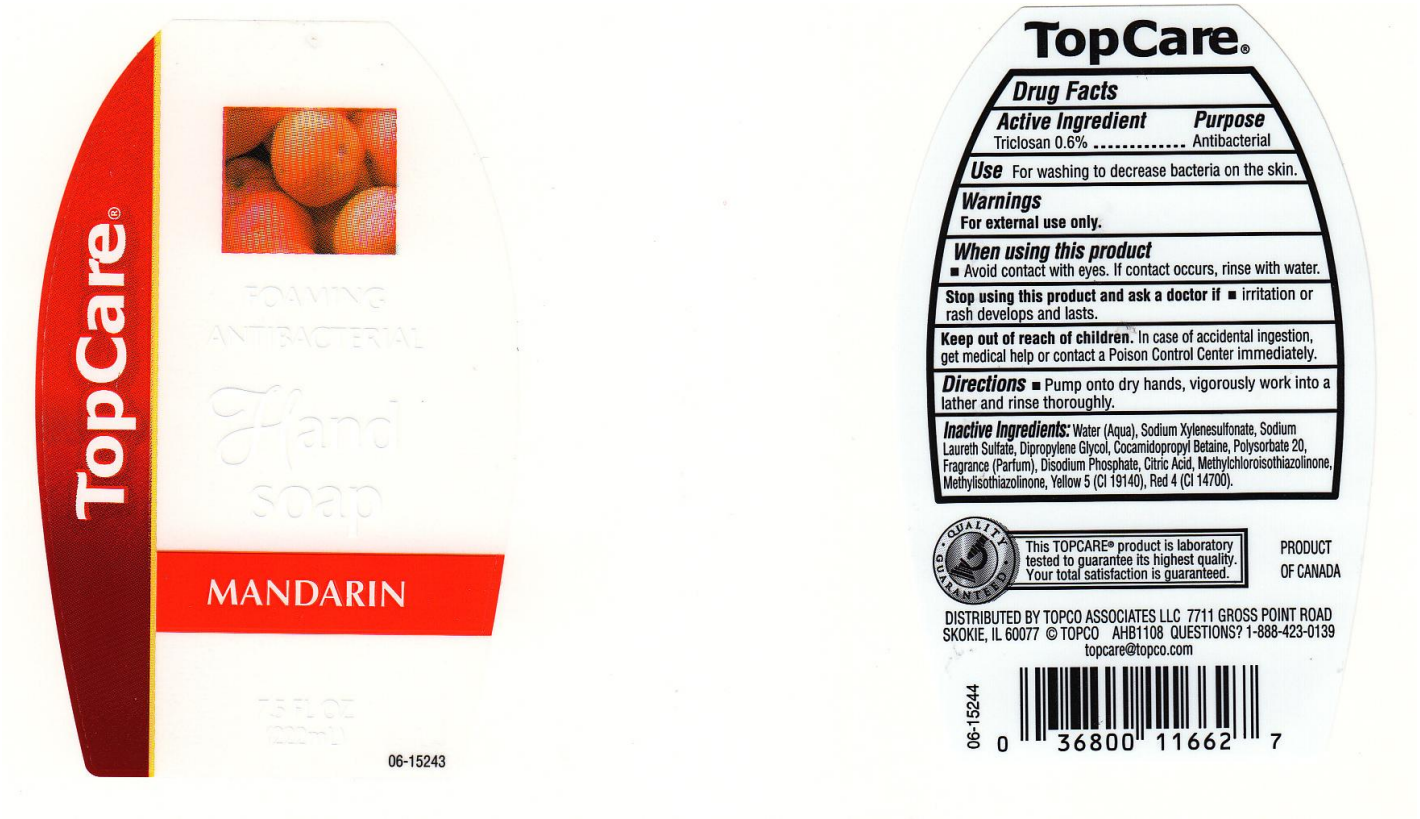
IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

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

INACTIVE INGREDIENTS

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



ANTIBACTERIAL MANDARIN

triclosan solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.6 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-066-08	222 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	08/23/2011	

Labeler - TOPCO ASSOCIATES L LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 8/2011 TOPCO ASSOCIATES L LLC