TOPCO ANTIBACTERIAL- triclosan liquid
TOPCO ASSOCIATES 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

ACTIVE INGREDIENT

TRICLOSAN 0.6%

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 USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR RASH DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

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

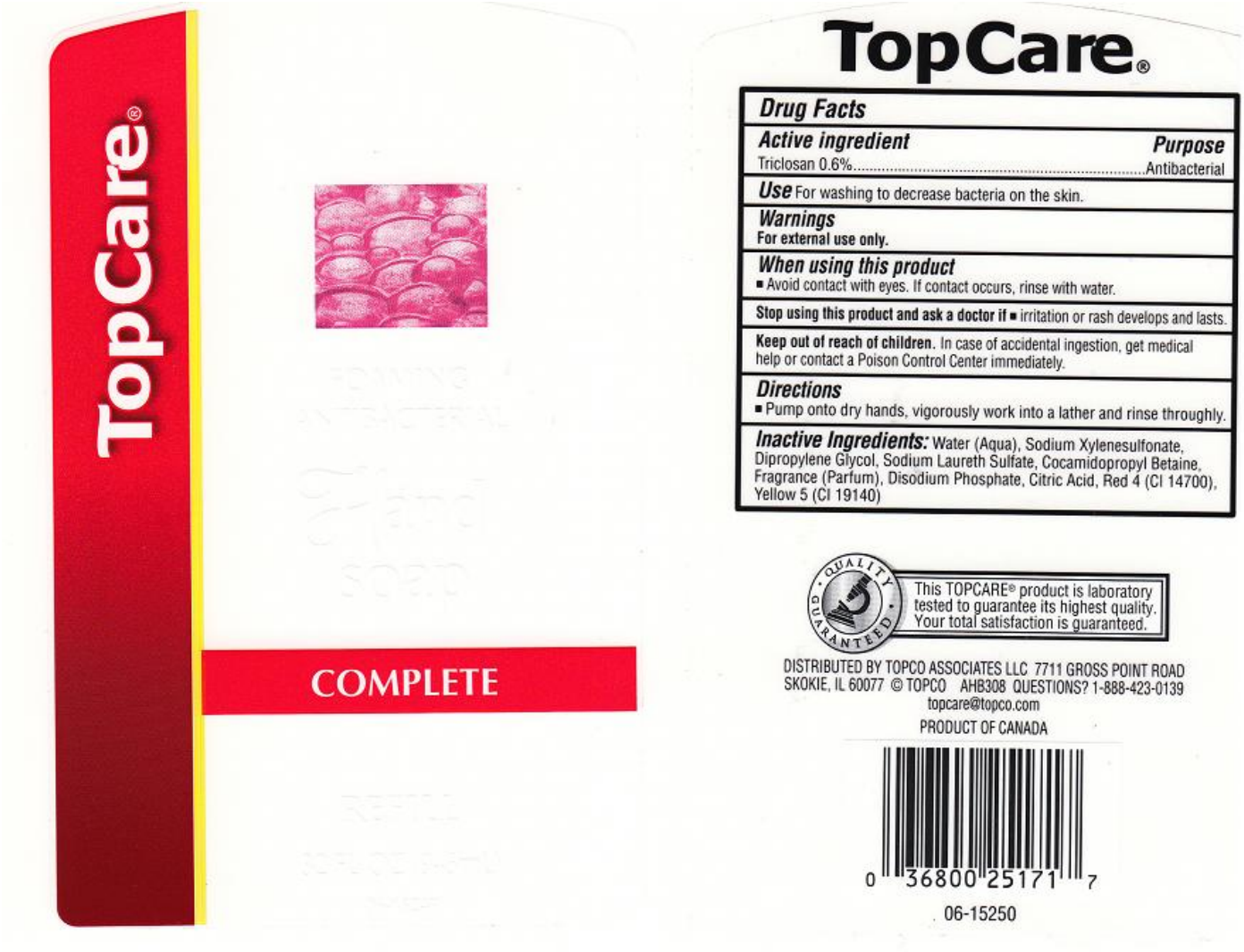
DIRECTIONS

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

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM XYLENESULFONATE, DIPROPYLENE GLYCOL, SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, FRAGRANCE (PARFUM), DISODIUM PHOSPHATE, CITRIC ACID, RED 4 (CI 14700), YELLOW 5 (CI 19140)

LABEL COPY



TOPCO ANTIBACTERIAL

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-178
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 (UNII: SE337SVY37)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-178-32	936 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	11/18/2011	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 11/2011 TOPCO ASSOCIATES LLC