ANTIBACTERIAL FOAMING - 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 0.6%

Purpose

Antibacterial

Uses

For handwashing 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 redness develops and lasts.

Keep out of reach of children

In case of accidental ingestion, get medical help and contact a Poison Control Center immediately.

Directions

- Use only to refill a foaming hand soap pump bottle.
- From pump bottle apply onto dry hands.
- Lather into rich foam and rinse.

Other information

Store at room temperature.

Inactive Ingredients

WATER, SODIUM XYLENE SULFONATE, DIPROPYLENE GLYCOL, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, FRAGRANCE, DISODIUM PHOSPHATE, CITRIC ACID, RED 4 (CI 14700), YELLOW 5 (CI 19140).

ANTIBACTERIAL FOAMING

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-168
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)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
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:41520-168-08	946 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/06/2011	

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: 10/2011 AMERICAN SALES COMPANY