

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 0.46%

Purpose

Antibacterial

Uses

For hand 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 and redness develop.

Keep out of reach of children

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

Directions

Pump onto dry hands, work into a lather and rinse thoroughly.

OTHER INFORMATION

Store at room temperature.

Inactive Ingredients

WATER, SODIUM XYLENE SULFONATE, DIPROPYLENE GLYCOL, GLYCERIN, SODIUM PCA, AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-10, FRAGRANCE, DISODIUM PHOSPHATE, CETYL ALCOHOL, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLPARABEN, PROPYLPARABEN, YELLOW 5 (CI 19140), YELLOW 6 (CI 15985).



ANTIBACTERIAL FOAMING

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-161
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.46 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

METHYL PARABEN (UNII: A218C7H9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-161-08	221 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	05/16/2011	

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: 5/2011

AMERICAN SALES COMPANY