ANTIBACTERIAL FOAMING - triclos an 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, RED 4 (CI 14700), YELLOW 5 (CI 19140).



ANTIBACTERIAL FOAMING

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-169

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthTRICLO SAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)TRICLOSAN0.46 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SO DIUM XYLENESULFO NATE (UNII: G4LZF950 UR)	
DIPRO PYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469OTG57A2)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SO DIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516 E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

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ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-169-08	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		20 19 0 12 0 9	manufacture		

Revised: 5/2011 AMERICAN SALES COMPANY