ANTIBACTERIAL FOAMING FRESH PEAR - triclosan liquid FRED'S INC

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 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 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

Pump onto dry hands, work into a lather. Rinse thoroughly.

Questions or Comments

1-866-322-2439

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, GREEN 3 (CI 42053), YELLOW 10 (CI 47005).

LABEL COPY





ANTIBACTERIAL FOAMING FRESH PEAR

triclosan liquid

Dro	duct	Info	ита	tion
Prn			14114	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55315-184

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: 059QF0KO0R)			
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
GLYCERIN (UNII: PDC6A3C0OX)			
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG 57A2)			
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			

POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-184-08	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	07/08/2011		

Labeler - FRED'S INC (005866116)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

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

Revised: 7/2011 FRED'S INC