ANTIBACTERIAL FOAMING REFILL- triclosan liquid
DZA BRANDS 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 0.46%

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, RED 4 (CI 14700), YELLOW 5 (CI 19140).

ANTIBACTERIAL FOAMING REFILL

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55316-177
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: G4LZF950UR)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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:55316-177-08	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	03/22/2011	

Labeler - DZA BRANDS LLC (090322194)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 3/2011 DZA BRANDS LLC