

ANTIBACTERIAL FOAMING REFILL- triclosan liquid
KMART CORPORATION

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

Use only to refill a foaming hand soap bottle.

From pump bottle apply on to dry hands. Lather and rinse.

Other Information

Store at room temperature.

Inactive Ingredients

WATER, SODIUM XYLENESULFONATE, 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:49738-168
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: PDC6A3C00X)
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: 9425516E2T)
CETYL ALCOHOL (UNII: 936JST6JCN)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
METHYLPARABEN (UNII: A218C7H9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
FD&C RED NO. 4 (UNII: X3W0AMIJLX)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-168-32	944 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	06/02/2011	

Labeler - KMART CORPORATION (008965873)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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