ANTIBACTERIAL 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 0.15%

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 THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION AND REDNESS DEVELOPS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY ONTO WET HANDS, WORK INTO A LATHER, RINSE THOROUGHLY.

QUESTIONS OR COMMENTS

1-800-842-7886

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, COCAMIDROPROPYL BETAINE, SODIUM CHLORIDE, COCAMIDOPROPYL HYDROXYSULTAINE, GLYCERIN, FRAGRANCE, POLYQUATERNIUM-7, PPG-2 HYDROXYETHYL COCO/ISOSTEARAMIDE, DMDM HYDANTOIN, TETRASODIUM EDTA, CITRIC ACID, YELLOW 5 (CI 19140), RED 4 (CI 14700).



ANTIBACTERIAL REFILL

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49738-294

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthTRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)TRICLOSAN0.15 L in 100 L

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				

COCAMIDO PRO PYL HYDRO XYSULTAINE (UNII: 62V75NI93W)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49738-294-08	0.221 L in 1 BOTTLE, PUMP				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333E	06/27/2011				

Labeler - KMART CORPORATION (008965873)

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: 6/2011 KMART CORPORATION