ANTIBACTERIAL MANDARIN AND GRAPEFRUIT- triclos an 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 THROUGHLY 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 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 (Aqua), Sodium Laureth Sulfate, Decyl Glucoside, Cocamidopropyl Betaine, Sodium Chloride, Cocamide MEA, Fragrance (Parfum), PEG-120 Methyl Glucose Dioleate, PEG- 18 Glyceryl Oleate/Cocoate, Aloe Barbadensis Leaf Juice, Polyquaternium-7, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, Red 33 (CI 17200), Yellow 6 (CI 15985).





ANTIBACTERIAL MANDARIN AND GRAPEFRUIT

triclosan liquid

Product Information

HUMAN OTC DRUG Product Type Item Code (Source)

NDC:49738-215

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.15 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)	
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	

1-GLYCERYL MONOOLEATE (UNII: D3AEF6S35P)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:49738-215-08	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	07/07/2011	

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

Revised: 7/2011 KMART CORPORATION