RITE AID RENEWAL ANTIBACTERIAL- triclos an liquid RITE AID 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 USE AND ASK A DOCTOR

IF IRRITATION OR REDNESS DEVELOPS AND LASTS MORE THAN 7 DAYS.

KEEP OUT OF REACH OF CHILDREN

IF INGESTED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

APPLY A SMALL AMOUNT ONTO WET HANDS. WORK INTO A RICH LATHER AND RINSE CLEAN.

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM C14-16 OLEFIN SULFONATE, LAURAMIDE DEA, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, FRAGRANCE (PARFUM), CITRIC ACID, DMDM HYDANTOIN, GLYCERIN, TETRASODIUM EDTA, POLYQUATERNIUM-7, HYDROLYZED SILK PROTEIN, ALOE BARBADENSIS LEAF JUICE, RED 40 (CI 16035), YELLOW 5 (CI 19140), RED 33 (CI 17200).

LABEL COPY





Drug Facts

Active ingredient Triclosan 0.15%.....

bacteria on the skin

Warnings

Drug Facts (continued)

a Poison Control Center right away

Directions - Apply a small amount onto well hands - Work into a rich lather and rinse clean. Uses For hand washing to decrease

Inactive ingredients Water (Aqua), Sodium C14-16 Olefin Sulfonate, Lauramide

DEA, Sodium Chloride, Cocamidopropyl Betaine, Fragrance (Parfum), Citric Acid, DMDM Hydantoin, Glycerin, Tetrasodium EDTA, Polyquaternium-7 Hydrolyzed Silk Protein, Aloe Barbadensis Leaf Juice, Red 40 (Cl 16035), Yellow 5 (Cl 19140), Red 33 (CI 17200).

nore than 7 days. Keep out of reach of children. If

irritation or redness develops and lasts ingested, get medical help or contact

When using this product ■ avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor # If

This product is not manufactured or distributed by Colgate-Palmolive Company, distributor of Softsoap® Antibacterial Hand Soap with Light Moisturizers.

DISTRIBUTED BY: ITE AID, 30 HUNTER LANE CAMP HILL, PA 17011 MADE IN CANADA





RITE AID RENEWAL ANTIBACTERIAL

triclosan liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-2160

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

1	110010 0 11010101101101010		
	Ingredient Name	Basis of Strength	Strength
	TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.5 mg in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) LAURIC DIETHANO LAMIDE (UNII: 12912VHG38) SODIUM CHLORIDE (UNII: 451W47IQ8X) COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX) CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) **DMDM HYDANTO IN (UNII: BYR0546 TOW)** GLYCERIN (UNII: PDC6A3C0OX) EDETATE SODIUM (UNII: MP1J8420LU) POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)

SILK, BASE HYDROLYZED (1000 MW) (UNII: UMQ31C11AY)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

I	Packaging				
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:11822-2160-8	221 mL in 1 BOTTLE, PLASTIC			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	12/21/2012		

Labeler - RITE AID CORPORATION (014578892)

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(11822-2160)	

Revised: 12/2012 RITE AID CORPORATION