RITE AID ANTIBACTERIAL - triclosan soap 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.

Active Ingredient

Triclosan 0.15%

Purpose

Antibacterial

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 or contact a Poison Control Center immediately.

Directions

Apply onto wet hands, work into a lather, rinse thoroughly.

Uses

For washing to decrease bacteria on the skin

Inactive Ingredients

Water (Aqua), Sodium Laureth Sulfate, Ammonium Lauryl Sulfate, Decyl Glucoside, Cocamidopropyl Betaine, Glycerin, Sodium Chloride, PEG-18 Glyceryl Oleate/cocoate, Fragrance (Parfum), Cocamide MEA, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, Yellow 5 (CI 19140), Red 4 (CI 14700)

Package Front and Back Labels

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RITE AID ANTIBACTERIAL

triclosan soap

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-2202

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive	

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822-2202-0	591 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	10/07/2010		

Labeler - RITE AID CORPORATION (014578892)

Revised: 10/2010 RITE AID CORPORATION