SAFEWAY CARE REFILL- triclos an liquid SAFEWAY INC

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

HELPS REDUCE 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 A 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

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

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

LABEL COPY



Drug Facts

Active ingredient

Purpose

Triclosan 0.15 %

. Antibacterial

Uses - Helps reduce 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 a doctor if a 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.

Other information - Store at room temperature.

Inactive ingredients Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Cocamidopropyl Betaine, Cocamidopropyl Hydroxysultaine, Glycerin, Fragrance (Parfum), Polyquaternium-7, PPG-2 Hydroxyethyl Coco/Isostearamide, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, Yellow 5 (Cl 19140), Red 4 (Cl 14700).

DISTRIBUTED BY SAFEWAY INC. P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-SAFEWAY www.safeway.com

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OUR PROMISE
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SAFEWAY CARE REFILL

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:21130-094

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

 Ingredient Name
 Basis of Strength
 Strength

 TRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)
 TRICLOSAN
 1.5 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

SODIUM LAURETH SULFATE (UNII: BPV390UAP0)

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
COCAMIDO PRO PYL HYDRO XYSULTAINE (UNII: 62V75NI93W)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
PPG-2 HYDRO XYETHYL STEARAMIDE (UNII: F92MZG0I1A)	
DMDM HYDANTO IN (UNII: BYR0 546 TOW)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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:21130-094-64	1890 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	11/24/2013					

Labeler - SAFEWAY INC (009137209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment						
Name	Address	ID/FEI	Business Operations			
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(21130-094)			

Revised: 11/2013 SAFEWAY INC