CARE ONE ANTIBACTERIAL TANGERINE SPICE- triclos an liquid AMERICAN SALES COMPANY

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 0.3%

PURPOSE

ANTIBACTERIAL

USES

FOR WASHING TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

STOP USING THIS PRODUCT AND ASK DOCTOR

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

APPLY TO DRY HANDS, WORK INTO A RICH FOAMY LATHER AND RINSE THOROUGHLY.

WATER, SODIUM XYLENESULFONATE, GLYCERIN, DIPROPYLENE GLYCOL, COCAMIDOPROPYL BETAINE, SODIUM LAURETH SULFATE, DISODIUM PHOSPHATE, FRAGRANCE (PARFUM), METHYLPARABEN, PROPYLPARABEN, POLYSORBATE-20, SODIUM PCA, POLYQUATERNIUM-10, TOCOPHERYL ACETATE, CITRIC ACID, CETYL ALCOHOL, RED 33 (CI 17200), ORANGE 4 (CI 15510).

LABEL COPY



Drug Facts

Active ingredient Purpose Triclosan 0.3%...........Antibacterial

Uses ■ For washing to decrease bacteria on the skin.

Warnings

For external use only.

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

Stop using this product and ask dactor ii if irritation or redness develops and lasts more than 7 days.

Keep out of reach of children = In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions - Apply to dry hands, work into a rich fearny lather and rinse thoroughly.

Inactive ingredients: Water, Sodium Xylenesulionate, Glycerin, Dipropylene Glycol, Cocamidopropyl Betaine, Sodlum Laureth Sulfate, Disodium Phosphale, Fragrance (Parlum), Methylparaben, Propylparaben, Polysorbale-20, Sodium PCA, Polyqualernium-10, Tocopheryl Acetate, Citric Acid, Cetyl Alcohol, Red 33 (Cl 17200), Orange 4 (CI 15510).

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CARE ONE ANTIBACTERIAL TANGERINE SPICE

triclosan liquid

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Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-191

Route of Administration TOPICAL

A	ctive	Ingred	lie nt/ <i>E</i>	Active	Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER BUFFALO (UNII: 0 A4PW6 CRAI)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 20 (UNII: 7T1F30 V5YH)	
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469OTG57A2)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	

Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:41520-191-08	237 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	09/27/2012						

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment								
Name	Address	ID/FEI	Business Operations					
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture (41520 - 191)					

Revised: 9/2012 AMERICAN SALES COMPANY