

CARE ONE PEPPERMINT SWIRL- triclosan 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 0.46%

PURPOSE

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 DOCTOR 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 FOAMY LATHER AND RINSE THOROUGHLY

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, DISODIUM LAURETH SULFOSUCCINATE, COCAMIDOPROPYLAMINE OXIDE, POLYSORBATE 20, GLYCERIN, PEG-7 GLYCERYL COCOATE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, TETRASODIUM EDTA, FRAGRANCE (PARFUM), PROPYLENE GLYCOL, CITRIC ACID, ALOE BARBADENSIS LEAF JUICE, BENZOPHENONE-4, HYDROXYPROPYL METHYLCELLULOSE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 33 (CI 17200), RED 4 (CI 14700), BLUE 1 (CI 42090)

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Drug Facts

Active ingredient Purpose
Triclosan 0.46%..... 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 doctor 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 foamy lather and rinse thoroughly.

Other information ■ Store at room temperature.

Inactive ingredients: Water (Aqua), Sodium Laureth Sulfate, Disodium Laureth Sulfosuccinate, Cocamidopropylamine Oxide, Polysorbate 20, Glycerin, PEG-7 Glyceryl Cocoate, Guar Hydroxypropyltrimonium Chloride, Tetrasodium EDTA, Fragrance (Parfum), Propylene Glycol, Citric Acid, Aloe Barbadosensis Leaf Juice, Benzophenone-4, Hydroxypropyl Methylcellulose, Methylchlorisothiazolinone, Methylisothiazolinone, Red 33 (CI 17200), Red 4 (CI 14700), Blue 1 (CI 42090).

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CARE ONE PEPPERMINT SWIRL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM50 39 Y5X) (TRICLOSAN - UNII:4NM50 39 Y5X)	TRICLOSAN	4.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-119-08	237 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	10/27/2013	

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(41520-119)