

CARE ONE ANTIBACTERIAL 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

PURPOSE

ANTIBACTERIAL

USES

FOR WASHING TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

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.

INACTIVE INGREDIENTS:

WATER (AQUA), SODIUM LAURETH SULFATE, DISODIUM LAURETH SULFOCCINATE, COCAMIDOPROPYLAMINE OXIDE, GLYCERIN, SODIUM CHLORIDE, PEG-7 GLYCERYL COCOATE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, TETRASODIUM EDTA, PROPYLENE GLYCOL, POLYSORBATE 60, ALOE BARBADENSIS LEAF JUICE, BENZOPHENONE-4, HYDROXYPROPYL METHYLCELLULOSE, RED 33 (CI 17200), RED 4 (CI 14700), BLUE 1 (CI 42090), METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE.



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 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.

Inactive Ingredients: Water, Sodium Laureth Sulfate, Disodium Laureth Sulfosuccinate, Cocamidopropylamine Oxide, Glycerin, Sodium Chloride, PEG-7 Glyceryl Cocoate, Guar Hydroxypropyltrimonium Chloride, Tetrasodium EDTA, Propylene Glycol, Polysorbate 60, Aloe Barbadensis Leaf Juice, Benzophenone-4, Hydroxypropyl Methylcellulose, Red 33 (CI 17200), Red 4 (CI 14700), Blue 1 (CI 42090), Methylchloroisothiazolinone, Methylisothiazolinone.

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CARE ONE ANTIBACTERIAL PEPPERMINT SWIRL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-193
Route of Administration	TOPICAL		

Active Ingredient/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 (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
CO CAMIDO PROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-193-08	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(41520-193)