

CAREONE LIME BASIL- triclosan liquid
AMERCIAN 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, SODIUM LAURETH SULFATE, POLYSORBATE 20, FRAGRANCE (PARFUM),
COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-7, PEG-8, PEG-7 GLYCERYL COCOATE,
TETRASODIUM EDTA, BHT, BENZOPHENONE-4, CITRIC ACID,
METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090),
YELLOW 5 (CI 19140)

LABEL COPY



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, Sodium Laureth Sulfate, Polysorbate 20, Fragrance (Parfum), Cocamidopropyl Betaine, Polyquaternium-7, PEG-8, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA, BHT, Benzophenone-4, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Yellow 5 (CI 19140).	

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CAREONE LIME BASIL

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	4.6 mg in 1 mL		
Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)				
EDETATE SODIUM (UNII: MP1J8420LU)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
SULISOBENZONE (UNII: 1W6L629B4K)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-106-08	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	02/06/2014		

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(41520-106)