# AURORA ANTIBACTERIAL BASIL KEY LIME- triclos an liquid APOLLO HEALTH AND BEAUTY CARE

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.

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

Made in Canada Distributed by: Apollo Health & Beauty Care, 1 Apollo Place, Toronto ON, M3J 0H2 1-866-695-3030



#### **AURORA ANTIBACTERIAL BASIL KEY LIME**

triclosan liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-106

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	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)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)		
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)		
EDETATE SO DIUM (UNII: MP1J8420LU)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
SULISOBENZONE (UNII: 1W6L629B4K)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)		
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:63148-106-08	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	0 1/13/20 15		

## Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

### Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(63148-106)		

Revised: 1/2015 APOLLO HEALTH AND BEAUTY CARE