# CARE ONE LEMON VERBENA- 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.

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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.

KEEP OUT OF REACH OF CHILDREN

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

#### **DIRECTIONS**

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

#### **INACTIVE INGREDIENTS:**

WATER (AQUA), SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, SODIUM XYLENESULFONATE, PEG-8, FRAGRANCE (PARFUM), POLYSORBATE 20, SODIUM PCA, DISODIUM PHOSPHATE, ALOE BARBADENSIS LEAF JUICE, 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 m if irritation or redness develops and lasts.

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

Directions 
Apply onto dry hands, work into a rich foamy lather, rinse and dry thoroughly.

Inactive ingredients: Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Xylenesulfonate, PEG-8, Fragrance (Parfum), Polysorbate 20, Sodium PCA, Disodium Phosphate, Aloe Barbadensis Leaf Juice, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (Cl 42090), Yellow 5 (Cl 19140).

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### CARE ONE LEMON VERBENA

triclosan liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-199
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRICLO SAN (UNII: 4NM5039 Y5X) (TRICLO SAN - UNII:4NM5039 Y5X)	TRICLOSAN	4.6 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
SO DIUM XYLENESULFO NATE (UNII: G4LZF950 UR)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (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:41520-199-08	237 mL in 1 BOTTLE, PLASTIC		

Marketing Infor	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/20/2013	

## Labeler - AMERICAN SALES COMPANY (809183973)

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

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
APOLLO HEALTH AND BEAUTY CARE		20 19 0 120 9	manufacture(41520-199)

Revised: 2/2013 AMERICAN SALES COMPANY