# CARE ONE SUN KISSED PEAR- 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), SODIUM PCA, DISODIUM PHOSPHATE, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).





## **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.

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), Sodium PCA, Disodium Phosphate, Aloe Barbadensis Leaf Juice, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Yellow 5 (CI 19140).

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06-18455



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-197
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)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469 OTG57A2)	
SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MO NO HYDRATE (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)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-197-08	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	02/20/2013		

## 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(41520-197)	

Revised: 2/2013 AMERICAN SALES COMPANY