

**CARE ONE PINE- 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.*

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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, COCAMIDOPROPYL BETAINE, FRAGRANCE (PARFUM), POLYQUATERNIUM-7, PEG-7 GLYCERYL COCOATE, PEG-8, TETRASODIUM EDTA, BHT, BENZOPHENONE-4, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140), RED 40 (CI 16035).

**LABEL COPY**



Drug Facts	
Active ingredient	Purpose
Triclosan 0.46%.....	Antibacterial
<b>Uses</b> ■ 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.	
<b>Directions</b> ■ Apply to dry hands, work into a rich foamy lather and rinse thoroughly.	
<b>Other information</b> ■ Store at room temperature.	
<b>Inactive ingredients:</b> Water (Aqua), Sodium Laureth Sulfate, Polysorbate 20, Cocamidopropyl Betaine, Fragrance (Parfum), Polyquaternium-7, PEG-7 Glyceryl Cocoate, PEG-8, Tetrasodium EDTA, BHT, Benzophenone-4, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Yellow 5 (CI 19140), Red 40 (CI 16035).	

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CARE ONE PINE			
triclosan liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-121
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: 5OCF3011KX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-121-08	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	10/27/2013	

**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(41520-121)

Revised: 10/2013

AMERICAN SALES COMPANY