

CARE ONE VANILLA APPLE BLOSSOM- 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.

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, RED 33 (CI 17200), 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, Red 33 (CI 17200), Blue 1 (CI 42090), Yellow 5 (CI 19140).

DISTRIBUTED BY
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 LANDOVER, MD 20785
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06-18453

CARE ONE VANILLA APPLE BLOSSOM			
triclosan liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-198
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: 059QF0K00R)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)				
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-198-08	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(41520-198)

Revised: 2/2013

AMERICAN SALES COMPANY