CARE ONE VANILLA BEAN- 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.

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

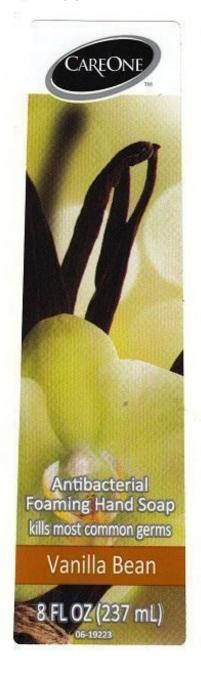
OTHER INFORMATION

STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, PEG-40 HYDROGENATED CASTOR OIL, COCAMIDOPROPYL BETAINE, POLYQUATERNIUM-7, FRAGRANCE (PARFUM), PEG-7 GLYCERYL COCOATE, PEG-8, TETRASODIUM EDTA, BENZOPHENONE-4, BHT, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYCINNAMATE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, EXT. VIOLET 2 (CI 60730), RED 33 (CI 17200), 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 in 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 feamy lather and rinse thoroughly.

Other information
Store at room temperature.

Inactive ingredients: Water (Aqua), Sodium Laureth Sufate, PEG-40 Hydrogenated Castor Oil, Cocamidopropyl Betaine, Polyquaternium-7, Fragrance (Parfum), PEG-7 Glyceryl Cocoate, PEG-8, Tetrasodium EDTA, Benzophenone-4, BHT, Pentaerythrityl Tetra-Di-t-Butyl Hydroxyhydrocinnamate, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Ext. Violet 2 (Cl 60730), Red 33 (Cl 17200), Yellow 5 (Cl 19140).

DISTRIBUTED BY
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
1-877-846-9949
© 2013 S&S Brands, LLC - Made in Canada
Quality guaranteed or your money back.



CARE ONE VANILLA BEAN

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-116

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	ricave ingredient reave intolety		
	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: BPV390 UAP0)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
EDETATE SO DIUM (UNII: MP1J8 420 LU)	
SULISOBENZONE (UNII: 1W6L629B4K)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PRO PIO NATE) (UNII: 255PIF62MS)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
D&C VIOLET NO. 2 (UNII: 350 KA7O6 HK)	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41520-116-08	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(41520-116)	

Revised: 10/2013 AMERICAN SALES COMPANY