CAREONE VANILLA BROWN SUGAR- 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 WASHIG 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 A 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, SODIUM LAURETH SULFATE, DISODIUM LAURETH SULFOSUCCINATE, COCAMIDOPROPYLAMINE OXIDE, PPG-1-PEG-9 LAURYL GLYCOL ETHER, FRAGRANCE (PARFUM), PEG-7 GLYCERYL COCOATE, BENZOPHENONE-4, GLYCERIN, TETRASODIUM EDTA, SODIUM CHLORIDE, BENZYL ALCOHOL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, CAMELLIA SINENSIS LEAF EXTRACT, ALOE BARBADENSIS LEAF JUICE, VANILLA PLANIFOLIA FRUIT EXTRACT, PROPYLENE GLYCOL, HYDROXYPROPYL METHYLCELLULOSE, CITRIC ACID, SODIUM HYDROXIDE,

METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, YELLOW 5 (CI 19140), RED 33 (CI 17200), BLUE 1 (CI 42090)

LABEL COPY





CAREONE VANILLA BROWN SUGAR

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-107
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)	
DISO DIUM LAURETH SULFO SUCCINATE (UNII: D6 DH1DTN7E)	
COCAMIDO PRO PYLAMINE O XIDE (UNII: M4SL82J7HK)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
SULISOBENZONE (UNII: 1W6L629B4K)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
VANILLA (UNII: Q74T35078H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-107-08	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	02/06/2014	

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41520-107)

Revised: 2/2014 AMERICAN SALES COMPANY