CARE ONE CREAMY COCONUT- 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.

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), POLYSORBATE 20, SODIUM PCA, DISODIUM PHOSPHATE, ALOE BARBADENSIS LEAF JUICE, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE.

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 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), Polysorbate 20, Sodium
PCA, Disodium Phosphate, Aloe
Barbadensis Leaf Juice, Citric
Acid, Methylchloroisothiazolinone,
Methylisothiazolinone.

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06-18457



CARE ONE CREAMY COCONUT

triclosan liquid

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-196
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: BPV390 UAPO)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3O11KX)			
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
SODIUM PYRROLIDONE CARBO XYLATE (UNII: 469 OTG57A2)			
SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5 QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-196-08	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(41520-196)	

Revised: 2/2013 AMERICAN SALES COMPANY