TOPCARE COCONUT CREAM- ethyl alcohol liquid TOPCO ASSOCIATES LLC

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

ETHYL ALCOHOL 62%

PURPOSE

ANTISEPTIC

USES

TO DECREASE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM SOURCE OF HEAT OR FIRE.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE 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 COPNTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY.

OTHER INFORMATION

STORE AT A TEMPERATURE BELOW 110F (43C).

INACTIVE INGREDIENTS:

WATER (AQUA), FRAGRANCE (PARFUM), PROPYLENE GLYCOL, CARBOMER, GLYCERIN, AMINOMETHYL PROPANOL, ISOPROPYL MYRISTATE, ALOE BARBADENSIS LEAF JUICE, TOCOPHERYL ACETATE, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE.

QUESTIONS OR COMMENTS?

1-888-423-0139

LABEL COPY



TopCare.

ANTIBACTERIAL hand sanitizer

with moisture beads

COCONUT CREAM

8.75 FL OZ (259mL)

06-18308

Drug Facts

Active ingredient Ethyl Alcohol 62%

Purpose.... Antiseptic

Uses ■To decrease bacteria on the skin.

Warnings For external use only. Flammable. Keep away from source of heat or fire.

When using this product

 avoid contact with eyes. If contact occurs, rinse with

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 - Wet hands thoroughly and rub together until dry.

Other information - Store at a temperature below 110°F (43°C).

Inactive ingredients:

Water (Aqua), Fragrance (Parfum), Propylene Glycol, Carbomer, Glycerin, Aminomethyl Propanol, Isopropyl Myristate, Aloe Baroadensis Leaf Juice, Tocopheryl Acetate, Mannitol, Cellulose, Hydroxypropyl Methylcellulose.

Questions or comments? 1-888-423-0139

MADE IN CANADA DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 1-888-423-0139 @TOPCO AHB1112 topcare@topco.com



06-18309

TOPCARE COCONUT CREAM

ethyl alcohol liquid

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-464

Route of Administration

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-464-09	259 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	03/19/2012	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture(36800-464)	

Revised: 3/2013 TOPCO ASSOCIATES LLC