

CAREONE TAHITIAN COCONUT- ethyl alcohol 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

ETHYL ALCOHOL 65%

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 SECTION

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER

STOP USING THIS PRODUCT AND ASK A 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 A SMALL AMOUNT TO YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 YEARS OLD SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

OTHER INFORMATION

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

INACTIVE INGREDIENTS

WATER, FRAGRANCE (PARFUM), CARBOMER, GLYCERIN, ISOPROPYL ALCOHOL, PROPYLENE GLYCOL, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, BENZOPHENONE-4, AMINOMETHYL PROPANOL, TOCOPHERYL ACETATE, IRON OXIDES (CI 77491, CI 77492, CI 77499), RED 4 (CI 14700), RED 33 (CI 17200), YELLOW 5 (CI 19140)

LABEL COPY



<p>Drug Facts</p> <p>Active ingredient Ethyl Alcohol 65%</p> <p>Purpose.... Antiseptic</p> <p>Uses • To decrease bacteria on the skin.</p> <p>Warnings <ul style="list-style-type: none"> • For external use only. • Flammable. Keep away from source of heat or fire. </p> <p>When using this product <ul style="list-style-type: none"> • avoid contact with eyes. If contact occurs, rinse with water. </p> <p>Stop using this product and ask doctor if • irritation or redness develops and lasts.</p> <p>Keep out of reach of children. • In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.</p> <p>Directions • Apply a small amount to your palm and rub hands together briskly until dry. • Children under 6 years old should be supervised when using this product</p> <p>Other information • Store at a temperature below 110°F (43°C).</p> <p>Inactive ingredients: Water, Fragrance (Parfum), Carbomer, Glycerin, Isopropyl Alcohol, Propylene Glycol, Mannitol, Cellulose, Hydroxypropyl Methylcellulose, Benzophenone-4, Aminomethyl Propanol, Tocopheryl Acetate, Iron Oxides (CI 77491), CI 77492, CI 77499, Red 4 (CI 14700), Red 33 (CI 17200), Yellow 5 (CI 19140).</p>
--

*Effective at eliminating over 99.99% of many common harmful germs and bacteria in as little as 30 seconds.

DISTRIBUTED BY FOODHOLD U.S.A., LLC
 LANDOVER, MD 20785 • 1-877-846-9949
 © 2014 S&S Brands, LLC • Made in Canada
 Quality guaranteed or your money back.



CAREONE TAHITIAN COCONUT

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-401

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	CARBOMER 934 (UNII: Z135WT9208)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	ISOPROPYL ALCOHOL (UNII: ND2M416302)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	MANNITOL (UNII: 3OWL53L36A)			
	POWDERED CELLULOSE (UNII: SMD1X3XO9M)			
	HYPROMELLOSES (UNII: 3NXW29V3WO)			
	SULISOBENZONE (UNII: 1W6L629B4K)			
	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
	FERRIC OXIDE RED (UNII: 1K09F3G675)			
	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
	FERROSFERRIC OXIDE (UNII: XM0M87F357)			
	FD&C RED NO. 4 (UNII: X3W0AM1JLX)			
	D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-401-09	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	02/06/2014	

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(41520-401)

