

CAREONE COUNTRY APPLE- 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 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 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), RED 33 (CI 17200), RED 40 (CI 16035), YELLOW 5 (CI 19140)

LABEL COPY



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 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 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), Red 33 (CI 17200), Red 40 (CI 16035), Yellow 5 (CI 19140)

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

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CAREONE COUNTRY APPLE

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-410	
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)				
SULIBENZONE (UNII: 853Z42ZYAS)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-410-09	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	02/20/2014		

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(41520-410)

