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.

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 room temperature below 110°F (43°C)

Inactive ingredients

Water (Aqua), Fragrance (Parfum), Carbomer, Aminomethyl Propanol, Tocopheryl Acetate, Isopropyl Alcohol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Glycerin, Mannitol, Cellulose, Hydroxypropyl Methylcellulose, Iron Oxides (CI 77491), Red 33 (CI 17200), Red 40 (CI 16035), Yellow 5 (CI 19140).

Label Copy

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)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
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:41520-410-08	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2017	
2	NDC:41520-410-03	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/16/2017	

Labeler - American Sales Company (809183973)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(41520-410)

Revised: 5/2017 American Sales Company