

CAREONE ANTIBACTERIAL SANITIZER LIMONCELLO- 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 use 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

- put enough product in your palm to cover hands and rub hands together until dry.
- children under 6 years should be supervised when using this product.

Inactive ingredients

Water (Aqua), Fragrance (Parfum), Carbomer, Glycerin, Isopropyl Alcohol, Isopropyl Myristate, Aminomethyl Propanol, Aloe Barbadensis Leaf Juice, Mannitol, Cellulose, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Chromium Hydroxide Green (CI 77289), Blue 1 (CI 42090), Yellow 5 (CI 19140).

Label Copy



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

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CAREONE ANTIBACTERIAL SANITIZER LIMONCELLO

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-411
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: 059QF0K00R)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-411-03	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/25/2017	

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(41520-411)

Revised: 4/2017

American Sales Company