

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 I 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), PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, CARBOMER, AMINOMETHYL PROPANOL, BENZOPHENONE-4, GLYCERIN, TOCOPHERYL ACETATE, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, FRAGRANCE (PARFUM), CHROMIUM HYDROXIDE GREEN (CI 77289), BLUE 1 (CI 42090), YELLOW 5 (CI 19140)

LABEL COPY



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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
SULISOBENZONE (UNII: 1W6L629B4K)	

GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
MANNITOL (UNII: 3OWL53L36A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
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:41520-411-02	59 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	03/03/2015	

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(41520-411)

Revised: 3/2015

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