

**CAREONE ANTIBACTERIAL SANITIZER FRESH WATER- 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 HELP 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 THOROUGHLY WITH WATER

STOP USING 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 HAND TOGETHER UNTIL DRY
- CHILDREN UNDER 6 YEARS SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

OTHER INFORMATION

- STORE AT A TEMPERATURE BELOW 110°F (43°C)
- MAY DISCOLOR CERTAIN FABRICS OR SURFACES

INACTIVE INGREDIENTS

WATER (AQUA), PROPYLENE GLYCOL, ISOPROPYL ALCOHOL, CARBOMER, AMINOMETHYL PROPANOL, GLYCERIN, FRAGRANCE (PARFUM), BENZOPHENONE-4,

POLYETHYLENE, ULTRAMARINES (CI 77007), BLUE 1 (CI 42090), RED 33 (CI 17200)

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CAREONE ANTIBACTERIAL SANITIZER FRESH WATER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-412
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
SULISOBENZONE (UNII: 1W6L629B4K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-412-02	59 mL in 1 BOTTLE, PLASTIC		
2	NDC:41520-412-09	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	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(41520-412)

Revised: 3/2015

AMERICAN SALES COMPANY