CAREONE APPLE BERRY- 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

APPLY A SMALL AMOUNT TO YOU PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 YEARS OLD SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

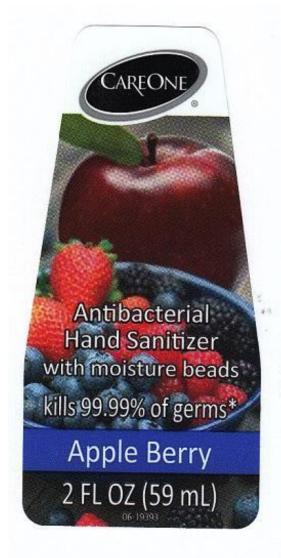
OTHER INFORMATION

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, IRON OXIDES (CI 77491), BLUE 1 (CI 42090), RED 33 (CI 17200), YELLOW 5 (CI 19140)

LABEL COPY





CAREONE APPLE BERRY

ethyl alcohol liquid

P	ro	duct	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-424

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: 6 DC9 Q16 7 V3)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SULIBENZONE (UNII: 853Z42ZYAS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41520-424-02	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	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(41520-424)		

Revised: 2/2014 AMERICAN SALES COMPANY