CARE ONE PINE- 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 YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 YEARS OLD SHOULD BE SUPERVISED WHEN USING THIS PRODUCT

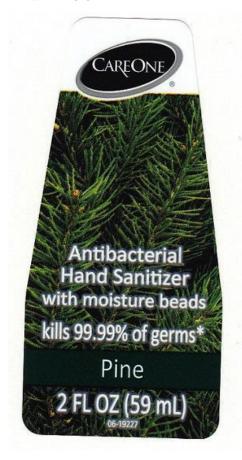
OTHER INFORMATION

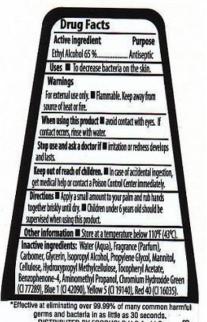
STORE AT A TEMPERATURE BELOW 110°F (43°C)

INACTIVE INGREDIENTS

WATER (AQUA), FRAGRANCE (PARFUM), CARBOMER, GLYCERIN, ISOPROPYL ALCOHOL, PROPYLENE GLYCOL, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, TOCOPHERYL ACETATE, BENZOPHENONE-4, AMINOMETHYL PROPANOL, CHROMIUM HYDROXIDE GREEN (CI 77289), BLUE 1 (CI 42090), YELLOW 5 (CI 19140) RED 40 (CI 16035)

LABEL COPY







CARE ONE PINE

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-499

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (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: 6DC9Q167V3)			
MANNITOL (UNII: 3OWL53L36A)			
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
SULISOBENZONE (UNII: 1W6L629B4K)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CHROMIUM HYDRO XIDE GREEN (UNII: RV8FT8XF5R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-499-02	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	10/27/2013		

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(41520-499)	

Revised: 10/2013 AMERICAN SALES COMPANY