CAREONE ANTIBACTERIAL SANITIZER PEPPERMINT CANDY- 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

WARNING

FOR EXTERNAL USE ONLY.

- FLAMMABLE
- KEEP AWAY FROM SOURCE OF HEAT AND FIRE

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONATCT 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), PROPYLENE GLYCOL, ISOPROPYL ALCOHOL, CARBOMER, AMINOMETHYL PROPANOL, BENZOPHENONE-4, GLYCERIN, FRAGRANCE (PARFUM), MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, TOCOPHERYL ACETATE, IRON OXIDES (CI 77491), BLUE 1 (CI 42090), RED 40 (CI 16035).

LABEL COPY





CAREONE ANTIBACTERIAL SANITIZER PEPPERMINT CANDY

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-420

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (50 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) SULISOBENZONE (UNII: 1W6L629B4K) GLYCERIN (UNII: PDC6A3C0OX) MANNITOL (UNII: 3OWL53L36A)

PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:41520-420- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333E	06/23/2015				

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(41520-420)			

Revised: 6/2015 AMERICAN SALES COMPANY