CAREONE ANTIBACTERIAL SANITIZER PECAN PUMPKIN PIE- 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 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, IRON OXIDES (CI 77491, CI 77492, CI 77499), BLUE 1(CI 42090), RED 40 (CI 16035), YELLOW 5 (CI 19140)

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CAREONE ANTIBACTERIAL SANITIZER PECAN PUMPKIN PIE

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-421

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)ALCOHOL650 mg in 1 mL

Inactive Ingredients				
Strength				

PO WDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:41520-421- 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 - 421)				

Revised: 6/2015 AMERICAN SALES COMPANY