CARE ONE 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

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

WARNINGS

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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

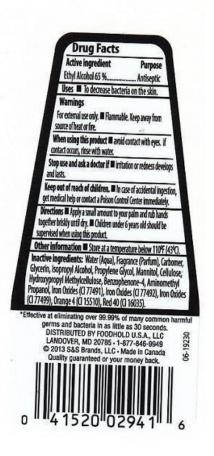
STORE AT A TEMPERATURE BELOW 110°F (43°C)

INACTIVE INGREDIENTS

WATER (AQUA), FRAGRANCE (PARFUM), CARBOMER, GLYCERIN, ISOPROPYL ALCOHOL, PROPYLENE GLYCOL, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, BENZOPHENONE-4, AMINOMETHYL PROPANOL, IRON OXIDE (CI 77491), IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), ORANGE 4 (CI 15510), RED 40 (CI 16035)

LABEL COPY





CARE ONE PUMPKIN PIE

ethyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-496	
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: PDC6 A3C0 OX)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)		
MANNITOL (UNII: 30WL53L36A)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
SULISOBENZONE (UNII: 1W6L629B4K)		
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)		
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-496-02	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(41520-496)	

Revised: 10/2013 AMERICAN SALES COMPANY