# CARE ONE VANILLA BEAN- 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

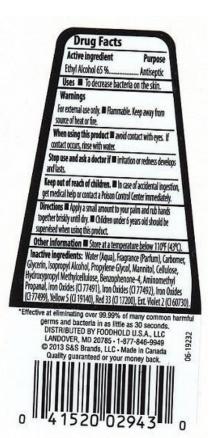
STORE AT A TEMPERATURE BELOW 110°F (43°C)

#### **INACTIVE INGREDIENTS**

WATER (AQUA), FRAGRANCE (PARFUM), CARBOMER, GLYCERIN, ISOPROPYL ALCOHOL, PROPYLENE GLYCOL, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, BENZOPHENONE-4, AMINOMETHYL PROPANOL, IRON OXIDES (CI 77491), IRON OXIDES (CI 77492), IRON OXIDES (CI 77499), YELLOW 5 (CI 19140), RED 33 (CI 17200), EXT. VIOLET 2 (CI 60730)

#### LABEL COPY





### CARE ONE VANILLA BEAN

ethyl alcohol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-500

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: 6DC9Q167V3)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

SULISOBENZONE (UNII: 1W6L629B4K)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438 O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C VIOLET NO. 2 (UNII: 350 KA7O6 HK)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-500-02	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(41520-500)	

Revised: 10/2013 AMERICAN SALES COMPANY