GIANT EAGLE VANILLA BEAN HAND SANITIZER- ethyl alcohol liquid Apollo Health and Beauty Care Inc.

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 help reduce 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 thoroughly 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. 1-800-222-1222

Directions

- Put enough hand sanitizer in your palm to cover hands and rub hands together until dry.
- Children under 6 years should be supervised when using this product.

Other information

- Store at a temperature below 110°C (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Propylene Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Red 33 (CI 17200), Yellow 5 (CI 19140).

Label Copy







Drug Facts (continued)

Directions

- Put enough hand sanitizer in your palm to cover hands and rub hands together until dry
- Children under 6 years should be supervised when using this product

Other information

- Store at a temperature below 110°F (43°C
- May discolor certain fabrics or surfaces

Inactive ingredients Water

(Aqua), Isopropyl Alcohol, Propylene Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Red 33 (Cl 17200), Yallow C (Cl 10140)

*EFFECTIVE AT ELIMINATING 99.99% OF COMMON GERMS AND BACTERIA.

GIANT EAGLE VANILLA BEAN HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-014

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

ALCOHOL (UNII: 3K9958V90M) ALCOHOL 650 mg in 1 mL

Inactive Ingredients

 Ingredient Name
 Strength

 WATER (UNII: 059QF0KO0R)

ISOPROPYL ALCOHOL (UNII: ND2M416302)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

GLYCERIN (UNII: PDC6A3C0OX)

ISOPROPYL MYRISTATE (UNII: 0 RE8K4LNJS)

.ALPHA.-TO COPHERO L ACETATE, DL- (UNII: WR1WPI7EW8)

CARBOMER 934 (UNII: Z135WT9208)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

D&C RED NO.33 (UNII: 9DBA0SBB0L)

FD&C YELLOW NO.5 (UNII: I753WB2F1M)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63148-014- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2018	

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part333E	06/17/2018						

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment							
Name	Address	ID/FEI	Business Operations				
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-014)				

Revised: 6/2018 Apollo Health and Beauty Care Inc.