CAREONE VANILLA BUTTERCREAM HAND SANITIZER- 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

- helps 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 eyes thoroughly with water.

Stop using this product 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

- wet hands thoroughly and rub together until dry.

Other information

store at a temperature below 110°F (43°C)

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

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1-877-846-9949

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0 41520 11158 6

06-21878

CAREONE VANILLA BUTTERCREAM HAND SANITIZER

ethyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-058
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)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

.ALPHA.-TOCOPHEROL 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:41520-058-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/25/2017	
2	NDC:41520-058-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/25/2017	

Labeler - American Sales Company (809183973)

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(41520-058)

Revised: 9/2017 American Sales Company