VANILLA CREAM AND APPLE BLOSSOM ANTIBACTERIAL HAND SANITIZER - ethyl alcohol gel HEB

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 62 PERCENT

PURPOSE

ANTISEPTIC

USES

TO HELP REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK 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 SMALL AMOUNT TO YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

OTHER INFORMATION

STORE AT A TEMPERATURE BELOW 110⁰F (43⁰C).

QUESTIONS OR COMMENTS

1-866-695-3030

INACTIVE INGREDIENTS

WATER, PROPYLENE GLYCOL, GLYCERIN, ISOPROPYL MYRISTATE, AMINOMETHYL PROPANOL, CARBOMER, TOCOPHERYL ACETATE, FRAGRANCE, VANILLA PLANIFOLIA FRUIT EXTRACT, PYRUS MALUS (APPLE) FRUIT EXTRACT, ALOE BARBADENSIS LEAF JUICE, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, IRON OXIDES (CI 77491), RED 33 (CI 17200).

PACKAGE FRONT AND BACK LABELS



VANILLA CREAM AND APPLE BLOSSOM ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-265	
Route of Administration	TOPICAL			
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Active Ingredient/Active M	oiety			
Ingredient Name		Basis of Streng	th Strength	
ALCOHOL (UNII: 3K9958V90M) (A	ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	
Inactive Ingredients				
Ingredient Name				
WATER (UNII: 059QF0KO0R)				

GLYCERIN (UNII: PDC6A3C0OX)							
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)							
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)							
CARBOMER 934 (UNII: Z135WT9208)							
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)							
VANILLA (UNII: Q74T35078H)							
APPLE (UNII: B423VGH5S	9)						
ALOE VERA LEAF (UNII:	ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)						
MANNITOL (UNII: 30WL53L36A)							
POWDERED CELLULOSE (UNII: SMD1X3XO9M)							
HYPROMELLOSES (UNII: 3NXW29V3WO)							
FERRIC OXIDE RED (UNII: 1K09F3G675)							
D&C RED NO. 33 (UNII: 9DBA0SBB0L)							
D 1 1							
Packaging							
# Item Code	Package Description	Marketin	ig Start Date	Ma	rketing End Date		
1 NDC:37808-265-02	59 mL in 1 BOTTLE, PUMP						
Marketing Information							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date M		Marketing End Date		
OTC monograph not final	part333E		0 1/0 3/20 11				

Labeler - HEB (007924756)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 1/2011