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			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER 934 (UNII: Z135WT9208)	
.ALPHATO COPHERO L ACETATE, D- (UNII: A7E6112E4N)	
VANILLA (UNII: Q74T35078H)	
APPLE (UNII: B423VGH5S9)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
MANNITOL (UNII: 30WL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-265-08	236 mL in 1 BOTTLE, PUMP		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	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 HEB