ANTIBACTERIAL HAND SANITIZER POMEGRANATE AND ACAI- ethyl alcohol gel APOLLO HEALTH AND BEAUTY CARE

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 OR 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.

QUESTIONS OR COMMENTS

1-866-695-3030

INACTIVE INGREDIENTS

WATER, PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, ACRYLATES/C10-30 ALKYL ACRYLATES CROSSPOLYMER, GLYCERIN, FRAGRANCE, AMINOMETHYL PROPANOL, TOCOPHERYL ACETATE, MANNITOL, CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, IRON OXIDES (CI 77491), RED 4 (CI 14700), BLUE 1 (CI 42090), YELLOW 6 (CI 15985).





ANTIBACTERIAL HAND SANITIZER POMEGRANATE AND ACAI

ethyl alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63148-271

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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l	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

WATER (UNII: 059QF0KO0R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)	
MANNITOL (UNII: 3OWL53L36A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63148-271-09	259 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	04/15/2011		

Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture	

Revised: 4/2011 APOLLO HEALTH AND BEAUTY CARE