

HAND SANITIZER - ethyl alcohol gel
DZA BRANDS LLC

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

ETHYL ALCOHOL 62%

PURPOSE

ANTIMICROBIAL

USES

HAND SANITIZER TO HELP REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM FIRE.

WHEN USING THIS PRODUCT

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

STOP USING AND ASK A DOCTOR IF

IRRITATION OR RASH 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

PUT ENOUGH PRODUCT IN YOUR PALM TO THOROUGHLY COVER YOUR HANDS. RUB HANDS TOGETHER BRISKLY UNTIL DRY. CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

OTHER INFORMATION

STORE AT A TEMPERATURE BELOW 110 FAHRENHEIT (43 DEGREES CELCIUS).

WATER, GLYCERIN, ISOPROPYL MYRISTATE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL, CARBOMER, FRAGRANCE.



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-268
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: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER 934 (UNII: Z135WT9208)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-268-02	59 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/14/2011	

Labeler - DZA BRANDS LLC (090322194)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

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

Revised: 3/2011

DZA BRANDS LLC