

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

ACTIVE INGREDIENT

ETHYL ALCOHOL 65%

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

WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY.

OTHER INFORMATION

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

QUESTIONS AND COMMENTS

1-866-322-2439

INACTIVE INGREDIENTS

WATER, GLYCERIN, ISOPROPYL MYRISTATE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL, CARBOMER, FRAGRANCE, ALOE BARBADENSIS LEAF JUICE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).



Drug Facts	
Active ingredient Ethyl Alcohol 62%	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 ■ Wet hands thoroughly and rub together until dry.	
Other information ■ Store at a temperature below 110°F (43°C).	
Questions/comments? 1-866-322-2439	
Inactive ingredients Water (Aqua), Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Aminomethyl Propanol, Carbomer, Fragrance (Parfum), Aloe Barbardensis Leaf Juice, Blue 1 (CI 42090), Yellow 5 (CI 19140).	

* This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, the distributor of Purell® Hand Sanitizer with Aloe.

Distributed by:
DZA Brands, LLC
2110 Executive Drive
Salisbury, NC 28147
1-866-322-2439.
MADE IN CANADA



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-223
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)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-223-08	236 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/23/2011	

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: 6/2011

DZA BRANDS LLC