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 65%

PURPOSE

ANTISEPTIC

USES

TO HELP REDUCE BACTERIA ON THE SKIN.

OTHER INFORMATION

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 AND ASK A 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 RIGHT AWAY.

APPLY A SMALL AMOUNT IN 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 110 FAHRENHEIT (43 DEGREES CELCIUS).

QUESTIONS AND COMMENTS

1-866-322-2439

INACTIVE INGREDIENTS

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

LABEL COPY





Drug Facts (continued)

When using this product avoid contact with eyes. If contact occurs, rinse with water.

Stop using and ask a 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 right away.

Directions Apply a small amount in your palm and rub hands together briskly until dry. Children under 6 should be supervised when using this product.

Other information Do not store above 110°F (43°C).

Questions/comments? 1-866-322-2439

Inactive ingredients: Water (Aqua), Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Propylene Glycol, Isopropyl Myristate, Tocopheryl Acetate.

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55316-253

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)ALCOHOL650 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
.ALPHATO CO PHERO L ACETATE, D- (UNII: A7E6112E4N)	

Packaging									
#	Item Code	Package Description	Marketing	Start Date Ma	arketing End Date				
1 1	NDC:55316-253-02	59 mL in 1 BOTTLE							
Marketing Information									
N	Marketing Category	Application Number or Monog	raph Citation	Marketing Start Date	Marketing End Date				
ОТ	C monograph not final	part333E		05/28/2013					

Labeler - DZA BRANDS LLC (090322194)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment								
Name	Address	ID/FEI	Business Operations					
APOLLO HEALTH AND BEAUTY CARE		20 19 0 120 9	manufacture(55316-253)					

Revised: 5/2013 DZA BRANDS LLC