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 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, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Actate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum).

Label Copy





Drug Facts (continued) When using this product = graid (

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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 Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

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Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) ISOPROPYL ALCOHOL (UNII: ND2M416302) GLYCERIN (UNII: PDC6A3C0OX) ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) ALOE VERA LEAF (UNII: ZY81Z83H0X) .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:55316-253- 03	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2017			
П						

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333E	04/27/2017					

Labeler - DZA Brands LLC (090322194)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment								
Name	Address	ID/FEI	Business Operations					
Apollo Health and Beauty Care Inc.		201901209	manufacture(55316-253)					

Revised: 4/2017 DZA Brands LLC