ANTI-BACTERIAL HAND SANITIZER- ethyl alcohol gel Fun Zone, Inc.

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.

Active Ingredient:

Ethyl Alcohol 63%

Purpose:

Antiseptic

Warnings:

For external use only. Flammable, keep away from fire, flame and direct sunlight.

Stop using this product and consult a doctor If irritation or redness develops. Stop using this product and consult a doctor If irritation or redness develops.

Directions

- Rub dime sized amount between hands until dry.
- For use by children under 6 years, adult supervision is required.

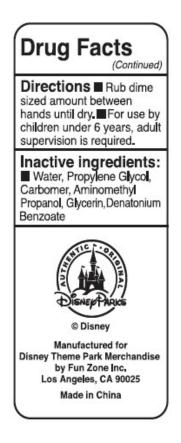
Water, Propylene Glycol, Carbomer, Aminomethyl Propanol, Glycerin, Denotonium Benzoate **Uses** To help reduce bacteria on hands.

When using this product Avoid contact with eyes and lips. If contact occurs, rinse with water.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.



Drug Facts Active ingredient Ethyl Alcohol 63% Purpose Antiseptic Uses ■ To help reduce bacteria on hands. Warnings For external use only. Flammable, keep away from fire, flame and direct sunlight. When using this product ■ Avoid contact with eyes and lips. If contact occurs, rinse with Stop using this product and consult a doctor If irritation or redness develops. Keep out of reach of children ■ If swallowed, get medical help or contact a poison control center immediately.



ANTI-BACTERIAL HAND SANITIZER

ethyl alcohol gel

Droduct	Information
FIVUUCL	IIIIVI IIIAUVII

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)		
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)		

Packaging

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69583-003- 00	29 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/12/2015	

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/12/2015	

Labeler - Fun Zone, Inc. (803572929)

Revised: 2/2017 Fun Zone, Inc.