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.

ANTI-BACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69583-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging				
#	**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

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)

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Fun Zone, Inc.