HAND SANITIZER- alcohol gel Mixologie, 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.

Hand Sanitizer

Drug Facts

Active ingredient[s]

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentilly can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

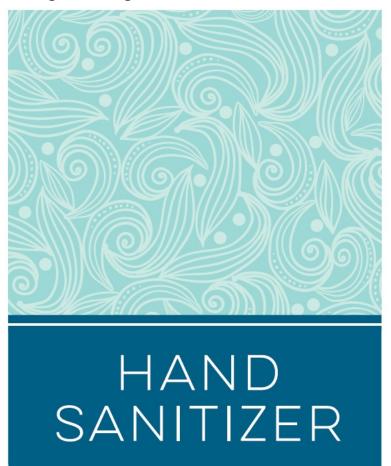
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Package Labeling:



70% Alcohol Antiseptic Hand Gel



Drug Facts

Active ingredient[s] Purpose
Ethyl Alcohol 70% v/v...... Antiseptic

Use[s]: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings: For external use only. Flammable. Keep away from heat or flame

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients carbomer, glycerin, triethanolamine, deionized water

Packaged by Mix-o-logie, LLC Smithville, TX mymixologie.com



HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76942-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)		
GLYCERIN (UNII: PDC6A3C0OX)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:76942-001-01	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	

Marketing Inform	larketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	04/29/2020			

Labeler - Mixologie, LLC (080088494)

Revised: 5/2020 Mixologie, LLC