

**SURE HAND SANITIZER- ethyl alcohol gel**  
**Sir Limited Liability Company**

*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.*

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**Sure Sanitizer (Gel):**

**4 FL OZ (120 mL) NDC: 80163-0001-4**

**1 LITER (1000 mL) NDC: 80163-0001-1**

**6.7 FL OZ (200 mL) NDC: 80163-0001-6**

**Active Ingredient(s)**

Alcohol 80% (v/v)

**Purpose**

Antiseptic

**Use**

- 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.

**Do not use**

- in children less than 2 months of age
- on open skin wounds
- 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 (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Hydrogen peroxide 0.125% (v/v), glycerol 1.45% (v/v), boiled cold water

**Package Label - Principal Display Panel****DISTRIBUTED BY:****Sure Sanitizer**

Jacksonville FL

[www.suresanitizer.com](http://www.suresanitizer.com)

***Sure Sanitizer (gel):***

***4 FL OZ (120 mL) NDC: 80163-0001-4***



hand sanitizer

**KILLS 99.99% OF GERMS\***

4 FL OZ (120 mL)





\*Effective at eliminating 99.99% of many common harmful germs & bacteria.

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### Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% 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.

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### Warnings

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

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#### Do not use

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

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**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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**Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition.

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**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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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.

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#### Other Information

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

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**Inactive ingredients** glycerol, hydrogen peroxide, boiled cold water

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Made in U.S.A.

US-FL-200701

Distributed By  
Sure Sanitizer  
Jacksonville, FL  
www.suresanitizer.com



**1 LITER (1000 mL) NDC: 80163-0001-1**



hand sanitizer

**KILLS 99.99% OF GERMS\***

1 LITER (1000 mL)





\*Effective at eliminating 99.99% of many common harmful germs & bacteria.

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**Drug Facts**

<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 80% v/v .....	Antiseptic

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**Use(s)** Hand sanitizer to help reduce bacteria that potentially can cause disease.  
For use when soap and water are not available.

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**Warnings**

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

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**Do not use**

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

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**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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**Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition.

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**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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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.

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**Other Information**

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

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**Inactive ingredients** glycerol, hydrogen peroxide, boiled cold water

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Made in U.S.A.

US-FL-200701

Distributed By  
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**6.7 FL OZ (200 mL) NDC: 80163-0001-6**



hand sanitizer

**KILLS 99.99% OF GERMS\***

6.7 FL OZ (200 mL)





\*Effective at eliminating 99.99% of many common harmful germs & bacteria.

**Drug Facts**

<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 80% w/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.

**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 (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients** glycerol, hydrogen peroxide, boiled cold water

Made in U.S.A.

US-FL-200701

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Jacksonville, FL  
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**SURE HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80163-0001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	12.5 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80163-0001-4	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/27/2020	
2	NDC:80163-0001-1	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/27/2020	
3	NDC:80163-0001-6	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/27/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/26/2020	

**Labeler** - Sir Limited Liability Company (058941499)

### Establishment

Name	Address	ID/FEI	Business Operations
Sir Limited Liability Company		058941499	manufacture(80163-0001)

Revised: 11/2021

Sir Limited Liability Company