

**SANTOTIZER PURE I75- isopropyl alcohol liquid**  
**Santolubes 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.*

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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

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.

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

### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

<b>SantoLubes® SantOtizer™</b>															
<b>Isopropyl Alcohol 75%</b>															
<b>Hand Sanitizer</b>															
<b>Non-sterile Solution</b>															
<b>4 oz</b>															
<i>FDA Packager Code: 73976-3303-5</i>															
<i>For Questions or Comments? Call 864-699-3024</i>															
	<b>FOR CHEMICAL EMERGENCY – Spill, Leak, Fire, Exposure or Accident</b> <b>Call CHEMTREC: Day or Night 1-800-424-9300 (In U.S.)</b> <b>1-703-527-3887 (Outside U.S.)</b>														
	<b>DRUG FACTS LABEL</b>														
<b>For More Information:</b> SantoLubes Manufacturing LLC™ 2155 W Croft Circle Spartanburg SC 29302 Phone: 864-585-3661 Fax: 864-208-1220 www.santolubes.com	<table border="1"><tr><td><b>Drug Facts</b></td><td></td></tr><tr><td><b>Active ingredient(s)</b> Isopropyl alcohol 75% v/v</td><td><b>Purpose</b> Antiseptic</td></tr><tr><td><b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td><td></td></tr><tr><td><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. <b>Do not use</b><ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul><b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b> <b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b> <b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b></td><td></td></tr><tr><td><b>Directions</b><ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul></td><td></td></tr><tr><td><b>Other information</b><ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul></td><td></td></tr><tr><td><b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP</td><td></td></tr></table>	<b>Drug Facts</b>		<b>Active ingredient(s)</b> Isopropyl alcohol 75% v/v	<b>Purpose</b> Antiseptic	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> <b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b> <b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b> <b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>		<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>		<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>		<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	
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# SantoLubes® SantOitizer™

Isopropyl Alcohol 75%

Hand Sanitizer

Non-sterile Solution

275 Gallons

FDA Packager Code: 73976-3303-4

For Questions or Comments? Call 864-699-3024



For additional safety and health information, refer to the Safety Data Sheet for this product.

**FOR CHEMICAL EMERGENCY – Spill, Leak, Fire, Exposure or Accident**  
**Call CHEMTREC: Day or Night 1-800-424-9300 (In U.S.)**  
**1-703-527-3887 (Outside U.S.)**

#### DRUG FACTS LABEL

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Isopropyl alcohol 75% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

#### For More Information:

SantoLubes Manufacturing LLC™  
2155 W Croft Circle  
Spartanburg SC 29302  
Phone: 864-585-3661  
Fax: 864-208-1220  
www.santolubes.com

# SantoLubes® SantOitizer™

Isopropyl Alcohol 75%

Hand Sanitizer

Non-sterile Solution

5 Gallons

FDA Packager Code: 73976-3303-2

For Questions or Comments? Call 864-699-3024



For additional safety and health information, refer to the Safety Data Sheet for this product.

**FOR CHEMICAL EMERGENCY – Spill, Leak, Fire, Exposure or Accident**  
Call CHEMTREC: Day or Night **1-800-424-9300** (In U.S.)  
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www.santolubes.com

# SantoLubes® SantOtizer™

## Isopropyl Alcohol 75% Hand Sanitizer Non-sterile Solution 55 Gallons

FDA Packager Code: 73976-3303-3

For Questions or Comments? Call 864-699-3024



For additional safety and health information, refer to the Safety Data Sheet for this product.

**FOR CHEMICAL EMERGENCY – Spill, Leak, Fire, Exposure or Accident**  
**Call CHEMTREC: Day or Night 1-800-424-9300 (In U.S.)**  
**1-703-527-3887 (Outside U.S.)**

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# SantoLubes® SantOtizer™

Isopropyl Alcohol 75%

Hand Sanitizer

Non-sterile Solution

1 Gallon

FDA Packager Code: 73976-3303-1

For Questions or Comments? Call 864-699-3024



For additional safety and health Information, refer to the Safety Data Sheet for this product.

**FOR CHEMICAL EMERGENCY – Spill, Leak, Fire, Exposure or Accident**  
**Call CHEMTREC: Day or Night 1-800-424-9300 (In U.S.)**  
**1-703-527-3887 (Outside U.S.)**

**DRUG FACTS LABEL**

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3.6 L NDC: 73976-3303-1

18 L NDC: 73976-3303-2

200 L NDC: 73976-3303-3

1022 L NDC: 73976-3303-4

## SANTOTIZER PURE I75

isopropyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73976-3303
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73976-3303-1	3600 mL in 1 PAIL; Type 0: Not a Combination Product	05/18/2020	
2	NDC:73976-3303-2	18000 mL in 1 PAIL; Type 0: Not a Combination Product	05/18/2020	
3	NDC:73976-3303-3	200000 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	
4	NDC:73976-3303-4	1022000 mL in 1 TANK; Type 0: Not a Combination Product	05/18/2020	
5	NDC:73976-3303-5	118.294 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

**Labeler** - Santolubes LLC (144734980)

**Registrant** - Santolubes LLC (144734980)

### Establishment

Name	Address	ID/FEI	Business Operations
Santolubes LLC		144734980	manufacture(73976-3303)

Revised: 9/2020

Santolubes LLC