

**HAND SANITIZER- alcohol liquid**  
**Loyola University Chicago**

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

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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. Benzyl Acetate (Fragrance) (0.05% v/v).
- e. Sterile distilled water or boiled cold water.

**Active Ingredient(s)**

Alcohol 80% 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, benzyl acetate (fragrance), purified water USP

**Package Label - Principal Display Panel**



**LOYOLA  
UNIVERSITY  
CHICAGO**

Alcohol Antiseptic 80% Topical Solution  
Hand Sanitizer Non-Sterile Solution

1032 W Sheridan Rd. Chicago, IL 60660

**LOYOLA HAND SANITIZER**

2 oz / 60 mL


<b>Drug Facts</b>	<b>NDC: 77798-002-02</b>
<b>Active ingredient(s)</b> Alcohol 80% w/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> • 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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60 mL NDC: 77798-002-02

3,785 mL NDC: 77798-002-01

<b>Drug Facts</b>	<b>NDC: 77798-002-01</b>
<b>Active ingredient(s)</b> Alcohol 80% w/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> • 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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<b>Inactive ingredients</b> glycerin, hydrogen peroxide, benzyl acetate (fragrance), purified water USP	

**LOYOLA  
HAND SANITIZER**

  
 LOYOLA  
UNIVERSITY CHICAGO  
 AD MAIOREM DEI GLORIAM  
 Preparing people to lead extraordinary lives

Alcohol Antiseptic 80% Topical Solution  
Hand Sanitizer Non-Sterile Solution  
1 Gallon / 3,785 mL

Proudly Produced by  
Loyola University Chicago  
1032 W Sheridan Road  
Chicago, IL 60660

  
**MADE IN USA**

# HAND SANITIZER

alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77798-002
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
BENZYL ACETATE (UNII: 0ECG3V79ZJ)	0.05 mL in 100 mL

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77798-002-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020	
2	NDC:77798-002-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/19/2020	

**Labeler** - Loyola University Chicago (074368911)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Loyola University Chicago		074368911	manufacture(77798-002)