

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.

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. 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. 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)

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, purified water USP

Package Label - Principal Display Panel



The image shows the principal display panel of a Loyola Hand Sanitizer package. At the top left is the Loyola University Chicago logo. To its right, the text reads: "Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution" and "1052 W Sheridan Rd. Chicago, IL 60660". Below this is a dark red banner with "LOYOLA HAND SANITIZER" in gold and "2 oz / 60 mL" in white. The main body of the label is a white box with a dark red border, containing the following information:

Drug Facts	NDC: 77798-001-02
Active ingredient(s) Alcohol 80% v/v	Purpose 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: <ul style="list-style-type: none">• on children less than 6 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 <ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Supervise children under 6 years of age when using the product to avoid swallowing.	
Other information <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

60 mL NDC: 77798-001-02

3785 mL NDC: 77798-001-01

Drug Facts	NDC: 77798-001-01
Active ingredient[s] Alcohol 80% v/v.....	PurposeAntiseptic
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.	
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**LOYOLA
HAND SANITIZER**


 LOYOLA
UNIVERSITY CHICAGO
1870
AD • MAJOREM • 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77798-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060 AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0 KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77798-001-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
2	NDC:77798-001-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/29/2020	

Marketing Information

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

Labeler - Loyola University Chicago (074368911)

Establishment

Name	Address	ID/FEI	Business Operations
Loyola University Chicago		074368911	manufacture(77798-001)

Revised: 6/2020

Loyola University Chicago