### 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 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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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.

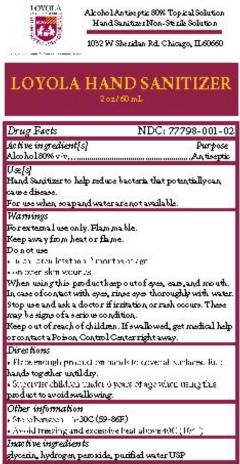
### Other information

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

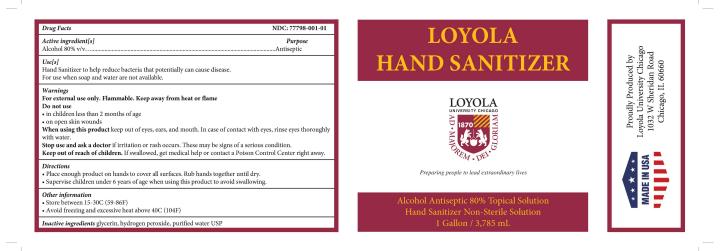
### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel



60 mL NDC: 77798-001-02



alcohol liquid	ΓIZER						
Product Inform	nation						
Product T ype		HUMAN OTC DRUG	Item Code (Source)		) NDC:77798-001		
Route of Adminis	tration	TOPICAL					
Active Ingredi	ent/Active Mo	iety					
Ingredient Name				Basis of Strength		Strength	
ALCOHOL (UNII: 3	K9958V90M) (AL	COHOL - UNII:3K9958V90M)		ALCOHO	L	80 mL in 100 mL	
Inactive Ingree							
Ingredient Name					Strength		
	,	60 A N9 V)			l.45 mL in 100		
GLYCERIN (UNII: F HYDROGEN PERO WATER (UNII: 059)	XIDE (UNII: BBX0	60 AN9 V)			l.45 mL in 100 ).125 mL in 10		
HYDRO GEN PERO WATER (UNII: 059)	XIDE (UNII: BBX0	60 AN9 V)					
HYDROGEN PERO WATER (UNII: 059) Packaging	XIDE (UNII: BBX0	60 AN9 V) Package Description					
HYDROGEN PERO WATER (UNII: 059) Packaging # Item Code	XIDE (UNII: BBX0 QF0KO0R)		o mbinatio n		eting Start Date	0 mL Marketing End	
HYDROGEN PERO WATER (UNII: 059) Packaging # Item Code 1 NDC:77798-001- 01	XIDE (UNII: BBX0 QF0KO0R) 3785 mL in 1 BO Product	Package Description		Mark	eting Start Date	0 mL Marketing End	
HYDROGEN PERO WATER (UNII: 059) <b>Packaging</b> <b>Item Code</b> 1 NDC:77798-001- 01 2 NDC:77798-001- 02	XIDE (UNII: BBX0 QF0KO0R) 3785 mL in 1 BO Product 60 mL in 1 BOT Product	<b>Package Description</b> TTLE, PLASTIC; Type 0: Not a C		Mark 05/18/20	eting Start Date	0 mL Marketing End	
HYDRO GEN PERO WATER (UNII: 059) Packaging # Item Code 1 NDC:77798-001- 01 2 NDC:77798-001-	XIDE (UNII: BBX0 QF0KO0R) 3785 mL in 1 BO Product 60 mL in 1 BOT Product	<b>Package Description</b> TTLE, PLASTIC; Type 0: Not a C	nbinatio n	Mark 05/18/20 06/29/20	eting Start Date	0 mL Marketing End	

Labeler - Loyola University Chicago (074368911)
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Establishment								
Name	Address	ID/FEI	<b>Business Operations</b>					
Loyola University Chicago		074368911	manufacture(77798-001)					

Revised: 6/2020

Loyola University Chicago