

## **HAND SANITIZER- 80% ethanol liquid**

**Wineclectic 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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### **Hand Sanitizer**

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

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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

**Hand Sanitizer**

**WHO 8oz.jpg**

237 mL NDC: 75492-001-01

# DECADENT SAINT<sup>®</sup>



# HAND SANITIZER

8oz

ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH #

## DRUG FACTS

Active ingredients(s)	Purpose
Alcohol 80% v/v .....	Antiseptic

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

MADE BY DECADENT SAINT  
1849 CHERRY ST. #3. LOUISVILLE  
COLORADO. 80027. 720 772 0703  
INFO@DECADENTSAINT.COM



Hand Sanitizer  
WHO 16oz.jpg

473 mL NDC: 75492-001-02

# DECADENT SAINT®



# HAND SANITIZER

16oz

ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH#

## DRUG FACTS

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Alcohol 80% v/v .....	Antiseptic

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Hand Sanitizer  
WHO 32oz.jpg

946 mL 95492-001-03

# DECADENT SAINT®



# HAND SANITIZER

32 OZ

ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH#

## DRUG FACTS

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Hand Sanitizer  
WHO 1gallon.jpg

3785 mL 75492-001-04

# DECADENT SAINT®



# HAND SANITIZER

128oz / 1 GALLON  
ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH#

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Hand Sanitizer  
WHO 5gallon.jpg

18927 mL 75492-001-05

# DECADENT SAINT®



# HAND SANITIZER

**5 GALLONS (640 OZ)**  
ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH#

## DRUG FACTS

Active ingredients(s)	Purpose
Alcohol 80% v/v .....	Antiseptic

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Hand Sanitizer  
WHO 55gallon.jpg

208198 mL 75492-001-06

# DECADENT SAINT®



# HAND SANITIZER

55 GALLONS (7,040 OZ)

ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
NON-STERILE SOLUTION

BATCH#

## DRUG FACTS

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## HAND SANITIZER

80% ethanol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75492-001
Route of Administration	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)	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:75492-001-01	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
2	NDC:75492-001-02	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
3	NDC:75492-001-03	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
4	NDC:75492-001-04	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
5	NDC:75492-001-05	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	
6	NDC:75492-001-06	208198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

**Labeler** - Wineclectic LLC (068766910)

**Registrant** - Wineclectic LLC (068766910)

## Establishment

Name	Address	ID/FEI	Business Operations
Wineclectic LLC		068766910	manufacture(75492-001)

Revised: 4/2020

Wineclectic LLC