

**CODE ONE- hand sanitizer liquid**  
**Sauce Crafters**

*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 away.

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

- 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

473 mL N

Here at Sauce Crafters we have been making delicious hot sauces since 1991. Although hot sauce is our specialty, we have shifted gears to help in this situation by producing Hand Sanitizer

We would like to give a special thank you to all of the Doctors Nurses, and First Responders that put themselves at risk to help everyone.

May we all come together as Americans during this crisis by sharing and showing consideration for one another.

**CODE ONE**  
**HAND SANITIZER**  
16 FL OZ (473 ml)

**Drug Facts**  
**Active ingredient(s)** Purposes: Antiseptic  
Alcohol 60% v/v

**Useful**  
Hands care personal hand rub to help reduce bacteria that potentially can cause disease.

**Warnings**  
For external use only, Flammable, Keep away from heat or flame  
Do not use  
• In children less than 2 months of age  
• Do not use on wounds  
• Do not use on irritated skin  
• Do not use on inflamed skin  
• Do not use on broken skin  
• Do not use on children under 6 years of age  
• Do not use on children under 6 years of age when using this product to avoid swallowing.

**Directions**  
• Rub 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

Distributed By:  
Sauce Crafters, Inc.  
3695 Interstate Park Way #2  
Riviera Beach FL, 33404  
saucecrafters.com

DC: 73878-201-01

### CODE ONE

hand sanitizer liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73878-201	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
<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: 059QF0KO0R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73878-201-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<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	03/30/2020		

**Labeler** - Sauce Crafters (161702949)

**Registrant** - Sauce Crafters (161702949)

### Establishment

Name	Address	ID/FEI	Business Operations
Sauce Crafters		161702949	manufacture(73878-201)

Revised: 3/2020

Sauce Crafters