

**HAND SANITIZER- alcohol spray**  
**Casabela Shoppe 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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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 with the addition of lemon and eucalyptus essential oils.

The hand sanitizer is manufactured using 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.

Additionally, the firm uses the following essential oils:

- a. Eucalyptus Globulus Leaf Oil (0.172% v/v).
- b. Citrus Limon Fruit Oil (0.172% v/v).

**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
- while pregnant. It may be a possible irritant to sensitive skin.

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, lemon and eucalyptus essential oils

**Package Label - Principal Display Panel**



*Alcohol Antiseptic 80%*  
*Topical Solution*  
*Hand Sanitizer*  
*Non-sterile Solution*  
60 ML



*Alcohol Antiseptic 80%*  
*Topical Solution*  
*Hand Sanitizer*  
*Non-sterile Solution*

*120 ML*




*Alcohol Antiseptic 80%*

*Topical Solution*

*Hand Sanitizer*

*Non-sterile Solution*

*470 ML*

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethanol Alcohol 80% v/v.....	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>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> <li>• while pregnant. It may be a possible irritant to sensitive skin</li> </ul>	
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.	
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<b>Directions</b>	
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<b>Other information</b>	
<ul style="list-style-type: none"> <li>• Store between 15-30C (59-86F)</li> <li>• Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin USP, hydrogen peroxide, purified water, lemon and eucalyptus essential oils	
	

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81035-100
<b>Route of Administration</b>	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: 059QF0KO0R)	
CITRUS LIMON FRUIT OIL (UNII: 0HNC1J1YED)	0.172 mL in 100 mL
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	0.172 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81035-100-02	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:81035-100-04	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:81035-100-16	470 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Casabela Shoppe LLC (117519499)

## Establishment

Name	Address	ID/FEI	Business Operations
Casabela Shoppe LLC		117519499	manufacture(81035-100)

Revised: 11/2020

Casabela Shoppe LLC