

## **CAYUGA INGREDIENTS HAND SANITIZER- hand sanitizer liquid**

**Cayuga Ingredients, 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.

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

**BOS Hand Sanitizer is partly derived from whey, a by-product of dairy manufacturing.** For every gallon of ethanol created (the main ingredient in BOS Hand Sanitizer), 5 gallons of pure water are produced. At Cayuga Ingredients, we seek to lead the world in sustainable, renewable, and responsible ethanol production. We invite you to join us on our journey forward.



**MADE in the USA**  
**CAYUGA INGREDIENTS**  
2185 TOWN LINE RD  
KING FERRY, NY 13081  
(888) 475-7775

<b>Drug Facts</b>	
<b>Active Ingredient[s]</b> Alcohol 80% v/v.....	<b>Purpose</b> 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>Directions</b> ▪ 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.
<b>Do not use</b> ▪ On 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.	
If rash or irritation occurs, stop use and consult a doctor. These may be signs of a serious condition.	
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center IMMEDIATELY.	
<b>Other information</b> ▪ Store between 59 - 86F/15 - 30C	▪ Avoid freezing and excessive heat above 104F/40C
<b>Inactive Ingredients</b> glycerin, hydrogen peroxide, purified water USP	

# Alcohol Antiseptic 80% Topical Solution

## Hand Sanitizer Non-sterile Solution

1 Gallon (3785 mL)

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 80% v/v.....	<b>Purpose</b> 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 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.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

3785mL 74219-0001-1

CAYUGA INGREDIENTS HAND SANITIZER

hand sanitizer liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74219-0001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

<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: 059QF0K00R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74219-0001-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74219-0001-2	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74219-0001-3	1040875 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74219-0001-4	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

<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** - Cayuga Ingredients, LLC (081361197)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cayuga Ingredients, LLC		081361197	manufacture(74219-0001)