

## **SCHOOL HEALTH HAND SANITIZER- alcohol gel**

### **Commercial Beverage Concepts, 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.*

-----

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. Isopropyl Alcohol (75%, 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)**

Ethyl Alcohol 70% v/v

### **Purpose**

Antiseptic

### **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 ingest or inhale.

### **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. Condition persists for more than 72 hours.

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, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water

## Package Label - Principal Display Panel

237 mL NDC: 75594-090-01

 <b>ANTISEPTIC GEL</b> <b>HAND SANITIZER</b>	<b>Drug Facts</b>			
	<table border="1"><thead><tr><th>Active Ingredient(s)</th><th>Purpose</th></tr></thead><tbody><tr><td>Ethyl Alcohol 70% v/v</td><td>Antiseptic</td></tr></tbody></table>	Active Ingredient(s)	Purpose	Ethyl Alcohol 70% v/v
Active Ingredient(s)	Purpose			
Ethyl Alcohol 70% v/v	Antiseptic			
<ul style="list-style-type: none"><li>• Unscented</li><li>• Alcohol 70% v/v</li><li>• With Vitamin E</li><li>• Non-sticky, no residue</li><li>• Quick drying</li><li>• Moisturizing</li></ul>	<b>Uses:</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; hands. ■ Flammable, keep away from heat or flame ■ Do not ingest or inhale			
<p>Reorder # 1020133 SchoolHealth.com 866-323-5465</p> <p><b>Unscented</b> 8 fl oz (237 mL)</p>	<b>Do not use</b> ■ for children less than 2 months of age ■ on open skin wounds			
	<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.			
<p>Manufactured for School Health Corporation by: Commercial Beverage Concepts, LLC 2408 Karbach St., Houston, Texas 77092</p>  8 50019 69930 2	<b>Stop use and ask a doctor if</b> ■ irritation or rash occurs ■ condition persists for more than 72 hours			
	<b>Keep out of reach of children.</b> 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 and rub hands together until dry ■ Supervise children under 6 years of age when using this product			
	<b>Other information</b> ■ Store between 15-30C (59-86F) ■ Avoid freezing and storage above 40C (104F)			
	<b>Inactive ingredients:</b> Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water			

473 mL NDC: 75594-090-02



ANTISEPTIC GEL  
**HAND SANITIZER**

- Unscented
- Alcohol 70% v/v
- With Vitamin E
- Non-sticky, no residue
- Quick drying
- Moisturizing

Reorder # 1020134  
SchoolHealth.com  
866-323-5465

**Unscented**  
16 fl oz (473 mL)

946 mL NDC: 75594-090-03

Drug Facts	
Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>■ For external use only; hands.</li> <li>■ Flammable, keep away from heat or flame</li> <li>■ Do not ingest or inhale</li> </ul>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ for children less than 2 months of age</li> <li>■ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>■ Irritation or rash occurs</li> <li>■ condition persists for more than 72 hours</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ Place enough product on hands to cover all surfaces and rub hands together until dry</li> <li>■ Supervise children under 6 years of age when using this product</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>■ Store between 15–30C (59–86F)</li> <li>■ Avoid freezing and storage above 40C (104F)</li> </ul>	
<b>Inactive ingredients:</b> Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	

Manufactured for School Health  
Corporation by:  
Commercial Beverage Concepts, LLC  
2408 Karbach St., Houston, Texas 77092



1020134



ANTISEPTIC GEL  
**HAND SANITIZER**

- Unscented
- Alcohol 70% v/v
- With Vitamin E
- Non-sticky, no residue
- Quick drying
- Moisturizing

Reorder # 1020156  
SchoolHealth.com  
866-323-5465

**Unscented**  
32 fl oz (946 mL)

3.785 L NDC: 75594-090-04

Drug Facts	
Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>■ For external use only; hands.</li> <li>■ Flammable, keep away from heat or flame</li> <li>■ Do not ingest or inhale</li> </ul>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ for children less than 2 months of age</li> <li>■ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>■ Irritation or rash occurs</li> <li>■ condition persists for more than 72 hours</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ Place enough product on hands to cover all surfaces and rub hands together until dry</li> <li>■ Supervise children under 6 years of age when using this product</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>■ Store between 15–30C (59–86F)</li> <li>■ Avoid freezing and storage above 40C (104F)</li> </ul>	
<b>Inactive ingredients:</b> Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	

Manufactured for School Health  
Corporation by:  
Commercial Beverage Concepts, LLC  
2408 Karbach St., Houston, Texas 77092



1020156



ANTISEPTIC GEL  
**HAND SANITIZER**

- Unscented
- Alcohol 70% v/v
- With Vitamin E
- Non-sticky, no residue
- Quick drying
- Moisturizing

Reorder # 1020135  
SchoolHealth.com  
866-323-5465

**Unscented**  
1 gal (3,785 mL)

Drug Facts	
Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses:</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<input type="checkbox"/> For external use only; hands. <input type="checkbox"/> Flammable, keep away from heat or flame <input type="checkbox"/> Do not ingest or inhale	
<b>Do not use</b>	
<input type="checkbox"/> for children less than 2 months of age <input type="checkbox"/> on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
<input type="checkbox"/> Irritation or rash occurs <input type="checkbox"/> condition persists for more than 72 hours	
<b>Keep out of reach of children.</b> If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions</b>	
<input type="checkbox"/> Place enough product on hands to cover all surfaces and rub hands together until dry <input type="checkbox"/> Supervise children under 6 years of age when using this product	
<b>Other information</b>	
<input type="checkbox"/> Store between 15-30C (59-86F) <input type="checkbox"/> Avoid freezing and storage above 40C (104F)	
<b>Inactive ingredients:</b> Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	

Manufactured for School Health  
Corporation by:  
Commercial Beverage Concepts, LLC  
2408 Karbach St., Houston, Texas 77092



1020135

**SCHOOL HEALTH HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75594-090(NDC:74221-003)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

**Inactive Ingredients**


Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75594-090-02	0.437 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
2	NDC:75594-090-03	0.946 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
3	NDC:75594-090-04	3.785 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
4	NDC:75594-090-01	0.237 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	



**Drug Facts**

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

**Uses:** 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: hands. ■ Flammable, keep away from heat or flame
- Do not ingest or inhale

**Do not use**

- for 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, flush eyes thoroughly with water.

**Stop use and ask a doctor if**

- irritation or rash occurs ■ condition persists for more than 72 hours

**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 and rub hands together until dry ■ Supervise children under 6 years of age when using this product

**Other information**

- Store between 15–30C (59–86F) ■ Avoid freezing and storage above 40C (104F)

**Inactive ingredients:** Glycerin, Isopropyl Myristate, Polyethylene Glycol/ Acrylates Copolymer, Tocopheryl Acetate, Water




- Unscented
- Alcohol 70% v/v
- With Vitamin E
- Non-sticky, no residue
- Quick drying
- Moisturizing

Reorder # 1020133  
SchoolHealth.com  
866-323-5465

**Unscented**  
8 fl oz (237 mL)

Manufactured for School Health Corporation by:  
Commercial Beverage Concepts, LLC  
2408 Karbach St., Houston, Texas 77092



8 50019 69930 2

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/28/2020	

**Labeler** - Commercial Beverage Concepts, LLC (080925174)

## Establishment

Name	Address	ID/FEI	Business Operations
Commercial Beverage Concepts, LLC		080925174	pack(75594-090) , label(75594-090) , relabel(75594-090) , repack(75594-090)

