

**HAND SANITIZER- ethyl alcohol spray**  
**Tekware, Inc. d.b.a. Gloucester Bio**

*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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**Alcohol (Ethyl Alcohol or Ethanol)**

Ethyl Alcohol

**Hand Sanitizer**

OTC Antiseptic Drug Products

**Inactive Ingredients**

water, glycerin, hydrogen peroxide, fragrance

**Uses**

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

**Keep out of reach of children**

If swallowed, get medical help or contact Poison Control Center right away.

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under six years of age when using this product to avoid swallowing.

**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 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 occur. These may be signs of a serious condition.

**473mL NDC: 74128-080-16**

**ADVANCED**

# ***HAND SANITIZER***

*Enriched with Moisturizers*



***GLOUCESTER BIO***

**16 FL OZ (473mL)**

- **In as little as 15 seconds, effective at eliminating more than 99.9% of many common germs and bacteria that may cause illness.**
- **Use anytime, anywhere, without water or towels.**
- **Moisturizing formula with glycerin leaves hands feeling soft.**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
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></ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<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> water, glycerin, hydrogen peroxide, fragrance	

DSP-MA-21044

**Distributed by: Gloucester Bio**

11 Dory Road, Gloucester, MA 01930

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Made in the U.S.A.

GBDrugfacts16oz

**3785mL NDC: 74128-080-01**

3785mL NDC: 74128-080-01

# ***ADVANCED HAND SANITIZER***

*Enriched with Moisturizers*





# ***GLOUCESTER BIO***

## **1 GALLON (3.78L)**

GBDrugFacts1gal

- **In as little as 15 seconds, effective at eliminating more than 99.9% of many common germs and bacteria that may cause illness.**
- **Use anytime, anywhere, without water or towels.**
- **Moisturizing formula with glycerin leaves hands feeling soft.**

<b><i>Drug Facts</i></b>	
<b><i>Active ingredient[s]</i></b>	<b><i>Purpose</i></b>
Alcohol 80% v/v.....	Antiseptic
<b><i>Use[s]</i></b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b><i>Warnings</i></b>	
For external use only. Flammable. Keep away from heat or flame	
<small>Do not use</small>	

**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 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*** water, glycerin, hydrogen peroxide, fragrance

DSP-MA-21044

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236mL NDC: 74128-070-08




**GLOUCESTER BIO**  
 Lemon Fresh  
 Enriched with Moisturizers



Plant-Based Antiseptic + Essential Oils

**ADVANCED  
 HAND  
 SANITIZER**



Made in USA  
 8 FL OZ (236 mL)

- In 15 seconds, effective at eliminating more than 99.9% of common germs and bacteria that may cause illness.
- Use anytime, anywhere, without water or towels.
- Moisturizing formula with glycerin leaves hands feeling soft.

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use[s]</b>	
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> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
• Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> water, glycerin, hydrogen peroxide, fragrance	


DSP-MA-21044

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236mL NDC: 74128-070-08


118mL NDC: 74128-070-04

**GLOUCESTER BIO**  
 Lemon Fresh  
 Enriched with Moisturizers



Plant-Based Antiseptic + Essential Oils

**ADVANCED  
 HAND  
 SANITIZER**



Made in USA  
 4 FL OZ (118 mL)

- In 15 seconds, effective at eliminating more than 99.9% of common germs and bacteria that may cause illness.
- Use anytime, anywhere, without water or towels.
- Moisturizing formula with glycerin leaves hands feeling soft.

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use[s]</b>	
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> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
• Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> water, glycerin, hydrogen peroxide, fragrance	

DSP-MA-21044

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118mL NDC: 74128-070-04

## HAND SANITIZER

ethyl alcohol spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74128-070
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEMON OIL (UNII: I9GRO824LL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74128-070-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74128-070-08	236 mL in 1 BOTTLE; 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	part356	03/30/2020	

## HAND SANITIZER

ethyl alcohol spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74128-080
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEMON OIL (UNII: I9GRO824LL)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74128-080-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74128-080-01	3785 mL in 1 BOTTLE; 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	part356	03/30/2020	

**Labeler** - Tekkware, Inc. d.b.a. Gloucester Bio (085078398)

**Registrant** - Tekkware, Inc. d.b.a. Gloucester Bio (085078398)

## Establishment

Name	Address	ID/FEI	Business Operations
Tekkware, Inc, d.b.a. Gloucester Bio		085078398	manufacture(74128-070, 74128-080)

Revised: 6/2020

Tekkware, Inc. d.b.a. Gloucester Bio