

## **HAND SANITIZER- alcohol liquid**

### **Balm of Gilead**

*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**

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.

### **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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### **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**

citrus aurantium bergamia (bergamot) peel oil, glycerin, hydrogen peroxide, purified water USP, zingiber officinale (ginger) root oil

**Package Label - Principal Display Panel**

 <p>06/22</p> <p>Distributed by cocobee.co. Rusk, TX 75785 Made in USA</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> .....<b>Purpose</b> Alcohol 80% v/v.....Antiseptic</p> <p><b>Use</b> · Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b></p> <p><b>Do not use</b> · in children less than 2 months of age · on open skin wounds</p> <p><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.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><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.</p> <p><b>Other information</b> · Store between 15-30C (59-86F) · Avoid freezing and excessive heat above 40C (104F)</p> <p><b>Inactive ingredients</b> citrus aurantium bergamia (bergamot) peel oil, glycerin, hydrogen peroxide, purified water USP, zingiber officinale (ginger) root oil</p>	<p><b>cocobee.co</b>™</p>  <p>ALCOHOL BASED <b>HAND SANITIZER</b></p> <p>BERGAMOT FRUIT OIL + GINGER ROOT OIL</p> <p>Alcohol Antiseptic 80% Topical Non-sterile solution with super-moisturizing glycerin</p> <p>NDC 74843-2627-1</p> <p>1 fl. oz. (30 ml)</p>	<p>no rinse wash   safe   effective</p>
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NDC 74843-2627-2

cocobee.co™



no rinse wash | safe | effective

ALCOHOL  BASED  
HAND SANITIZER

BERGAMOT FRUIT OIL +  
GINGER ROOT OIL

Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin

<b>Drug Facts</b>	
<b>Active ingredient</b> .....	<b>Purpose</b>
Alcohol 80% v/v.....	Antiseptic
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<b>Warnings</b>	
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<b>Do not use</b>	
· in 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, 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 a Poison Control Center right away.	
<b>Directions</b>	
· Place enough product on hands to cover all surfaces. Rub hands together until dry.	
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<b>Other information</b>	
· Store between 15-30C (59-86F)	
· Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> citrus aurantium bergamia (bergamot) peel oil, glycerin, hydrogen peroxide, purified water USP, zingiber officinale (ginger) root oil	

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06/22

Distributed by cocobee.co.  
Rusk, TX 75785

MADE IN USA

2 fl. oz. (59 ml)

NDC 74843-2627-2



NO RINSE WASH | SAFE | EFFECTIVE

ALCOHOL  based  
HAND SANITIZER

Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin



<b>Drug Facts</b>	
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06/22

Balm of Gilead  
Rusk, TX 75785 USA

ALLNATURALBALM.COM

2 fl. oz. (59 ml)

If your skin came with instructions, it would say,  
"USE BALM OF GILEAD"

BERGAMOT FRUIT OIL  
& GINGER ROOT OIL

# ALCOHOL BASED CO HAND SANITIZER

*Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin*

BERGAMOT FRUIT OIL +  
GINGER ROOT OIL

LIQUID/SPRAY REFILL (NON-GEL)  
3.78 L (1 Gallon US)

### **Drug Facts**

**Active ingredient** .....  
Alcohol 80% v/v.....

**Use** • Hand Sanitizer to help reduce bacteria and viruses that cause disease. For use when soap and water are not available.

### **Warnings**

**For external use only. Flammable. Keep away from heat and flame. Do not use**

- in children less than 2 months of age
- on open skin wounds

**When using this product keep out of reach of children. In case of contact with eyes, rinse eyes with water. Stop use and ask a doctor if irritation persists or if you experience any of the following symptoms. May be signs of a serious condition.**

**Keep out of reach of children. If swallowed, 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. Avoid swallowing product to avoid swallowing.

### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 30C (86F)

**Inactive ingredients** citrus aurantium bergamot, hydrogen peroxide, purified water USP, zingiber officinale

Distributed by cocobee.co. | Rusk, TX 75783

NDC 74843-2621-3  
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# ALCOHOL based Hand sanitizer



*Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin*

**BERGAMOT FRUIT OIL  
& GINGER ROOT OIL**



**LIQUID/SPRAY REFILL (NON-GEL)  
3.78 L (1 Gallon US)**

NDC 74843-2627-3 6 43307 18585 0



NO RINSE WASH | SAFE | EFFECTIVE

### Drug Facts

**Active ingredient** .....  
Alcohol 80% v/v.....

**Use** • Hand Sanitizer to help reduce cause disease. For use when soap

### Warnings

**For external use only. Flammable. K Do not use**

- in children less than 2 months of
- on open skin wounds

**When using this product keep out** In case of contact with eyes, rinse

**Stop use and ask a doctor** if irrita may be signs of a serious conditior

**Keep out of reach of children.** If or contact a Poison Control Center

### Directions

- Place enough product on hands t hands together until dry.
- Supervise children under 6 years product to avoid swallowing.

### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive hea

**Inactive ingredients** citrus aurantium hydrogen peroxide, purified water USP, zingibe

If your skin came with instructions, it would say, "USE BALM

# ALCOHOL BASED CO HAND SANITIZER

*Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin*

BERGAMOT FRUIT OIL +  
GINGER ROOT OIL

LIQUID/SPRAY REFILL (NON-GEL)  
208.20 L (55 Gallon US)

### **Drug Facts**

**Active ingredient** .....  
Alcohol 80% v/v.....

**Use** • Hand Sanitizer to help reduce bacteria and viruses that cause disease. For use when soap and water are not available.

### **Warnings**

**For external use only. Flammable. Keep out of reach of children. Do not use**

- in children less than 2 months of age
- on open skin wounds

**When using this product keep out of reach of children. In case of contact with eyes, rinse eyes with water. Stop use and ask a doctor if irritation or rash persists. May be signs of a serious condition.**

**Keep out of reach of children.** If swallowed, do not induce vomiting. Call a Poison Control Center right away.

### **Directions**

- Place enough product on hands to cover all surfaces of hands together until dry.
- Supervise children under 6 years of age when using product to avoid swallowing.

### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 30C (86F)

**Inactive ingredients** citrus aurantium bergamot, glycerin, hydrogen peroxide, purified water USP, zingiber officinale

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NDC 74843-2621-4

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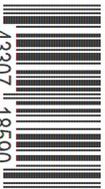


# ALCOHOL BASED CO HAND SANITIZER

Alcohol Antiseptic 80%  
Topical Non-sterile solution  
with super-moisturizing glycerin

BERGAMOT FRUIT OIL +  
GINGER ROOT OIL

NDC 74843-2627-5 6 43307 18590 4



LIQUID/SPRAY REFILL (NON-GEL)  
1041 L (275 Gallon US)

### Drug Facts

**Active ingredient** .....  
Alcohol 80% v/v.....

**Use** • Hand Sanitizer to help reduce bacteria that can cause disease. For use when soap and water are not available.

### Warnings

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- in children less than 2 months of age
- on open skin wounds

**When using this product keep out of reach of children. In case of contact with eyes, rinse eyes with water. Stop use and ask a doctor if irritation or other symptoms may be signs of a serious condition.**

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### Directions

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### Other information

- Store between 15-30C (59-86F)
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**Inactive ingredients** citrus aurantium bergamot, hydrogen peroxide, purified water USP, zingiber officinale

Distributed by cocobee.co. | Rusk, TX 75783

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74843-2627
<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)	
GINGER OIL (UNII: SAS9Z1SVUK)	0.2 mL in 100 mL
BERGAMOT OIL (UNII: 39W1PKE3J)	1.5 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74843-2627-3	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74843-2627-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74843-2627-2	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74843-2627-4	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74843-2627-5	1040988 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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** - Balm of Gilead (099144632)

## Establishment

Name	Address	ID/FEI	Business Operations
Balm of Gilead		099144632	manufacture(74843-2627)

Revised: 5/2020

Balm of Gilead