

**GAIA HERBS HAND SANITIZER- alcohol solution**  
**GAIA HERBS ANTISEPTIC HAND RUB- alcohol solution**  
**Gaia Herbs, Inc**

*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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**Gaia Hand Sanitizer / Antiseptic Hand Rub**

***Drug Facts***

***Active ingredient***

Alcohol 80% v/v

***Purpose***

Antiseptic

***Use***

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

ANTISEPTIC HAND RUB: Healthcare personnel hand rub to help reduce bacteria that potentially can cause disease.

***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.

***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°-30°C (59°-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

***Inactive ingredients*** glycerin, hydrogen peroxide, purified water USP

Gaia Herbs, Inc.

101 Gaia Herbs Drive

Brevard, NC 28712

**gaia® HERBS**  
**HAND SANITIZER**  
Alcohol Antiseptic 80%  
Topical Solution

Non-sterile Solution

2 FL OZ (59 mL)

**gaia**  
HERBS

**HAND  
SANITIZER**

Alcohol Antiseptic 80%

Topical Solution  
Non-sterile Solution

2 FL OZ (59 mL)

**Drug Facts**

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

Gaia Herbs, Inc., 101 Gaia Herbs Drive  
Brevard, NC 28712

PEEL BACK FOR CONTINUED DRUG FACTS

LOT # XXXXXXXX

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**Drug Facts (continued)**

**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.

**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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

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Brevard, NC 28712

**gaia® HERBS**  
**ANTISEPTIC HAND RUB**  
Alcohol Antiseptic 80%  
Topical Solution  
Non-Sterile Solution  
**1 GALLON (3.79 L)**



# ANTISEPTIC HAND RUB

Alcohol Antiseptic 80%

Topical Solution  
Non-sterile Solution

1 GALLON (3.79 L)



### Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v	Antiseptic

**Use**  
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

**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.

**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 15-30°C (59-86°F)  
- Avoid freezing and excessive heat above 40°C (104°F)

**Inactive ingredients**  
glycerin, hydrogen peroxide, purified water USP

Gaia Herbs, Inc.,  
101 Gaia Herbs Drive  
Brevard, NC 28712



## GAIA HERBS HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74817-001
<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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74817-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/21/2020	

## GAIA HERBS ANTISEPTIC HAND RUB

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74817-002
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

### Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74817-002-01	3.79 L in 1 JUG; Type 0: Not a Combination Product	04/21/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/21/2020	

**Labeler** - Gaia Herbs, Inc (623101664)

### Establishment

Name	Address	ID/FEI	Business Operations
Gaia Herbs, Inc		623101664	manufacture(74817-001, 74817-002)

Revised: 4/2020

Gaia Herbs, Inc