

## **HAND SANITIZER- alcohol liquid**

### **Radical Awesomers 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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### **Hand sanitizer**

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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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, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

59 mL NDC:80809-000-02

 <p><b>ADAM</b> HAND SANITIZER</p>	Artisanal Small Batch Recipe Number: _____	<p><b>Lavender Lemongrass Rosemary</b></p> <p>with Moisturizing Organic Aloe Vera</p>
	Made in Los Angeles loveadamsani.com	

<b>Drug Facts</b>	
<b>Active Ingredient</b> Ethyl Alcohol 80% v/v.....	<b>Purpose</b> .....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> ■ For external use only ■ Flammable. Keep away from fire or flame. When using this product avoid contact with the eyes. In case of contact, flush eyes thoroughly with water. Stop use and contact a doctor if irritation or redness develops or lasts for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Shake well ■ Apply liberally to hands ■ Rub together 20-30 seconds (fingertips, between fingers + back of hands) ■ Air dry without wiping ■ Supervise children under 6 years old	
<b>Other Information</b> ■ Store at room temperature 20°-25°C (66°-77°F). ■ May discolor certain fabrics ■ Keep out of direct sunlight	
<b>Inactive Ingredients</b> Distilled Water, Hydrogen Peroxide (3%), Glycerol (98%), Organic Aloe Vera, Organic Lavender Essential Oil, Organic Lemongrass Essential Oil, Organic Rosemary Essential Oil	
<b>Questions?</b>	info@loveadamsani.com

DIST. + SOLD EXCLUSIVELY BY RADICAL AWESOMERS LLC. LOS ANGELES, CA 90068
WHO-RECOMMENDED HANDRUB FORMULATION
NOT TESTED ON ANIMALS


DISPOSE OF RESPONSIBLY
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237 mL NDC:80809-000-08



Artisanal Small Batch Recipe  
Number: \_\_\_\_\_

**Lavender  
Lemongrass  
Rosemary**

with Moisturizing  
Organic Aloe Vera

Made in Los Angeles  
loveadamsani.com

8 fl oz (237mL)



### Drug Facts

<b>Active Ingredient</b> Ethyl Alcohol 80% v/v.....	<b>Purpose</b> .....Antiseptic
<b>Uses</b> ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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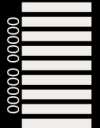
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WHO-RECOMMENDED HANDRUB FORMULATION


NOT TESTED ON ANIMALS

DISPOSE OF RESPONSIBLY



473 mL NDC:80809-000-16



Artisanal Small Batch Recipe  
Number: \_\_\_\_\_

**Lavender  
Lemongrass  
Rosemary**

with Moisturizing  
Organic Aloe Vera

Made in Los Angeles  
loveadamsani.com

16 fl oz (473mL)

### Drug Facts

<b>Active Ingredient</b> Ethyl Alcohol 80% v/v.....	<b>Purpose</b> .....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> ■ For external use only ■ Flammable. Keep away from fire or flame. When using this product avoid contact with the eyes. In case of contact, flush eyes thoroughly with water. Stop use and contact a doctor if irritation or redness develops or lasts for more than 72 hours. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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WHO-RECOMMENDED HANDRUB FORMULATION

NOT TESTED ON ANIMALS




DISPOSE OF RESPONSIBLY



## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80809-000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
<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: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80809-000-02	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:80809-000-08	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
3	NDC:80809-000-16	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/01/2021		

**Labeler** - Radical Awesomers LLC (117684823)

### Establishment

Name	Address	ID/FEI	Business Operations
Radical Awesomers LLC		117684823	manufacture(80809-000)

Revised: 1/2022

Radical Awesomers LLC