

## **EESOME HAND SANITIZER- alcohol gel**

### **Eesome**

*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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### 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

### Package Label - Principal Display Panel

237 mL NDC: 90087-5370-1

Drug Facts	
Active Ingredient	Purpose
Ethyl 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> Flammable. For external use only. Keep away from heat or flame. Do not use • on children less than 2 months of age • on open skin wounds When using this product keep out of reach of eyes, ears, and mouth. In case of contact with eyes, rinse 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.	
<b>Directions</b> Put enough product in your palm to cover hands and rub hands together briskly until dry.	
<b>Other information</b> • Store below 110°F (43°C). • May discolor fabrics or surfaces. • Avoid freezing and excessive heat.	
<b>Inactive Ingredients</b> Aloe Barbadosis Leaf Juice, Ammoniumethyl Propanol, Aqua (Water), Carbomer	

**Eesome**  
HAND  
SANITIZER  
FRAGRANCE FREE  
80% ETHYL ALCOHOL  
WITH ALOE  
8 fl.oz (237 mL)

**Eesome**  
Distributed by Eesome, LLC  
8046 Roswell Road, Suite 202  
Atlanta, GA 30350  
770-671-0657

473 mL NDC: 90087-5370-2 front



473 mL NDC: 90087-5370-2 back

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 80% w/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>	
Flammable. For external use only. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> <li>• on children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
When using this product keep out of reach of eyes, ears, and mouth. In case of contact with eyes, rinse 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.	
<b>Directions</b>	
Put enough product in your palm to cover hands and rub hands together briskly until dry.	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• Store below 110°F (43°C).</li> <li>• May discolor fabrics or surfaces.</li> <li>• Avoid freezing and excessive heat.</li> </ul>	
<b>Inactive Ingredients</b>	
Aloe Barbados Leaf Juice, Aminomethyl Propanol, Aqua (Water), Carbomer	
Distributed by Eesome, LLC 1770-671-0657 8046 Roswell Road, Suite 202   Atlanta, GA 30350	

3785 mL NDC: 90087-5370-3

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Distributed by Eesome, LLC  
8046 Roswell Road, Suite 202  
Atlanta, GA 30350  
770-671-0657

e e s o m e

# HAND SANITIZER

FRAGRANCE FREE

80% ETHYL ALCOHOL

WITH  ALOE

1 GALLON  
128 FL.OZ (3,785 ML)

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 80% w/v	Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use with soap and water as not a substitute.	
<b>Warnings</b> Flammable. For external use only. Keep away from heat or flame. Do not use - on children less than 2 months of age - on open wounds	
When using this product keep out of reach of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and seek doctor if irritation or rash occurs. This may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centering nearby.	
<b>Directions</b> Put enough product in your palm to cover hands and rub hands together for 20 seconds until dry.	
<b>Other Information</b> - Store below 118°F (42°C). - May discolor fabrics or surfaces. - Avoid freezing and excessive heat.	
<b>Inactive Ingredients</b> Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Aqua (Water), Carbomer	

## EESOME HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90087-5370
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
CARBOMER 934 (UNII: Z135WT9208)	0.5 mL in 100 mL

<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.36 mL in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	0.1 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90087-5370-1	10000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/20/2020	
2	NDC:90087-5370-2	10000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/20/2020	
3	NDC:90087-5370-3	10000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/20/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/20/2020	

**Labeler** - Eesome (116627537)

### Establishment

Name	Address	ID/FEI	Business Operations
Eesome		116627537	label(90087-5370)

### Establishment

Name	Address	ID/FEI	Business Operations
Draga Laboratories		610096534	manufacture(90087-5370)

Revised: 10/2020

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