

## **GERMIFREE ANTIMICROBIAL HAND GEL- ethyl alcohol gel**

**Acme United Corporation**

*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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### ***GermiFree* Antimicrobial Hand Gel**

#### **Drug Facts**

##### ***Active ingredient***

Ethyl alcohol 60% w/w

##### ***Purpose***

Antimicrobial

##### ***Use***

hand sanitizer to help reduce microbes on the skin

##### ***Warnings***

**Flammable.** Keep away from fire or flame

##### **For external use only**

**When using this product,** do not use in or near the eyes. If contact occurs, rinse thoroughly with water

**Stop use and ask a doctor** if redness or irritation develops and persists for more than 72 hours and continues

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

##### ***Directions***

- put enough gel in your palm to cover hands and rub hands together rapidly until dry
- children under 6 years of age should be supervised when using this product

##### ***Other information***

- store below 110°F (43°C)
- may discolor certain fabrics or surfaces

##### ***Inactive ingredients***

carbomer, fragrance, glycerin, propylene glycol, silicone, triethanolamine, water (aqua)

**Kill Germs up to 99.99%** of most common germs that may cause illness

Distributed by:

Acme United Corporation  
 55 Walls Drive  
 Fairfield, CT 06824  
 1-800-835-2263  
**Made in Egypt**

**Packaging**



**GermiFree**

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<b>Directions</b> <ul style="list-style-type: none"> <li>•put enough gel in your palm to cover hands and rub hands together rapidly until dry</li> <li>•children under 6 years of age should be supervised when using this product</li> </ul>	
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**GERMIFREE ANTIMICROBIAL HAND GEL**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-0400(NDC:28691-6000)
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<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	67.7 mL in 100 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	SILICON (UNII: Z4152N8IU)			
	TROLAMINE (UNII: 9O3K93S3TK)			
	WATER (UNII: 059QF0K00R)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0924-0400-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
2	NDC:0924-0400-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
3	NDC:0924-0400-03	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
4	NDC:0924-0400-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
5	NDC:0924-0400-05	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
6	NDC:0924-0400-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
<b>Marketing Information</b>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC monograph not final	part333A	06/11/2020	

**Labeler** - Acme United Corporation (001180207)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0400) , repack(0924-0400)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0400) , repack(0924-0400)