

## **FIRST AID ONLY INSTANT HAND SANITIZER- 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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### **First Aid Only Instant Hand Sanitizer Gel**

#### **Active Ingredient(s)**

Ethyl Alcohol 70% 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.

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 your hands and rub hand 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)

#### **Package Label - Principal Display Panel**



91190  
ANTISEPTICS

# Instant Hand Sanitizer Gel

Eliminates most  
common harmful  
germs and bacteria



2 FL OZ (60mL)



<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% w/w .....	Antimicrobial
<b>Uses</b> hand sanitizer to help reduce microbes on the skin	
<b>Warnings</b>	
<b>Flammable.</b> Keep away from fire or flame	
<b>For external use only</b>	
<b>When using this product,</b> do not use in or near the eyes. If contact occurs, rinse thoroughly with water	
<b>Stop use and ask a doctor</b> if redness or irritation develops and persists for more than 72 hours	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ put enough gel in your palm to cover your hands and rub hand together rapidly until dry</li> <li>■ children under 6 years of age should be supervised when using this product</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ store below 110°F (43°C)</li> <li>■ may discolor certain fabrics or surfaces</li> </ul>	
<b>Inactive ingredients</b>	
carbomer, fragrance, glycerin, propylene glycol, silicone, triethanolamine, water (aqua)	

Manufactured for: **Acme United Corporation**  
55 Walls Dr, Fairfield, CT 06824 [www.FirstAidOnly.com](http://www.FirstAidOnly.com)  
Made in Egypt 91190-001 -revA

LOT

EXP

60 mL NDC: 0924-0401-01

## FIRST AID ONLY INSTANT HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-0401(NDC:28691-0700)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
SILICON (UNII: Z4152N8IUJ)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0401-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	
2	NDC:0924-0401-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	
3	NDC:0924-0401-03	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	
4	NDC:0924-0401-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	
5	NDC:0924-0401-05	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	
6	NDC:0924-0401-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/09/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0401) , repack(0924-0401)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0401) , repack(0924-0401)

Revised: 6/2020

Acme United Corporation