

**HAND SANITIZER- alcohol gel**  
**Anhui Ruimei Pharmaceutical Co.,Ltd**

*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.*

-----

**Hand Sanitizer**

**Active Ingredient(s)**

Ethanol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

To help kill 99.9% proven effective against germs, including: intestinal pathogenic bacteria, pyogenic coccus, pathogenic yeast and common bacteria of hospital infection.

**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.

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

**Inactive ingredients**

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER,TETRAHYDROXYPROPYL

ETHYLENEDIAMINE, WATER

Package Label - Principal Display Panel

Address Anhui Ruimei Pharmaceutical Co., Ltd.  
 Building 1, Town Standardized Factory of Gongtou,  
 Intersection of North Waihuan 2nd Road and Lingqing  
 Road, Suzhou City High-Tech District, Anhui Province,  
 China All rights reserved. Made in China



<b>Drug Facts</b>	
<b>Active ingredient</b> Ethanol 75% (V/V)	<b>Purpose</b> Antiseptic
<b>Uses</b> To help kill 99.9% proven effective against germs, including: intestinal pathogenic bacteria, pyogenic coccus, pathogenic yeast and common bacteria of hospital infection.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> ·in children less than 2 months of age      ·on open skin wounds	
<b>When using this product</b> Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b> irritation or rash occur. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ·Place enough amount of product on hands to cover all surface. Rub hands until dry. ·Supervise children under 6 years old when using this product to avoid swallowing.	
<b>Other informations</b> ·Store between 15-30°C(59 - 86°F) ·Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> acrylates/c10-30 alkyl acrylate crosspolymer, tetrahydroxypropyl ethylenediamine, water	
<b>Batch code / Expiring Dating</b>	

100 mL NDC: 77467-001-01

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77467-001
<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	75 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		0.5 mL in 100 mL

<b>EDETOL</b> (UNII: Q4R969U9FR)	0.25 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77467-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

**Labeler** - Anhui Ruimei Pharmaceutical Co.,Ltd (554528665)

### Establishment

Name	Address	ID/FEI	Business Operations
Anhui Ruimei Pharmaceutical Co.,Ltd		554528665	manufacture(77467-001)

Revised: 5/2020

Anhui Ruimei Pharmaceutical Co.,Ltd