

## **HAND SANITIZER- ethyl alcohol gel**

### **AS Beauty**

*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. Isopropyl Alcohol (75%, 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)**



### Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol: 70% w/v	Antiseptic

**Usage:** Hand Sanitizer to help reduce bacteria on skin.

#### Warnings:

**For External Use Only. Flammable. Keep Away from Fire or Flame. Do Not Use** on children less than 2 years of age. On open wounds/cuts. When Using This Product Keep out 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 the Poison Control Center immediately.

#### Directions:

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

#### Other Information:

- Store below 100°F (40°C)
- May Discolor Certain Fabrics

#### Inactive Ingredients:

Deionized Water, Glycerol, Carbomer, Triethanolamine.

MANUFACTURED BY: ZHEJIANG RIFESHOW COSMETICS CO., LTD.



In Case of An Emergency:  
CHEMTREC 1-800-424-9300

chem-cosmo

Maven@julep.com  
MADE IN THE CHINA  
DISTRIBUTED BY: AS BEAUTY GROUP, LLC  
NEW YORK, NY 10018 | JULEP ROOM

UPC # 94910405320

Ethyl Alcohol 75% 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.

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**

glycerin, hydrogen peroxide, purified water USP

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



250 ml NDC 74884-075-01

**HAND SANITIZER**

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74884-075
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 75 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Product Characteristics

<b>Color</b>	white (Colorless Water White)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74884-075-01	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2020	

### Marketing Information

<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	05/18/2020	

**Labeler** - AS Beauty (116977536)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ZHEJIANG RIFESHOW COSMETICS CO.,LTD		560843477	manufacture(74884-075)