

**HAND SANITIZER- alcohol gel**  
**Jinhua City Wellmae Cosmetics 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.*

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**75427-006**  
**Hand Sanitizer**

**Active Ingredient(s)**

ETHYL ALCOHOL 75% V/V

**Purpose**

**Use**

HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE, FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

**Warnings**

**Do not use**

- ON CHILDREN LESS THAN 2 MONTHS OF AGE
- ON OPEN SKIN WOUNDS

KEEP OUT OF EYES, EARS AND MOUTH. IN CASE OF CONTACT WITH EYES, RINSE EYES THOROUGHLY WITH WATER.

IF IRRITATION OR RASH OCCURS. THESE MAY BE SIGNS OF A SERIOUS CONDITION.

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

PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE

## Package Label - Principal Display Panel

NDC 75427-006 16.9 FL OZ (500 mL) HAND SANITIZER TUJUN INTERNATIONAL, LLC MADE IN CHINA	<b>DRUG FACTS</b> <b>ACTIVE INGREDIENT(S)</b> ETHYL ALCOHOL, 75% V/V	<b>PURPOSE</b> ANTISEPTIC
	<b>(USE)</b> HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.	
	<b>WARNINGS</b> FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.	
	<b>DO NOT USE</b> • ON 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.	
<b>DIRECTIONS</b> • 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.		
<b>OTHER INFORMATION</b> • STORE BETWEEN 15-30C (59-86F) • AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F) <b>INACTIVE INGREDIENTS</b> PURIFIED WATER, PROPYLENE GLYCOL, GLYCERIN, CARBOMER, TRIETHANOLAMINE		



16.9 FL OZ (500 mL)

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KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.	
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DISTRIBUTED BY TUJUN INTERNATIONAL, TUCSON, AZ 85718-1477  
 43-443-020  
 ESP-000003



2 FL OZ (60 mL)

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75427-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75427-006-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75427-006-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - Jinhua City Wellmae Cosmetics Co., Ltd. (543459963)

### Establishment

Name	Address	ID/FEI	Business Operations
Jinhua City Wellmae Cosmetics Co., Ltd.		543459963	manufacture(75427-006)

Revised: 1/2022

Jinhua City Wellmae Cosmetics Co., Ltd.