

**HAND SANITIZER- ethyl alcohol gel**  
**Wenzhou Shengkai Technology Industry 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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**78019-800 75% Alcohol Hand Sanitizer**

**Active Ingredient**

Ethy Alcohol 75%

**Purpose**

Antiseptic

**Use**

Use: Help reduce bacteria that potentially can cause disease.

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.

Allergic to alcohol

When using this product

Keep out of eyes, ears, and mouth. In case of contact with eyes,

rinse eyes thoroughly with water.

Stop use: stop use and ask a doctor if irritation or rash occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

Take out the product and spread it on your skin until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

**Inactive ingredients**

Water, Carbomer

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 75%.....	Antiseptic
<i>Use: Help reduce bacteria that potentially can cause disease.</i>	
<b>Warnings</b>	
<i>For external use only. Flammable. Keep away from heat or flame.</i>	
<b>Do not use</b>	
<i>In children less than 2 months of age. On open skin wounds.</i>	
<i>Allergic to alcohol</i>	
<b>When using this product</b>	
<i>Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</i>	
<b>Stop use:</b> stop use and ask a doctor if irritation or rash occurs	

<b>Drug Facts(continued)</b>
<b>Keep out of reach of children</b>
<i>If swallowed, get medical help or contact a Poison Control Center right away.</i>
<b>Directions</b>
<i>Take out the product and spread it on your skin until dry.</i>
<i>Supervise children under 6 years of age when using this product to avoid swallowing.</i>
<b>Other information</b>
<i>Store between 15-30C (59-86F)</i>
<i>Avoid freezing and excessive heat above 40C(104F)</i>
<b>Inactive ingredients:</b> Water, Carbomer

# HAND SANITIZER

ethyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78019-800
<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 100 mL

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78019-800-01	2 mL in 1 BAG; Type 0: Not a Combination Product	06/29/2020	
2	NDC:78019-800-02	3 mL in 1 BAG; Type 0: Not a Combination Product	06/29/2020	
3	NDC:78019-800-03	5 mL in 1 BAG; Type 0: Not a Combination Product	06/29/2020	
4	NDC:78019-800-04	10 mL in 1 BAG; Type 0: Not a Combination Product	06/29/2020	
5	NDC:78019-800-05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
6	NDC:78019-800-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
7	NDC:78019-800-07	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
8	NDC:78019-800-08	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
9	NDC:78019-800-09	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
10	NDC:78019-800-10	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
11	NDC:78019-800-11	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	

## 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	part333E	06/29/2020	

**Labeler** - Wenzhou Shengkai Technology Industry Co., Ltd. (548518819)

**Establishment**

Name	Address	ID/FEI	Business Operations
Wenzhou Shengkai Technology Industry Co., Ltd.		548518819	manufacture(78019-800)

Revised: 2/2021

Wenzhou Shengkai Technology Industry Co., Ltd.