

**HAND SANITIZER- alcohol gel**  
**SHENG HE TAI INTERNATIONAL TRADING 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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**SHENG HE TAI INTERNATIONAL TRADING CO., LTD. Redo of second submittal where 003 is converted to 05 and 04 is converted to 06**

**Active Ingredient(s)**

Ethyl Alcohol 75%. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

For hand washing to decrease bacteria on the skin, only when water is not available.

**Warnings**

Flammable, keep away from fire and flames. For external use only

Do not get into eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation and redness develop.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Wet hands thoroughly with product and allow to dry without wiping.

**Other information**

Store in a cool, dry place below 104F

**Inactive ingredients**

Agua (water), Ammonium Acryloyldimethylteurate/VP Copolymer, Eucalyptus globulus (Eucalyptus) Oil

**Package Label - Principal Display Panel**



**Eucalyptus  
Hand Sanitizer Gel**

**75% Alcohol**



**Kills 99.9% Germs**  
Instant use Without water.

60ml  
Made In TAIWAN

**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 75%.....	.....Antiseptic

*Use* for hand-washing to decrease bacteria on the skin, only when water is not available.

**Warnings**

- Flammable, keep away from fire and flames ■ For external use only

*When using this product*

- do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water.

*Stop use and ask a doctor if*

- irritation and redness develop

*Keep out of reach of children* If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- wet hands thoroughly with product and allow to dry without wiping

**Inactive Ingredients** Alcohol, Aqua(Water), Ammonium Acryloyldimethyltaurate/VP Copolymer, Eucalyptus globulus(Eucalyptus) Oil.

**Other Information** Store in a cool, dry place below 104°F

**Capacity :** 60ml **Expiration date:** 3 years.  
**Company identification:**  
 SHENG HE TAI INTERNATIONAL TRADING CO., LTD.  
 14F.-5, NO.184, ZHONGYANG RD., CHANGHUA CITY,  
 CHANGHUA COUNTY 50056, TAIWAN




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**Made In TAIWAN**

60 mL NDC: 76584-005-06

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76584-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

EUCALYPTUS OIL (UNII: 2R04ONI662)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76584-005-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

**Labeler** - SHENG HE TAI INTERNATIONAL TRADING CO., LTD. (656359732)

### Establishment

Name	Address	ID/FEI	Business Operations
SHENG HE TAI INTERNATIONAL TRADING CO., LTD.		656359732	manufacture(76584-005)

Revised: 5/2020

SHENG HE TAI INTERNATIONAL TRADING CO., LTD.