## 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.

-----

# 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.

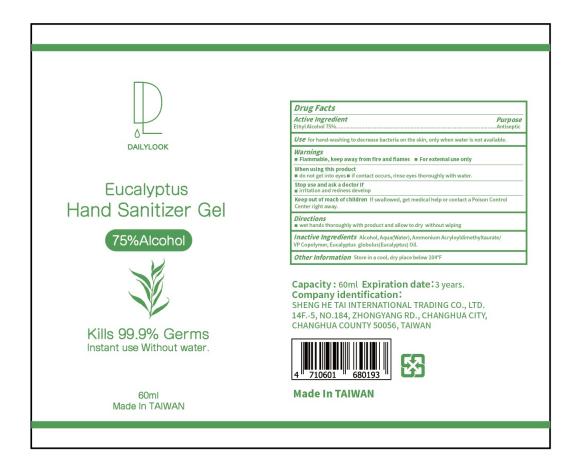
#### Other information

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



60 mL NDC: 76584-005-06

## HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76584-005	
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

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM ACRYLO YLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

## EUCALYPTUS OIL (UNII: 2R040NI662)

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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.