

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. converting 003-10 to 005,10

Active Ingredient(s)

Ethyl Alcohol 75%. Purpose: Antiseptic

Purpose

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.

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

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

Package Label - Principal Display Panel

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 : 100ml 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

4 710601 680223

Made In TAIWAN

100 mL NDC: 76584-005-10

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
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76584-005-10	100 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.