

HAND SANITIZER- alcohol liquid
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 2nd 001-08

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 or flames. For external use only.

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.

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

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

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

Other information

Store in a cool dry place below 104F

Inactive ingredients

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

Package Label - Principal Display Panel

proprietary name 2 : Hand Sanitizer
 NDC 2: 001-08

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 : 80ml 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

80 mL NDC: 76584-001-08

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76584-001
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)	
WATER (UNII: 059QF0KO0R)	

EUCALYPTUS OIL (UNII: 2R04ONI662)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76584-001-08	80 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/25/2020	

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(76584-001)

Revised: 4/2020

SHENG HE TAI INTERNATIONAL TRADING CO., LTD.