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

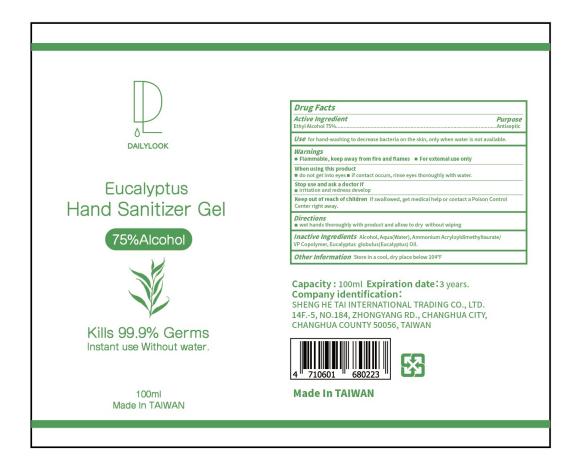
Other information

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



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			

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	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)

l	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.