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 TAII convert 004-08 to 006-08

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 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.

Directions

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

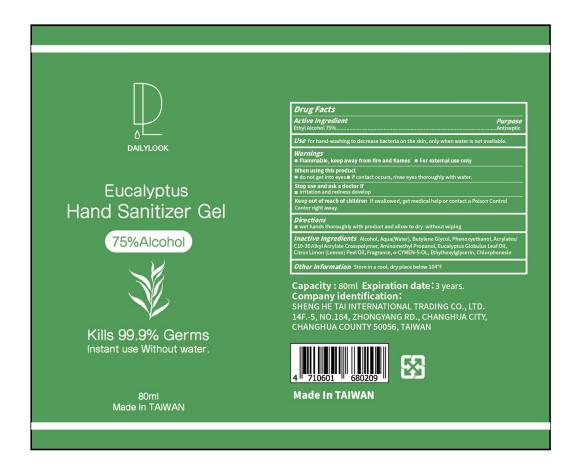
Other information

Store in a cool, dry place below 104F

Inactive ingredients

Aqua (Water), Butylene Glycol, Phenoxyethanol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Eucalyptus Globulus Leaf Oli, Citrus Limon (Lemon) Peel Oil, Frangrance, o-CYMEN-5-OL, Ethylhexyglycerin, Chlorophesin

Package Label - Principal Display Panel



80 mL NDC: 76584-006-08

HAND SANITIZER					
alcohol gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:76584-006	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	75	5 mL in 100 mL
Inactive Ingredients					

Inactive Ingredients		
Ingredient Name	Strength	
CITRUS LIMON FRUIT OIL (UNII: 0 HNC1J1YED)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
O-CYMEN-5-OL (UNII: H41B6Q1I9L)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:76584-006-	80 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 TAIINTERNATIONAL TRADING CO., LTD. (656359732)

Establishment				
Name	Address	ID/FEI	Business Operations	
SHENG HE TAI INTERNATIONAL TRADING CO., LTD.		656359732	manufacture(76584-006)	

Revised: 5/2020 SHENG HE TAI INTERNATIONAL TRADING CO., LTD.