

HAND SANITIZER- hand sanitizer liquid
Shenzhen Shierjie Biological Engineering 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.

43116-030
Hand Sanitizer

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Uses

- hand sanitizer to help reduce bacteria that potentially can cause disease
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in the eyes
- on children less than 2 years of age
- on open skin wounds

When using this product

keep out of eyes, ears, and mouth. In case of contact, rinse thoroughly with water.

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

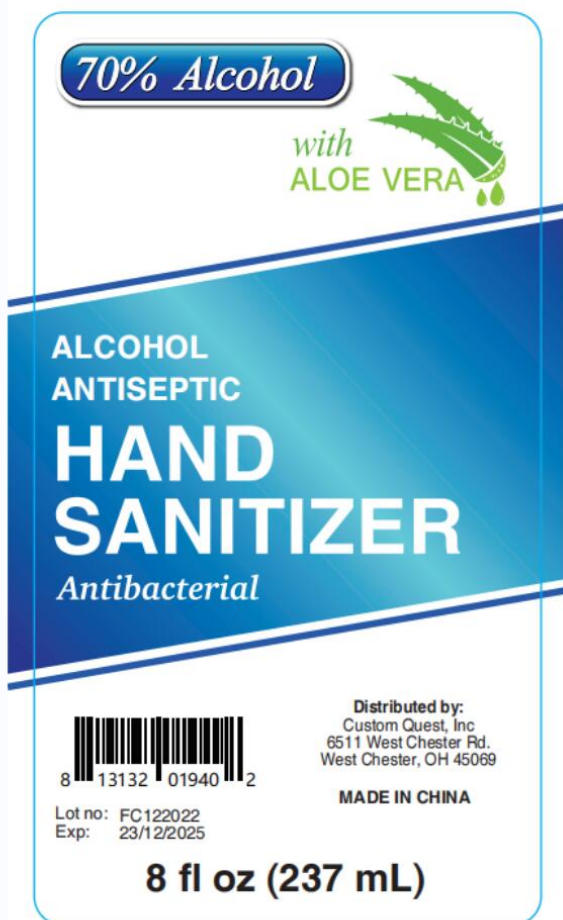
wet hands thoroughly with product and allow to dry without wiping
supervise children under 6 years of age when using this product

Other information

- Other information a store between 15-30°C (59-86F)
- avoid freezing and excessive heat above 40°C (104F)

Inactive ingredients

Aloe (*Aloe barbadensis*) Leaf Juice, Carbomer , Glycerin , Propylene Glycol , Tocopheryl Acetate ,Triethanolamine , Water



Drug Facts	
Active ingredient	Purpose
Alcohol 70% v/v.....	Antiseptic
Uses ■ hand sanitizer to help reduce bacteria that potentially can cause disease ■ for use when soap and water are not available	
Warnings	
Flammable, keep away from fire/flame	
For external use only	
Do not use ■ in the eyes ■ on children less than 2 years of age ■ on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact, rinse thoroughly with water.	
Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours	
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 ■ supervise children under 6 years of age when using this product	
Other information ■ store between 15-30°C (59-86°F) ■ avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Aloe (<i>Aloe barbadensis</i>) Leaf Juice, Carbomer, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water	
Questions? +1-513-644-0445	
You may also report serious side effects to this phone number. Monday through Friday, 8:30 am-4:30 pm Eastern Standard Time	

HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43116-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43116-030-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/06/2022	

Labeler - Shenzhen Shierjie Biological Engineering Co., LTD (547610261)**Registrant** - Shenzhen Shierjie Biotech Co.,LTD (547610261)**Establishment**

Name	Address	ID/FEI	Business Operations
Shenzhen Shierjie Biological Engineering Co., LTD		547610261	manufacture(43116-030)

Revised: 12/2022

Shenzhen Shierjie Biological Engineering Co., LTD