

**HAND SANITIZER- hand sanitizer gel**  
**FUJIAN ISHINE COSMETICS 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.*

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**HAND SANITIZER**

**Active Ingredient**

ALCOHOL 75%

**Purpose**

Antiseptic

**Uses:**

Hand Sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.

**Warnings**

Flammable. Keep away from fire. For external use only.

When using this product avoid contact with or near the eyes. In case of contact, rinse eyes thoroughly with water.

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

**Directions:**

Put enough product in your palm to thoroughly cover hands and rub hands together briskly until dry. Use as part of your daily cleansing routine.

**Other Information**

Store below 110°F (43°C) and keep seal after use.

**Inactive Ingredients:**

Aqua, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Cetareth-6 Oliviate, Parfum (Linalool, Linal, Hedione, Hydroxycitronellal, Iso Methyl Ionone, Citronellol, iso E Super), FD&C Yellow No.5 (CI 19140).

**Package Label**

External Application

Chamomile

HAND SANITIZER

Rinse free & non sticky

Clean/antibacterial

Disinfection/skin care

Net Wt:60ml / 2.0fl.oz

NDC: 54823-005-01



# 60ML

## HAND SANITIZER

hand sanitizer gel

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54823-005

<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	0.01 mL in 100 mL		
	CETEARETH-6 OLIVATE (UNII: 8834VWF9MO)	0.1 mL in 100 mL		
	LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.01 mL in 100 mL		
	METHYL DIHYDRO JASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	0.01 mL in 100 mL		
	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	0.01 mL in 100 mL		
	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	0.01 mL in 100 mL		
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.0001 mL in 100 mL		
	TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL		
	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	0.01 mL in 100 mL		
	.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	0.01 mL in 100 mL		
	1-(2,3,8,8-TETRAMETHYL-1,2,3,4,5,6,7,8-OCTAHYDRO NAPHTHALEN-2-YL)ETHANONE (UNII: 1GD7ODM28Y)	0.01 mL in 100 mL		
	WATER (UNII: 059QF0K00R)	23.9899 mL in 100 mL		
	GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL		
	CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	0.3 mL in 100 mL		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54823-005-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
<b>Marketing Information</b>				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC mono graph not final	part333A	04/09/2020	

**Labeler** - FUJIAN ISHINE COSMETICS CO., LTD. (548232812)

**Registrant** - FUJIAN ISHINE COSMETICS CO., LTD. (548232812)

### Establishment

Name	Address	ID/FEI	Business Operations
FUJIAN ISHINE COSMETICS CO., LTD.		548232812	manufacture(54823-005)