

**HAND SANITIZER- hand sanitizer gel**  
**Zhejiang Enchant Cosmetic 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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

- in children less than 2 months of age
- on open skin wounds

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.

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## Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

2000 ml in 1 bottle NDC: 52728-019-01



Kills germs without water

Wash-free, Effective antibacterial, Easy to carry

Ingredients: Alcohol, Water(Aqua), Acrylates Copolymer, Aminomethyl propanol, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate.

Effective Ingredient And Content: 75% Alcohol(V/V)

Antibacterial Category: Have antibacterial effect to staphylococcus aureus, escherichia coli, candida albicans

ingredients.

Range Of Use: Antibacterial and daily hand cleaning.

Direction For Use: 1.Squeeze out a small amount of formula properly and knead it with both hands.  
2. lasting for 1-3 minutes.

Caution: Do not take the external product orally; Do not touch the wound; Do not contact the child directly; If you contact the eyes carelessly, wash them with water in time; Do not use this product instead of drugs; Do not use it if you are allergic to alcohol.

Storage Conditions: Keep away from sunlight and store in a cool and dry place.

67.7 FL.OZ./ 2000ML

Manufacturer: Zhejiang Enchant Cosmetic Co., Ltd.

Add: 105 Kaiyuan North Street,Yidong Industrial District, Yiwu City, Zhejiang, China

Made in China



PE材质，彩色印刷，覆亮膜，格拉辛底，尺寸：130\*120mm

## HAND SANITIZER

hand sanitizer gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52728-019
Route of Administration	EXTRACORPOREAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1500 mL in 2000 mL

### Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	24 mL in 2000 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	5.6 mL in 2000 mL
WATER (UNII: 059QF0K00R)	468.38 mL in 2000 mL
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.02 mL in 2000 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	2 mL in 2000 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52728-019-01	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/26/2020	

**Labeler** - Zhejiang Enchant Cosmetic Co., Ltd. (527284802)

## Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Enchant Cosmetic Co., Ltd.		527284802	manufacture(52728-019)

Revised: 6/2020

Zhejiang Enchant Cosmetic Co., Ltd.