

**HAND SANITIZER- alcohol liquid**  
**Guangzhou Biosphere 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.*

-----

**Hand Sanitizer**

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. WATER
- c. GLYCERIN
- d. ALOE BARBADENSIS LEAF EXTRACT
- e. TOCOPHEROL
- f. PANTHENOL
- g. CARBOMER
- h. TROLAMINE

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)**

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.

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.

### 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

WATER  
GLYCERIN  
ALOE BARBADENSIS LEAF EXTRACT  
TOCOPHEROL  
PANTHENOL  
CARBOMER  
TROLAMINE

### Package Label - Principal Display Panel





**Drug Facts**

Active ingredient[s]	Purpose
Alcohol 75%	Antiseptic

**Uses**

- To decrease bacteria on the skin that could cause disease
- Recommended for repeated use

**Warnings**

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

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

**Directions**

- Place enough product on hands to cover all surfaces. rub hands together until dry
- Children under 6 years of age should be supervised when using to avoid swallowing.

**Other information**

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

**Inactive ingredients** Water, Glycerin, Aloe Barbadosis Leaf Extract, Carbomer, Trolamine, Tocopherol, Panthenol.

Manufacturer: Guangzhou Biosphere Cosmetics Co., Ltd

Made in China





**Drug Facts**

Active ingredient[s]	Purpose
Alcohol 75%.....	Antiseptic

**Uses**

- To decrease bacteria on the skin that could cause disease
- Recommended for repeated use

**Warnings**

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

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

**Directions**

- Place enough product on hands to cover all surfaces . rub hands together until dry
- Children under 6 years of age should be supervised when using to avoid swallowing.

**Other information**

- Store bellow 110°F (43°C)
- May discolor certain fabrics or surfaces

**Inactive ingredients** Water, Glycerin, Aloe Barbadensis Leaf Extract, Carbomer, Trolamine, Tocopherol, Panthenol.

Manufacturer: Guangzhou Biosphere Cosmetics Co., Ltd

Made in China





**Drug Facts**

Active ingredient[s]	Purpose
Alcohol 75%.....	Antiseptic

**Uses**

- To decrease bacteria on the skin that could cause disease
- Recommended for repeated use

**Warnings**

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

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

**Directions**

- Place enough product on hands to cover all surfaces . rub hands together until dry
- Children under 6 years of age should be supervised when using to avoid swallowing.

**Other information**

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

**Inactive ingredients** Water, Glycerin, Aloe Barbadensis Leaf Extract, Carbomer, Trolamine, Tocopherol, Panthenol.

Manufacturer: Guangzhou Biosphere Cosmetics Co., Ltd

Made in China





## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75767-101
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
PANTHENOL (UNII: WV9CM0O67Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75767-101-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75767-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75767-101-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75767-101-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75767-101-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Guangzhou Biosphere Cosmetics Co., Ltd. (550461448)

## Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Biosphere Cosmetics Co., Ltd.		550461448	manufacture(75767-101)

Revised: 7/2020

Guangzhou Biosphere Cosmetics Co., Ltd.