

**INSTANT HAND SANITIZER- alcohol gel**  
**Dongyang Mukang Pharmaceutical Factory**

*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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**mukang instant 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) (80%, 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. 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)**

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**

236 mL NDC: 75586-008-01,1000 mL NDC: 75586-008-02,2000 mL NDC: 75586-008-03

**Product Name:** Instant Hand Sanitizer

**Product Compositions:**ALCOHOL(75%v/v), water, Carbomer ,Triethanolamine Glycerin ,etc.

**Shelf Life:**24 months

**Production Date and Expiry Date:**see code

**Directions of Use:** Hand sanitizer to help decrease bacteria skin. Take a proper amount and put it on the palm directly. Rub the fingers of both hands on each other until the skin of hands and wrists is completely wet. It will work for 1-3 minutes and evaporate naturally.Not sticky use.No need to wash with water,protecting your health anytime,anywhere.

#### **Warnings:**

- 1.Flammable, please keep away from the fire source, store in a cool, dry and ventilated place.
- 2.Use with caution for alcohol-allergic people.
- 3.Not suitable for disinfecting the surface of fat soluble objects.
4. Keep out of reach of children

**Product Capacity:** xx ml

**Manufacturer:**Dongyang Mukang Pharmaceutical factory

Address:No.171 Xingye Street, Changsonggang Functional Area, Dongyang Economic

Development Zone, Dongyang City, Jinhua City, Zhejiang Province, China

Sanitary License: ZWXZZ (2020) No.0129

Executive Standard: GB26373-2010

Product Quality Inspection:Qualified

MADE IN CHINA TEL:15024588877

PRO: DD/MM/YY

EXP:DD/MM/YY

## INSTANT HAND SANITIZER

alcohol gel

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:75586-008 |
| Route of Administration | EXTRACORPOREAL |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 75 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| TROLAMINE (UNII: 9O3K93S3TK)                               |          |
| GLYCERIN (UNII: PDC6A3C0OX)                                |          |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| WATER (UNII: 059QF0KO0R)                                   |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    |  | Score        |  |
| Shape    |  | Size         |  |
| Flavor   |  | Imprint Code |  |
| Contains |  |              |  |

**Packaging**

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:75586-008-01 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020           |                    |
| 2 | NDC:75586-008-02 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020           |                    |
| 3 | NDC:75586-008-03 | 2000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020           |                    |

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## Marketing Information

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

**Labeler** - Dongyang Mukang Pharmaceutical Factory (554531139)

## Establishment

| Name                                   | Address | ID/FEI    | Business Operations    |
|--|---------|-----------|------------------------|
| Dongyang Mukang Pharmaceutical Factory |         | 554531139 | manufacture(75586-008) |

Revised: 5/2020

Dongyang Mukang Pharmaceutical Factory