# INSTANT HAND SANITIZER- instant hand sanitizer gel Yiwu Dieyuan 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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75612-100

#### **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

- 1. This product is for external use, no taken orally, avoid contact with eyes, and keep away from reach of children.
- 2. Flammable, please keep away from the fire source; do not close to the fire source before no volatilized completely when use.
- 3. If there is skin irritation, please stop using. If further irritation, please consult a doctor and keep it below.
- 4. Use with caution for alcohol allergy.

#### 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**

Aqua, glycerin, acrylates/C10-30 aklykl acrylate crosspolymer, tetrahydroxypropyl ethylenediamine, aloe barbadensis leaf extract, tocopheryl acetate

### Package Label - Principal Display Panel

60 mL NDC: 75612-100-01

Uses ■ To decrease bacteria on skin without soap or water ■ Recommended for repeated use  Warnings For external use only.Only on hands. Flammable,keep away from fire or flame.  Do not use in or near eyes.In case of contact, rinse thoroughly with water  Stop use and ask a doctor if irritation and redness develop and persists foe more than 72 hours  Keep out of reach of children. If swallowed,get medical help or contact a Poison Contri Center right away.  Directions ■ Put enough product on palm and rub hands until dry ■ Children under 6 years of age should be supervised while using this product  Inactive ingredients Aqua,Glycerin,Acrylates/C 10-30 Alkyl Acrylate Crosspotymer,Tetrahydroxypropyl Ethylenediamine, Aloe Barbadensis Leaf Extract,Tocopheryl Acetate  vu Dieyuan Cosmetics Co., Ltd. D : No. 199, Wulian Road, Yiting Town, Yiwu City, Zhejiang Provinced.: 0086 - 579 - 83801188	Drug Facts	3000
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### **INSTANT HAND SANITIZER**

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75612-100	
Route of Administration	EXTRACORPOREAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	45 mL in 60 mL	

Inactive Ingredients			
Ingredient Name	Strength		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
GLYCERIN (UNII: PDC6A3C0OX)			
EDETOL (UNII: Q4R969U9FR)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
7	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75612-100-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2020	

## Drug Facts

## Active Ingredient

Purpose

Ethyl Alcohol 75%......Antiseptic

### Uses

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- Recommended for repeated use

## Warnings

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LOT#:A08220069 EXP:06192022 NDC XXXXXXX



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

## Labeler - Yiwu Dieyuan Cosmetics Co., Ltd. (554531085)

Establishment				
Name	Address	ID/FEI	Business Operations	
Yiwu Dieyuan Cosmetics Co., Ltd.		554531085	manufacture(75612-100)	

Revised: 6/2020 Yiwu Dieyuan Cosmetics Co., Ltd.