## INSTANT HAND SANITIZER- ethyl alcohol gel Gemmytec (Shanghai) 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.

-----

## Gemmytec EA 75% GEL 60mL

## **Active Ingredient(s)**

Ethyl alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic

#### Use

Hand sanitizer to help reduce bacteria on the skin.

## 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. If 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 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 at 68-770(20-250).
- May discolor certain fabrics or surfaces.

#### **Inactive ingredients**

Water, Carbomer, Glycerin, 2-Amino-2-methyl-1-propanol, Fragrance.

### Package Label - Principal Display Panel



\*Kills 99.99% of most common germs that may cause illness

## Drug Facts

**Active ingredient** Purpose Ethyl alcohol 75% v/v...... Antiseptic

USE · Hand sanitizer to help reduce bacteria on the skin.

#### 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 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 at 68-77°F(20-25°C)
- May discolor certain fabrics or surfaces.

#### Inactive ingredients

Water, Carbomer, Glycerin, 2-Amino-2-methyl-1-propanol, Fragrance.

#### Produced by:

GEMMYTEC (SHANGHAI) CO., LTD

Room 606, Building 4#, No 123, Juli Road China

(Shanghai) Pilot Free Trade Zone. 201213

Tel: 400-820-6717

E-mail: salesmanager@gemmytec.com

www.gemmytec.com



#### INSTANT HAND SANITIZER

ethyl alcohol gel

## **Product Information**

HUMAN OTC DRUG NDC:81343-101 Product Type Item Code (Source)

TOPICAL **Route of Administration** 

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	45 mL in 60 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
LEMON OIL (UNII: 19 GRO 8 2 4 L L)				

## AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

Packaging					
	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1	NDC:81343-101-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/23/2020	

# Labeler - Gemmytec (Shanghai) Co., Ltd (554552122)

## **Registrant -** A03 Lab of BTS (548009541)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Shanghai Chuangshi Industry Group Co., Ltd		546872672	manufacture (8 1343-10 1)	

Revised: 12/2020 Gemmytec (Shanghai) Co., Ltd