

**HAND SANITIZER- hand sanitizer gel**  
**Sanlingyi(Guangdong)Medical Biotechnology 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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**Hand Sanitizer GEL**

**Active Ingredient(s)**

Alcohol 75%v/v

**Purpose**

Antiseptic

**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 SECTION**

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.

**OTC-STOP USE SECTION**

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

Alcohol Glycerin Trolamine Polyacrylic acid

## Package Label - Principal Display Panel



# HAND SANITIZER

hand sanitizer gel

## Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78351-001

Route of Administration TOPICAL

### 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
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78351-001-01	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:78351-001-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
3	NDC:78351-001-03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
4	NDC:78351-001-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
5	NDC:78351-001-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
6	NDC:78351-001-06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
7	NDC:78351-001-07	275 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
8	NDC:78351-001-08	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
9	NDC:78351-001-09	375 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
10	NDC:78351-001-10	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
11	NDC:78351-001-11	580 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
12	NDC:78351-001-12	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
13	NDC:78351-001-13	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
14	NDC:78351-001-14	5000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

**Labeler** - Sanlingyi(Guangdong)Medical Biotechnology Co.,Ltd. (554532954)

**Registrant** - Sanlingyi(Guangdong)Medical Biotechnology Co.,Ltd. (554532954)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sanlingyi(Guangdong)Medical Biotechnology Co.,Ltd.		554532954	manufacture(78351-001)

Revised: 5/2020

Sanlingyi(Guangdong)Medical Biotechnology Co.,Ltd.