# SANITIZERX- hand sanitizer gel gel Guangzhou caolyxiang 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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78414-004 HAND SANITIZER GEL

# Active Ingredient(s)

Ethyl Alcohol75%

# **Purpose**

Antiseptic

#### Use

Hand sanitizer to help reduce bacteria that potentially can cause disease

# **Warnings**

For external use only. Flammable. Keep away from heat or flame

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyesrinse eye thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition

### Do not use

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### WHEN USING SECTION

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyesrinse eye thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition

### STOP USE

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

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

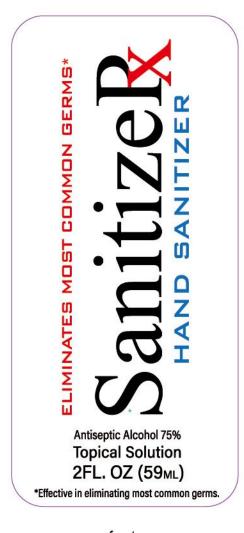
# Other information

Store between 15C-30C(59F-86F) Avoid freezing and excessive heat above 40C(104F)

# **Inactive ingredients**

purified water glycerin Hydrogen peroxide

Package Label - Principal Display Panel



DRUG FACTS

Active ingredient Purpose: Ethyl alcohol 75%...Antiseptic

Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease.

Inactive ingredients:

glycerin, hydrogen peroxide, purified water USP

#### 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 eye thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

#### **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°C-30°C (59°F-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)



back

front

Size:65x30mm

# **SANITIZERX**

hand sanitizer gel gel

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78414-004
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Route of Administration TOPICAL

### Active Ingredient/Active Moiety

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

Inactive Ingredients		
Ingredient Name	Strength	
1,1-BIS(TERT-BUTYLPEROXY)CYCLOHEXANE (UNII: JK62J3E3Q4)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6 A3C0 OX)		

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 N	IDC:78414-004-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
N.	larketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

09/01/2020

# **Labeler -** Guangzhou caolvxiang Biotechnology Co.,Ltd (547949400)

OTC monograph not final part333A

# **Registrant** - Guangzhou caolvxiang Biotechnology Co.,Ltd (547949400)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Guangzhou caolvxiang Biotechnology Co.,Ltd		547949400	manufacture(78414-004)		

Revised: 9/2020 Guangzhou caolvxiang Biotechnology Co.,Ltd