

HAND SANITIZER- hand sanitizer gel
Guangzhou caolvxiang 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.

Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 75%

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

keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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 15-30°C(59-86F)

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78414-002-06	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
2	NDC:78414-002-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
3	NDC:78414-002-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
4	NDC:78414-002-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
5	NDC:78414-002-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
6	NDC:78414-002-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
7	NDC:78414-002-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
8	NDC:78414-002-05	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

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

Name	Address	ID/FEI	Business Operations
Guangzhou caolvxiang Biotechnology Co.,Ltd		547949400	manufacture(78414-002)

Revised: 7/2020

Guangzhou caolvxiang Biotechnology Co.,Ltd