

SIMIKA- sanitizing gel gel
Guangzhou Ouzhuang Biological Technology 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.

Guangzhou SIMIKA 75% Gel

Active Ingredient(s)

Alcohol 75%

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

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 a serious condition.

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

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

aloe barbadensis leaf extract, fragrant Orchid, propylene glycol, carbomer, triethanolamine, purified

water

Package Label - Principal Display Panel

75% Alcohol Hand Sanitizer

Kills over 99.99% of germs

Dosage Form: Gel

Action:effectively kills 99.99% of pyogenic bacteria,enteropathogenic bacteria and pathogenic yeast(under testing environment)

Usage:squeeze on to skin of hand and rub for 2 minutes

Precautions:seal and place in a cool and dry place

Manufacturer: Guangzhou Ouzhuang Biological Technology Co., Ltd.

Refer package for production batch number & expiry date

Made in China

6 970539 700549

SIMIKA®

Disinfection Gel

Germ Killing Rate

99.99%

NET: 500ml / 16.9 Fl Oz

Drug Facts

Active Ingredient	Purpose
Alcohol 75%	Antiseptic
Use(s) 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. 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 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 of age when using this product to avoid swallowing.	
Other information • Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients propylene glycol, carbomer, triethanolamine, purified water, Aloe Barbadensis Leaf Extract, Fragrant Orchid	

500 mL NDC:77598-133-05

SIMIKA

sanitizing gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77598-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GYMNADENIA CONOPSEA WHOLE (UNII: TF911C619B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77598-133-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77598-133-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77598-133-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:77598-133-04	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
5	NDC:77598-133-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

6	NDC:77598-133-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
7	NDC:77598-133-07	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
8	NDC:77598-133-08	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
9	NDC:77598-133-10	30 mL in 1 PACKET; Type 0: Not a Combination Product	05/15/2020	
10	NDC:77598-133-11	10 mL in 1 PACKET; Type 0: Not a Combination Product	05/15/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/15/2020	

Labeler - Guangzhou Ouzhuang Biological Technology Co Ltd (418234821)

Establishment			
Name	Address	ID/FEI	Business Operations
Guangzhou Ouzhuang Biological Technology Co Ltd		418234821	manufacture(77598-133)

Revised: 7/2020

Guangzhou Ouzhuang Biological Technology Co Ltd