

SIMIKA- disinfection 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 Gel

Active Ingredient(s)

Alcohol 73% v/v. Purpose: Antiseptic

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

propylene glycol, carbomer, triethanolamine, purified water

Package Label - Principal Display Panel



— SIMIKA —
DISINFECTION GEL
 kills over 99.99% of germs

Drug Facts	
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Use(s)	
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propylene glycol, carbomer, triethanolamine, purified water	

Manufacturer: Guangzhou Ouzhuang Biological Technology Co., Ltd.
 Refer package for production batch number & expiry date
 Made in China



60 mL NDC: 77598-123-03

SIMIKA			
disinfection gel gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77598-123
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL
Inactive Ingredients			

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77598-123-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77598-123-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77598-123-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:77598-123-04	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
5	NDC:77598-123-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
6	NDC:77598-123-06	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
7	NDC:77598-123-07	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
8	NDC:77598-123-08	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
9	NDC:77598-123-09	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
10	NDC:77598-123-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
11	NDC:77598-123-11	3000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
12	NDC:77598-123-12	5000 mL in 1 BOTTLE; 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(77598-123)

Revised: 5/2020

Guangzhou Ouzhuang Biological Technology Co Ltd