OMEGACLEAN- 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-OmegaClean 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.

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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



59 mL NDC: 77598-122-20

OMEGACLEAN

sanitizing gel gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77598-122	
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: 6 DC9 Q167V3)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 903K93S3TK)			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:77598-122-20	59 mL in 1 TUBE; Type 0: Not a Combination Product	07/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/30/2020		

Labeler - Guangzhou Ouzhuang Biological Technology Co Ltd (418234821)

Establishment					
Name	Address	ID/FEI	Business Operations		
Guangzhou Ouzhuang Biological Technology Co Ltd		418234821	manufacture(77598-122)		

Revised: 7/2020 Guangzhou Ouzhuang Biological Technology Co Ltd