

ANTISEPTIC 80% TOPICAL GEL HAND SANITIZER- alcohol gel

Guangdong Genlese Cosmetics 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.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

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 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

Carbomer, triethanolamine, purified water USP

Package Label - Principal Display Panel

Alcohol Antiseptic

80%

Topical Gel

Hand Sanitizer

Non-sterile Gel



Net content: 500mL

Drug Facts

Active ingredient(s).....Purpose

Alcohol 80% v/v.....Antiseptic

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Manufactured by Guangdong Genlese Cosmetics CO., LTD.



ANTISEPTIC 80% TOPICAL GEL HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75579-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75579-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75579-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75579-001-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75579-001-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75579-001-05	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75579-001-06	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75579-001-07	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - Guangdong Genlese Cosmetics Co., Ltd. (543119089)

Establishment			
Name	Address	ID/FEI	Business Operations
Guangdong Genlese Cosmetics CO., LTD.		543119089	manufacture(75579-001)