75% ALCOHOL HAND SANITIZER GEL- hand sanitizer gel Jiaozi Chemical (guangzhou) Pty 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 75% 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

aloe, carbomer, glycerin, sterile distilled water, triethanolamine.

Package Label - Principal Display Panel

300 mL NDC: 78220-001-03



75% ALCOHOL HAND SANITIZER GEL

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78220-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	225 mL in 300 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ALOE (UNII: V5VD430 YW9)	0.258 mL in 300 mL		
GLYCERIN (UNII: PDC6A3C0OX)	10.2 mL in 300 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.771 mL in 300 mL		
WATER (UNII: 059QF0KO0R)	63 mL in 300 mL		
TROLAMINE (UNII: 9O3K93S3TK)	0.771 mL in 300 mL		

Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78220-001- 03	300 mL in 1 BOTTLE, PUMP; 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 - Jiaozi Chemical (guangzhou) Pty Ltd (679755413)

Registrant - Jiaozi Chemical (guangzhou) Pty Ltd (679755413)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jiaozi Chemical (guangzhou) Pty Ltd		679755413	manufacture(78220-001)	

Revised: 5/2020 Jiaozi Chemical (guangzhou) Pty Ltd