HAND SANITIZER- alcohol gel SHANTOU S.E.Z BAOJIE INDUSTRY 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 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.

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

Water, PEG-40 Hydrogenated Castor Oil, Chloroxylenol, Carbomer, Triethanolamine

Package Label - Principal Display Panel

60 ml NDC: 74913-668-05



100 ml NDC: 74913-668-06

Drug Facts

Active ingredient[s]

Purpose Alcohol 75% v/v.....Antiseptic

Use[s]

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Inactive Ingredients WATER, PEG-40 CASTOR OIL, CARBOMER 940, TROLAMINE, CHLOROXYLENOL



SHANTOU S.E.Z BAOJIE INDUSTRY CO..LTD SIHUANG ROAD LUGANG TOWN, CHAONAN DISTRICT, SHANTOU, CN 515144 MADE IN CHINA



237 ml NDC: 74913-668-07

Drug Facts

Active ingredient[s]

Purpose

Alcohol 75% v/v.....Antiseptic

Use[s

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SHANTOU S.E.Z BAOJIE INDUSTRY CO.,LTD SIHUANG ROAD LUGANG TOWN, CHAONAN DISTRICT, SHANTOU, CN 515144

MADE IN CHINA



Drug Facts

Active ingredient[s]

Purpose

Alcohol 75% v/v.....

..Antiseptic

Use[s

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Inactive Ingredients WATER, PEG-40 CASTOR OIL, CARBOMER 940, TROLAMINE, CHLOROXYLENOL

MANUFACTURED BY SHANTOU S.E.Z BAOJIE INDUSTRY CO.,LTD

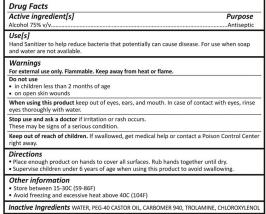
SIHUANG ROAD LUGANG TOWN, CHAONAN DISTRICT, SHANTOU, CN 515144



MADE IN CHINA

500 ml NDC: 74913-668-08





HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:749 13-668



Route of Administration

TOPICAL

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL		
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	0.5 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	23.2 mL in 100 mL		
CHLOROXYLENOL (UNII: 0F32U78 V2Q)	0.3 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74913-668- 05	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2020		
2	NDC:74913-668- 06	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2020		
3	NDC:74913-668- 07	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2020		
4	NDC:74913-668- 08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/08/2020		

Labeler - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)

Registrant - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)

Establishment					
Name	Address	ID/FEI	Business Operations		
SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD		546345856	manufacture(74913-668)		

Revised: 4/2020