

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 CASTOR OIL, CARBOMER 940, TROLAMINE, CHLOROXYLENOL

Package Label - Principal Display Panel

120 mL NDC: 74913-668-13



Kills 99% of Germs
75% Alcohol



INSTANT HAND SANITIZER



4 FL OZ / 120mL

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 75% v/v.....	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
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Inactive Ingredients WATER, PEG-40 CASTOR OIL, CARBOMER 940, TROLAMINE, CHLOROXYLENOL	
<p align="center">MANUFACTURED BY SHANTOU S.E.Z BAOJIE INDUSTRY CO.,LTD SIHUANG ROAD LUGANG TOWN, CHAONAN DISTRICT, SHANTOU, CN 515144</p>	
 4 897075 014102 MADE IN CHINA	

30 mL NDC: 74913-668-14



Kills 99% of Germs
75% Alcohol



INSTANT HAND SANITIZER



1 FL OZ / 30mL

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 75% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive Ingredients WATER, PEG-40 CASTOR OIL, CARBOMER 940, TROLAMINE, CHLOROXYLENOL	

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



MADE IN CHINA

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HAND SANITIZER

alcohol gel

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q)	0.3 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	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
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:749 13-668-14	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
2	NDC:749 13-668-13	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2020	

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(749 13-668)

Revised: 4/2020

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