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

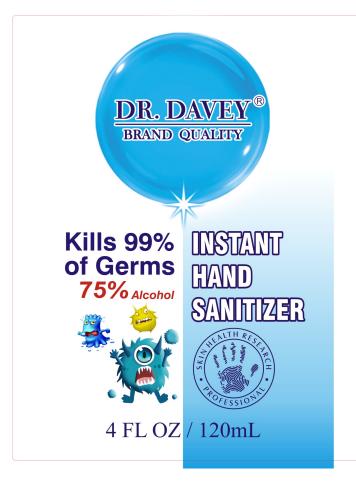
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

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

Package Label - Principal Display Panel

120 mL NDC: 74913-668-13





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

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



30 mL NDC: 74913-668-14



Drug Facts Alcohol 75% v/v.

Active ingredient[s]

Purpose .Antiseptic

Use[s]

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SHANTOU S.E.Z BAOJIE INDUSTRY CO.,LTD SIHUANG ROAD LUGANG TOWN, CHAONAN DISTRICT, SHANTOU, CN 515144 S 0 4 0 5 0 9 ∞ MADE IN CHINA 4

HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74913-668	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
P	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: 903K93S3TK)	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:74913-668- 14	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020		
2 NDC:74913-668- 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(74913-668)	

Revised: 4/2020 SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD