

HAND SANITIZE- 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.

Hand Sanitizer

active ingredients

Alcohol :62% v/v. Purpose: Antiseptic

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 throughly 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

Direction

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 Trolamine Chloroxyleneol



HAND SANITIZE

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:749 13-778
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)			0.5 mL in 100 mL	
CARBOMER 940 (UNII: 4Q93RCW27E)			0.5 mL in 100 mL	
WATER (UNII: 059QF0K00R)			23.2 mL in 100 mL	
CHLOROXYLENOL (UNII: 0F32U78V2Q)			0.3 mL in 100 mL	
TROLAMINE (UNII: 9O3K93S3TK)			0.5 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74913-778-16	30 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(74913-778)

Revised: 5/2020

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