

DR.DAVEY 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.

DR.DAVEY Hand Sanitizer

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, Carbomer, Trolamine, Aloe vera (ALOE VERA) extract

Package Label - Principal Display Panel

Uses for hand washing to decrease bacteria on the skin.
Warnings Flammable. Keep away from fire or flame.
For external use only.
 When using this product **keep out of eyes.** In case of contact with eyes, rinse with water.
Stop use and ask doctor if irritation and redness develops and persists.
Keep out of reach of children. If swallowed, get medical help promptly and contact poison control.

INGREDIENTS: Alcohol, Water, Aloe Vera Extract, PEG-40 Hydrogenated Castor Oil, Triethanolamine, Carbomer.
Directions: wet hands thoroughly with product and allow to dry without wiping.

SHANTOU S.E.Z. BAOJIE INDUSTRY CO., LTD.
 ADD: SHANG ROAD, LIGUANG TOWN, CHANGNIU DISTRICT, SHANTOU CITY, GUANGDONG PROVINCE.

GMP Certification
 EU 22716 Certification
 ISO9001:2015 Certification
PASSED:

16.9 fl.oz (500ml)

DV-6192 11Z

DR.DAVEY HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:749 13-669
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	0.4 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 mL in 100 mL
WATER (UNII: 059QF0KO0R)	23.8 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:749 13-669-02	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(74913-669)

Revised: 6/2020

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