

**HAND SANITIZER- alcohol liquid**  
**Tiantai Large Daily Necessities 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.*

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**75 ALCOHOL tiantai**

**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.

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**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

## Package Label - Principal Display Panel

500ML NDC 80557-001-01



## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80557-001
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
WATER (UNII: 059QF0K00R)	25 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80557-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020	
2	NDC:80557-001-02	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/2020	

**Labeler** - Tiantai Large Daily Necessities Co., Ltd (413984553)

**Registrant** - Tiantai Large Daily Necessities Co., Ltd (413984553)

## Establishment

Name	Address	ID/FEI	Business Operations
Tiantai Large Daily Necessities Co., Ltd		413984553	manufacture(80557-001) , label(80557-001)

Revised: 9/2020

Tiantai Large Daily Necessities Co., Ltd