

HAND SANITIZER- alcohol gel
Guangzhou Danting Bath&Body Care 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[s]

Alcohol 75% v/v

Purpose

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 and flame.

Do not use

- On 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 or occur. 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

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

Inactive ingredients

Deionized water, Glycerin, Fragrance, Benzalkonium chloride, Hydroxyethyl cellulose

Package Labeling

<p>HAND SANITIZER</p>  <p>PROTECTION with 75 % ALCOHOL</p> <p>Helps to reduce bacteria that potentially can cause disease</p> <p>500 ml</p>	<p>Active ingredient[s]..... Purpose Alcohol 75% v/v..... Antiseptic</p> <p>Use[s]: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame.</p> <p>Do not use * On children less than 2 months of age * On open skin wounds</p> <p>When using this product: Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor: If irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Directions * Put 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.</p> <p>Other Information * Store between 15-30°C (59-86°F) * Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive ingredients Deionized water, Glycerin, Fragrance, Benzalkonium chloride, Hydroxyethyl cellulose</p> <p>GUANGZHOU DANTING BATH&BODY CARE INDUSTRY CO., LTD 1st and 2nd of the second building, No.43, LiXin ninth Road, Zengcheng District, Guangzhou, China ITEM# 17599</p>  <p>(L) 402020-3 EXP 04/2023</p> <p>MADE IN CHINA</p>
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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75376-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75376-002-00	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/15/2020	

Labeler - Guangzhou Danting Bath&Body Care Industry Co. Ltd. (545337886)

Establishment

Name	Address	ID/FEI	Business Operations
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Guangzhou Danting Bath&Body Care Industry Co. Ltd.		545337886	manufacture(75376-002)
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Revised: 5/2020

Guangzhou Danting Bath&Body Care Industry Co. Ltd.