

RINSE-FREE HAND SANITIZER- ethanol gel
Guangzhou Dishu Pharmaceutical 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.

Rinse-free Hand Sanitizer

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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
 CARBOMER
 TRIETHANOLAMINE
 1,2-PROPANEDIOL

Package Label - Principal Display Panel

Rinse-free Hand Sanitizer

net content: 500ml

GOTDYA™ Rinse-free Hand Sanitizer

☛ Types of Microbes to Be Inhibited: Can inhibit staphylococcus aureus, Candida albicans and Escherichia coli.

☛ Main Active Ingredient and Latin Name: 75% Ethanol



☛ Usage: Put proper amount of the Hand Sanitizer into your palm and gently rub it over your palms, the back of your hands, fingers and the spaces between your fingers. Rub your hands together continuously until they are dry.

☛ Precautions: 1. This product is for external use only. Do not take it internally. 2. Do not use in case of wounds in the treated areas or of alcohol allergy. 3. This product is flammable. Keep away from sources of ignition. 4. Keep out of reach of children.

☛ Storage: Keep tightly closed in a cool, dark, dry place.

Distributor: Guangzhou Gotdya Fine Chemical Co., Ltd.
 Address: Tuanjie No.1 Industrial Park, Datangkou Economic Cooperative, Tuanjie Village, Xinya Street, Huadu District, Guangzhou, P.R. China
 Manufacturer: Guangzhou Dishu Pharmaceutical Co., Ltd.
 Address: 3F, Building H, Tangge Yongtuo Industrial Park, Baiyunhu Street, Baiyun District, Guangzhou, P.R. China
 Sanitary Permit for Disinfection Product Manufacturer: (Y)WXZZ(2016)No.8022
 Execution Standard: Q/DSYY 009
 See the indication for production batch number and expiration date.
 Place of Production: Guangzhou, Guangdong
 Qualified

GTY20200324
2022.03.23 QUALIFIED

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RINSE-FREE HAND SANITIZER

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79464-101
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79464-101-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79464-101-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

3	NDC:79464-101-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79464-101-04	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79464-101-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79464-101-06	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:79464-101-07	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:79464-101-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:79464-101-09	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:79464-101-10	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:79464-101-11	450 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:79464-101-12	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
13	NDC:79464-101-13	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
14	NDC:79464-101-14	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
15	NDC:79464-101-15	800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
16	NDC:79464-101-16	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
17	NDC:79464-101-17	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
18	NDC:79464-101-18	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Guangzhou Dishi Pharmaceutical Co., Ltd. (417671949)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Dishi Pharmaceutical Co., Ltd.		417671949	manufacture(79464-101)

Revised: 7/2020

Guangzhou Dishi Pharmaceutical Co., Ltd.