# HAND SANITIZER- hand soap gel Shenzhen Derun'en Science & Technology Development 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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#### HAND SANITIZER

# **Active Ingredient(s)**

Absolute ethanol Alcohol 75% v/v. glycerin 1%.....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

- 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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

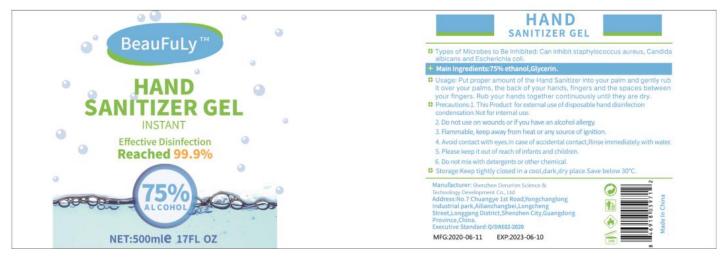
#### Other information

Keep tightly closed in a cool, dark, dry place. Save below 30.

# **Inactive ingredients**

### Package Label - Principal Display Panel

500ML IN 1 BOTTLE NDC:55029-002-01



# 1000ML IN 1 BOTTLE NDC:55029-002-02





# SANITIZER GEL



- Types of Microbes to Be Inhibited: Can inhibit staphylococcus aureus, Candida albicans and Escherichia coll.
- + Main Ingredients:75% ethanol, Glycerin.
- 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 for external use of disposable hand disinfection condensation. Not for internal use.
- 2. Do not use on wounds or if you have an alcohol allergy.
- 3. Flammable, keep away from heat or any source of ignition.
- 4. Avoid contact with eyes. In case of accidental contact, Rinse immediately with water,
- 5. Please keep it out of reach of infants and children.
- 6. Do not mix with detergents or other chemical.
- Storage: Keep tightly closed in a cool, dark, dry place. Save below 30°C.

Manufacturer: Shenzhen Derun'en Science & Technology Development Co., Ltd. Address:No.7 Chuangye 1st Road, Yongchanglong Industrial park, Ailianzhangbei, Longcheng Street, Longgang District, Shenzhen City, Guangdong Province, China. Executive Standard:Q/DRE02-2020

MFG:2020-06-11 EXP:2023-06-10





# HAND SANITIZER

hand soap gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55029-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1 mg in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

1	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:55029-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:55029-002-02	1000 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 - Shenzhen Derun'en Science & Technology Development Co., Ltd (550292933)

Registrant - Shenzhen Derun'en Science & Technology Development Co., Ltd (550292933)

Establishment			
Name	Address	ID/FEI	Business Operations
Shenzhen Derun'en Science & Technology Development Co., Ltd		550292933	manufacture(55029-002), label(55029-002)

Revised: 11/2020 Shenzhen Derun'en Science & Technology Development Co., Ltd