

DISINFECTANT SURGICAL HAND SANITIZER ANTIBACTERIAL GEL- alcohol gel
Echin(Shandong) Medical Equipment 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.

Surgical Hand Sanitizer Antibacterial Gel-Echin

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

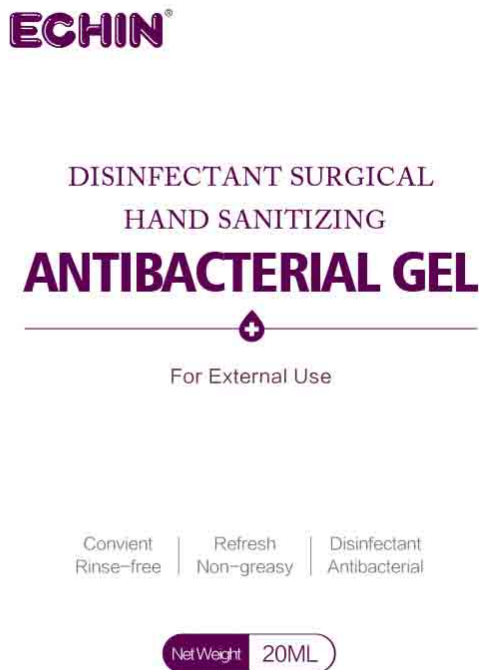
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

20 mL NDC: 77264-001-01



Echin (Shandong) Medical Equipment Co., Ltd.

40 mL NDC: 77264-001-02

ECHIN®

DISINFECTANT SURGICAL HAND SANITIZING ANTIBACTERIAL GEL

Type:Gel

Active Ingredient:75% alcohol by volume.

Microbes Targeted:Enteric pathogenic bacteria,pyogenic coccus,pathogenic yeast,etc.

Application: quick hand disinfectant for medical workers and regular people who need protection against virus and bacteria.

Mode of use:put enough product in your palm and rub hands together until absorbed. For children under 6, use with adult supervision.

Warning:

1-For external use only. Avoid ingesting orally. Keep out of reach of children.

2-Avoid contact with eyes and ears. People allergic to alcohol should use in caution.

3- Flammable. Keep away from fire or flame.

4-Avoid using it with anion and soaps,etc.

5-Keep it in a cool and dry place.

Standard:Q/37131 YQ 001-2020

Enterprises Sanitary Certificate No.for disinfection products:Shandong Hygiene Disinfection Certificate 2020-1207-27 Lin.

Manufacture:Echin (Shandong) Medical Equipment Co., Ltd

Address: Eastern part of Zhongxiwaihuan North Road,Wanggou town,Linyi city, Shandong Province

Tel:400-700-6606

Shelf life:24 months

Manufacturing Date: check on the package



ECHIN®

DISINFECTANT SURGICAL
HAND SANITIZING
ANTIBACTERIAL GEL



For External Use

Convenient | Refresh | Disinfectant
Rinse-free | Non-greasy | Antibacterial

Net Weight 40ML

Echin (Shandong) Medical Equipment Co., Ltd.

50 mL NDC: 77264-001-03

ECHIN®

DISINFECTANT SURGICAL
HAND SANITIZING
ANTIBACTERIAL GEL



For External Use

Convenient | Refresh | Disinfectant
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Net Weight 50ML

Echin (Shandong) Medical Equipment Co., Ltd.

60 mL NDC: 77264-001-04

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Net Weight 60ML

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80 mL NDC: 77264-001-05

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Net Weight 80ML

Echin (Shandong) Medical Equipment Co., Ltd.

100 mL NDC: 77264-001-06

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Net Weight 100ML

Echin (Shandong) Medical Equipment Co., Ltd.

120 mL NDC: 77264-001-07

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Net Weight 120ML

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245 mL NDC: 77264-001-08

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Net Weight 245ML

Echin (Shandong) Medical Equipment Co., Ltd.

300 mL NDC: 77264-001-09

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Net Weight 300ML

Echin (Shandong) Medical Equipment Co., Ltd.

500 mL NDC: 77264-001-10

1000 mL NDC: 77264-001-11

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DISINFECTANT SURGICAL HAND SANITIZER ANTIBACTERIAL GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77264-001
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77264-001-01	20 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77264-001-02	40 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77264-001-03	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77264-001-04	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
5	NDC:77264-001-05	80 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
6	NDC:77264-001-06	100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
7	NDC:77264-001-07	120 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
8	NDC:77264-001-08	245 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
9	NDC:77264-001-09	300 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
10	NDC:77264-001-10	500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
11	NDC:77264-001-11	1000 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - Echin(Shandong) Medical Equipment Co.,Ltd. (554531964)

Registrant - Echin(Shandong) Medical Equipment Co.,Ltd. (554531964)

Establishment

Name	Address	ID/FEI	Business Operations
Echin(Shandong) Medical Equipment Co.,Ltd.		554531964	manufacture(77264-001)

Revised: 5/2020

Echin(Shandong) Medical Equipment Co.,Ltd.