# DISINFECTANT- hypochlorous acid liquid Shanghai Qunli Enterprise (Group) Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### Disinfectant

The disinfectant is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (50%, 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. HYPOCHLOROUS ACID
- c. 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)

HYPOCHLOROUS ACID 1mg/100mL

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**

ALCOHOL WATER

# **Package Label - Principal Display Panel**

15 mL NDC: 74524-101-01 30 mL NDC: 74524-101-02 60 mL NDC: 74524-101-03 100 mL NDC: 74524-101-04



#### **DISINFECTANT**

hypochlorous acid liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74524-101	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>HYPO CHLO ROUS ACID</b> (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	1 mg in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)	50 mL in 100 mL			

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:74524-101-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74524-101-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74524-101-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74524-101-04	100 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
unapproved drug other		03/30/2020	

# Labeler - Shanghai Qunli Enterprise (Group) Co., Ltd. (553457671)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Shanghai Qunli Enterprise (Group) Co., Ltd.		553457671	manufacture(74524-101)	

Revised: 4/2020 Shanghai Qunli Enterprise (Group) Co., Ltd.