

**HAND SANITIZER- isopropyl alcohol liquid**  
**Dongguan City Dexu Toys 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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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. Isopropyl Alcohol (75%, 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)**

Isopropyl 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.

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.

## 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

350 ml NDC: 78048-002-14



The image shows the principal display panel of a hand sanitizer package. It features a large shield-shaped graphic with a blue border and a white center. Inside the shield, the words "HAND SANITIZER" are written in large, bold, pink letters. Below this, a green banner with white text reads "KILLS 99.9% OF GERMS". Underneath the banner, there is a red circle with a black border and a white background, containing a black germ icon with a red 'X' over it. Below this icon, the text "Kills Germs" is written in blue. To the left of this text is an icon of a hand with a checkmark, and to the right is an icon of hands being rubbed together. Below these icons, the words "Silver ion" and "Soothing Liquid" are written in blue. At the bottom of the shield, the words "FAST • SAFE • EFFECTIVE" are written in bold, blue letters. Below the shield, the volume "350ml" is written in large, blue letters. The background of the label is light blue with some circular patterns.

**Main ingredients:**  
Ethanol, AQUPEC SW701ER, Benzalkonium chloride solution  
Triethanolamine, Glycerin, Silver Solution - C, Optiphen™, Aqua

**Product performance:**  
This product has a high-efficiency sterilization function, and the killing rate of E. coli and Staphylococcus aureus is 99.9%

**Instructions for use:**  
Apply a small amount of the product to your hands, and gently rub the palms, and back of hands until they are completely evaporated.

**Precautions:**  
This product can only be used externally. If an abnormal reaction occurs during use. Please stop using it immediately. Please keep it out of each of infants and children to avoid high temperature and direct sunlight. Avoid contact with eyes. Do not mix with detergents or other chemical.

Company: Dongguan City Dexu Toys Co., LTD  
Address: Dongya Lake Industrial Park, Jiuwei Village, Qishi Town, Dongguan City, Guangdong Province, China



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**Made in China**

300 ml NDC: 78048-002-13

# HAND SANITIZER

KILLS 99.9% OF GERMS



Kills Germs



Silver ion



Soothing Liquid

**FAST • SAFE • EFFECTIVE**

300ml

## Main ingredients:

Ethanol, AQUPEC SW701ER, Benzalkonium chloride solution  
Triethanolamine, Glycerin, Silver Solution - C, Optiphen™, Aqua

## Product performance:

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**Made in China**

280 ml NDC: 78048-002-12

# HAND SANITIZER

KILLS 99.9% OF GERMS



Kills Germs



Silver ion



Soothing Liquid

**FAST • SAFE • EFFECTIVE**

280ml

## Main ingredients:

Ethanol, AQUPEC SW701ER, Benzalkonium chloride solution  
Triethanolamine, Glycerin, Silver Solution - C, Optiphen™, Aqua

## Product performance:

This product has a high-efficiency sterilization function, and the killing rate of E. coli and Staphylococcus aureus is 99.9%

## Instructions for use:

Apply a small amount of the product to your hands, and gently rub the palms, and back of hands until they are completely evaporated.

## Precautions:

This product can only be used externally. If an abnormal reaction occurs during use. Please stop using it immediately. Please keep it out of each of infants and children to avoid high temperature and direct sunlight. Avoid contact with eyes. Do not mix with detergents or other chemical.

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Address: Dongya Lake Industrial Park, Jiuwei Village, Qishi Town, Dongguan City, Guangdong Province, China



**Made in China**

240 ml NDC: 78048-002-11

**HAND SANITIZER**  
**KILLS 99.9% OF GERMS**

**Kills Germs**

Silver ion      Soothing Liquid

**FAST • SAFE • EFFECTIVE**  
**240ml**

**Main ingredients:**  
 Ethanol, AQUPEC SW701ER, Benzalkonium chloride solution  
 Triethanolamine, Glycerin, Silver Solution - C, Optiphen™, Aqua

**Product performance:**  
 This product has a high-efficiency sterilization function, and the killing rate of E. coli and Staphylococcus aureus is 99.9%

**Instructions for use:**  
 Apply a small amount of the product to your hands, and gently rub the palms, and back of hands until they are completely evaporated.

**Precautions:**  
 This product can only be used externally. If an abnormal reaction occurs during use. Please stop using it immediately. Please keep it out of each of infants and children to avoid high temperature and direct sunlight. Avoid contact with eyes. Do not mix with detergents or other chemical.

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 Address: Dongya Lake Industrial Park, Jiuwei Village, Qishi Town, Dongguan City, Guangdong Province, China

**Made in China**

## HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78048-002
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78048-002-11	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
2	NDC:78048-002-12	280 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
3	NDC:78048-002-13	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
4	NDC:78048-002-14	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/16/2020	

**Labeler** - Dongguan City Dexu Toys Co.,Ltd (403382659)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Dongguan City Dexu Toys Co.,Ltd		403382659	manufacture(78048-002)

Revised: 6/2020

Dongguan City Dexu Toys Co.,Ltd