

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.

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.

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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

120 ml NDC: 78048-002-04

250 ml NDC: 78048-002-05

500 ml NDC: 78048-002-06



The label features a central shield-shaped graphic with a blue border. Inside the shield, the words "HAND SANITIZER" are written in large, bold, pink letters. Below this, a green banner contains the text "KILLS 99.9% OF GERMS". Underneath the banner 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 are two smaller icons: one of a hand with a checkmark and the text "Silver ion", and another of hands being rubbed together with the text "Soothing Liquid". At the bottom of the shield, the text "Kills Germs" is written in blue. The background of the label is light blue with a subtle pattern of water droplets and light rays.

FAST • SAFE • EFFECTIVE

120ml

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

HAND SANITIZER

KILLS 99.9% OF GERMS



Kills Germs



Silver ion



Soothing Liquid

FAST • SAFE • EFFECTIVE

250ml

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:

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HAND SANITIZER
KILLS 99.9% OF GERMS

Kills Germs
 Silver ion Soothing Liquid

FAST • SAFE • EFFECTIVE
500ml

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%

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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
ECAMSULE DITRIETHANOLAMINE (UNII: 078Q4416CD)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78048-002-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2020	
2	NDC:78048-002-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2020	
3	NDC:78048-002-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/29/2020	

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

Establishment

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