

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.

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

200 ml NDC: 78048-002-10



The image shows the principal display panel of a hand sanitizer package. The label is light blue with a central shield graphic. Inside the shield, the words "HAND SANITIZER" are written in large, bold, pink letters. Below this, a green banner reads "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, the text "Kills Germs" is written in blue. To the left of this text is an icon of a hand with a checkmark, labeled "Silver ion". To the right is an icon of hands being rubbed together, labeled "Soothing Liquid". At the bottom of the shield, the words "FAST • SAFE • EFFECTIVE" are written in bold, dark blue letters. Below the shield, the volume "200ml" is printed in a large, dark blue font. To the right of the shield, the text "Main ingredients:" is followed by a list of ingredients: Ethanol, AQUPEC SW701ER, Benzalkonium chloride solution, Triethanolamine, Glycerin, Silver Solution - C, Optiphen™, and Aqua. Below this, the text "Product performance:" is followed by a description of the product's sterilization function and its 99.9% killing rate for E. coli and Staphylococcus aureus. The "Instructions for use:" section describes how to apply the product. The "Precautions:" section lists safety warnings. At the bottom right, the company name "Dongguan City Dexu Toys Co., LTD" and its address are provided. A barcode is located at the bottom right, with the number "6 971066 092008" printed below it. The words "Made in China" are printed in a large, bold, black font at the bottom right of the label.

Hand Sanitizer
KILLS 99.9% OF GERMS
Kills Germs
Silver ion Soothing Liquid
FAST • SAFE • EFFECTIVE
200ml

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

6 971066 092008

Made in China

80 ml NDC: 78048-002-09

HAND SANITIZER

KILLS 99.9% OF GERMS



Kills Germs



Silver ion



Soothing Liquid

FAST • SAFE • EFFECTIVE

80ml

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



Made in China

68 ml NDC: 78048-002-08

HAND SANITIZER

KILLS 99.9% OF GERMS



Kills Germs



Silver ion



Soothing Liquid

FAST • SAFE • EFFECTIVE

68ml

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



Made in China

30 ml NDC: 78048-002-07

HAND SANITIZER

KILLS 99.9% OF GERMS

Kills Germs

Silver ion Soothing Liquid

FAST • SAFE • EFFECTIVE

30ml

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

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

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:78048-002-07	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	
2	NDC:78048-002-08	68 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	
3	NDC:78048-002-09	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2020	
4	NDC:78048-002-10	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - 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