

**PHMB DISINFECTANT- polyhexamethylene biguanide spray**  
**Five Hertz (Xiamen) Medical Supplies 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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**PHMB Disinfectant**

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**Active Ingredient(s)**

Polyhexamethylene Biguanide 0.39mg/mL. Purpose: Antiseptic

**Purpose**

Antiseptic, PHMB Disinfectant

**Use**

PHMB Disinfectant 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**

- Suitable for the disinfection of human skin and object surface. Shake well before use, and then spray directly on the site to be disinfected - disinfecting time above 3 minutes.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

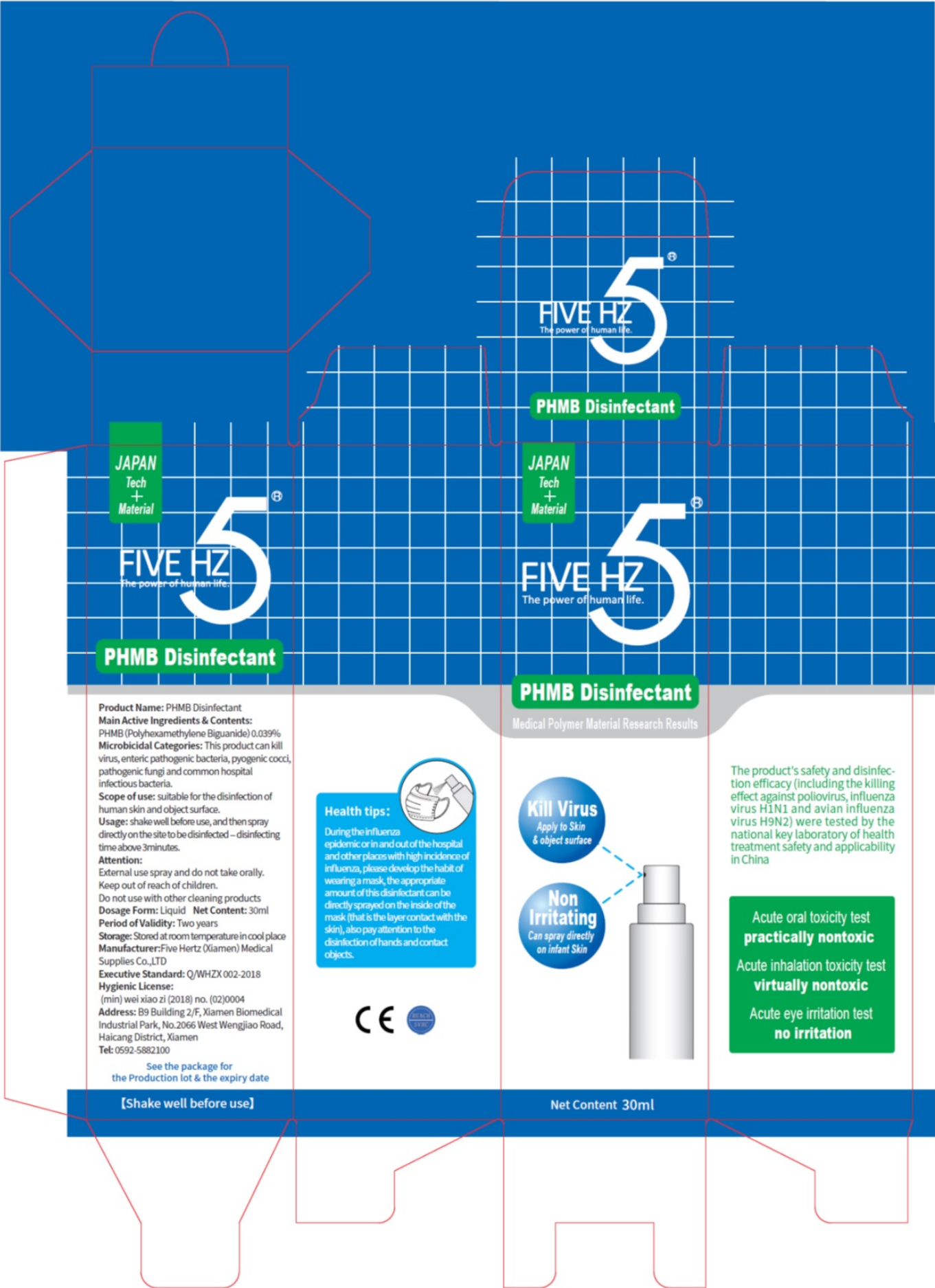
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

purified water USP

**Package Label - Principal Display Panel**





**FIVE HZ 5**  
The power of human life.

**PHMB Disinfectant**

JAPAN  
Tech  
+  
Material

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**PHMB Disinfectant**

**Product Name:** PHMB Disinfectant  
**Main Active Ingredients & Contents:**  
 PHMB (Polyhexamethylene Biguanide) 0.039%  
**Microbicidal Categories:** This product can kill virus, enteric pathogenic bacteria, pyogenic cocci, pathogenic fungi and common hospital infectious bacteria.  
**Scope of use:** suitable for the disinfection of human skin and object surface.  
**Usage:** shake well before use, and then spray directly on the site to be disinfected – disinfecting time above 3minutes.  
**Attention:**  
 External use spray and do not take orally. Keep out of reach of children. Do not use with other cleaning products  
**Dosage Form:** Liquid **Net Content:** 30ml  
**Period of Validity:** Two years  
**Storage:** Stored at room temperature in cool place  
**Manufacturer:** Five Hertz (Xiamen) Medical Supplies Co.,LTD  
**Executive Standard:** Q/WHZX 002-2018  
**Hygienic License:**  
 (min) wei xiao zi (2018) no. (02)0004  
**Address:** B9 Building 2/F, Xiamen Biomedical Industrial Park, No.2066 West Wengjiao Road, Haicang District, Xiamen  
**Tel:** 0592-5882100

See the package for the Production lot & the expiry date

**[Shake well before use]**

Medical Polymer Material Research Results



**Health tips:**

During the influenza epidemic or in and out of the hospital and other places with high incidence of influenza, please develop the habit of wearing a mask, the appropriate amount of this disinfectant can be directly sprayed on the inside of the mask (that is the layer contact with the skin), also pay attention to the disinfection of hands and contact objects.

**Kill Virus**

Apply to Skin & object surface

**Non Irritating**

Can spray directly on infant Skin



The product's safety and disinfection efficacy (including the killing effect against poliovirus, influenza virus H1N1 and avian influenza virus H9N2) were tested by the national key laboratory of health treatment safety and applicability in China

Acute oral toxicity test **practically nontoxic**  
 Acute inhalation toxicity test **virtually nontoxic**  
 Acute eye irritation test **no irritation**



Net Content 30ml

# PHMB DISINFECTANT

polyhexamethylene biguanide spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76579-201
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
POLIHEXANIDE (UNII: 322U039GMF) (POLIHEXANIDE - UNII:322U039GMF)	POLIHEXANIDE	0.39 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76579-201-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76579-201-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76579-201-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76579-201-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76579-201-05	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:76579-201-06	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:76579-201-07	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:76579-201-08	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		03/30/2020	

**Labeler** - Five Hertz (Xiamen) Medical Supplies Co., Ltd. (553972905)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Five Hertz (Xiamen) Medical Supplies Co., Ltd.		553972905	manufacture(76579-201)

Revised: 4/2020

Five Hertz (Xiamen) Medical Supplies Co., Ltd.