

**PFA STRONGHOLD HAND SANITIZER- benzalkonium chloride gel**  
**STRONGHOLD TRADING LLC**

*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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**80969-001-01 PFA HAND SANITIZER**

**Active ingredient**

Benzalkonium Chloride 0.066%

**Purpose**

Disinfectant

**Use**

Hand sanitizing to help reduce bacteria on the skin.

**Warnings**

For external use only.

Flammable. Keep away from fire or flame.

When using this product, avoid contact with the eyes.

In case of contact, flush eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develops and persists.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**

- Put enough product in the palm to cover hands & rub together briskly the liquid is dry.
- Children under 6 should be supervised when using Sanitizers.

**Other information**

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces.

## Inactive ingredients

Water, Glycerin, Carbomer, Triethanolamine, Mentha Piperita (Peppermint) Oil, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Morus Alba Bark Extract, Panthenol



The image shows the packaging for PFA Stronghold Hand Sanitizer. The main label is blue and white, featuring the PFA Stronghold logo at the top. Below the logo, it says "HAND SANITIZER" in large white letters on a blue background, followed by "KILLS 99.99%\* OF GERMS". There is a shield-shaped icon with a hand being washed. Below the icon, it says "ALCOHOL FREE DISINFECTANT" and "PROTECTION FOR ALL™". At the bottom of the label, it says "60 ml / 2 fl.oz".

To the right of the packaging is a "Drug Facts" label. It includes the following information:

- Drug Facts** 60 ML / 2.0 fl. oz.
- Active ingredient** Benzalkonium Chloride....0.066% **Purpose** Disinfectant
- Use** Hand sanitizing to help reduce bacteria on the skin.
- Warnings:** For external use only. Flammable. Keep away from fire or flame.
- When using this product** avoid contact with the eyes. In case of contact, flush eyes thoroughly with water.
- Stop use and ask a doctor** if irritation and redness develops and persists.
- Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.
- Directions** • Put enough product in the palm to cover hands & rub together briskly until the liquid is dry • Children under 6 should be supervised when using Sanitizers.
- Other information** • Store below 110°F (43°C) • May discolor certain fabrics or surfaces.
- Inactive ingredients** Water, Glycerin, Carbomer, Triethanolamine, Mentha Piperita (Peppermint) Oil, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Morus Alba Bark Extract, Panthenol
- ITM/CAT: SL22-7046-41-7046-41
- Barcode: 7 01575 26595 4
- PFA CERTIFIED** | \*During in vitro studies  
MADE IN KOREA | Distributed by Stronghold Trading, LLC  
5830 Grand Ave, Masspeth, NY 11378

## PFA STRONGHOLD HAND SANITIZER

benzalkonium chloride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80969-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.066 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>MORUS ALBA BARK</b> (UNII: 7O71A48NDP)	

<b>PANTHENOL</b> (UNII: W9CM0067Z)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80969-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/13/2021	

**Labeler** - STRONGHOLD TRADING LLC (117694134)

**Registrant** - STRONGHOLD TRADING LLC (117694134)

Revised: 8/2021

STRONGHOLD TRADING LLC