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.

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

PFA STRONGHOLD HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80969-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.066 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MORUS ALBA BARK (UNII: 7O71A48NDP)	

PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCYRRHIZA GLABRA (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