

PRISTINE HAND SANITIZER- alcohol gel**GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION**

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.

Pristine Hand Sanitizer Gel (125, 250, 500mL)**Active Ingredient(s)**

Alcohol 70% 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

water, glycerin, polysorbate, triethanolamine, carbomer, fragrance


Package Label - Principal Display Panel

125 mL NDC: 76938-001-01

Proveedora De Servicios De Hospedaje y Alimentos S.A. de C.V. Tempe AZ 85283.



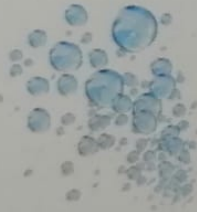
Hand Sanitizer Gel



Antibacterial Gel

KILLS 99.99%
OF MOST ILLNESS CAUSING GERMS

Moisturizing



4.2 Fl.Oz. (125ml.)

DRUG FACTS

Active Ingredient: Ethyl Alcohol 70%(v/v)	Purpose: Antiseptic
Uses: Helps reduce bacteria on skin. Repeated use is recommended.	
Warnings: For external use only: hands. Flammable. Keep away from fire or flame.	
When using this product: <ul style="list-style-type: none">• Keep out of eyes.• In case of contact with eyes, flush thoroughly with water.• Avoid contact with broken skin. Do not inhale or ingest.	
Stop use and ask a doctor if redness or irritation develops & condition persists for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: <ul style="list-style-type: none">• Wet hands thoroughly with product and allow to dry without wiping.• Children under 6 years of age, use only under adult supervision.• Not recommended for infants.• Dosage: 29 ml.	
Other information: <ul style="list-style-type: none">• Do not store above 110°F (43°C).• May discolor some fabrics and surfaces.	
Inactive Ingredients: Water, triethanolamine, glycerin, polysorbate, carbomer, fragrance.	
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.	

WARNING:
Cancer and Reproductive Harm
www.P51Warnings.ca.gov

Caution

Flammable

Corrosive

www.pristinegel.com
1-800-437-1004

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Made in Mexico by:
Gazti Proveedora De Servicios De Hospedaje y Alimentos S.A. de C.V.
Distributed by:
Universal Distributors LLC
NDC: 76540-100-02
61975 Rural Rd. Tempe AZ 85283.

250 mL NDC: 76938-001-02



Hand Sanitizer Gel

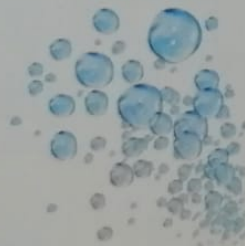


Antibacterial Gel

KILLS 99.99%

OF MOST ILLNESS CAUSING GERMS

Moisturizing



8.45 Fl.Oz. (250ml.)

DRUG FACTS

Active Ingredient: Ethyl Alcohol 70%(v/v)..... **Purpose:** Antiseptic

Uses: Helps reduce bacteria on skin. Repeated use is recommended.

Warnings: For external use only: hands.
Flammable. Keep away from fire or flame.

When using this product:

- Keep out of eyes.
- In case of contact with eyes, flush thoroughly with water.
- Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if redness or irritation develops & condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Wet hands thoroughly with product and allow to dry without wiping.
- Children under 6 years of age, use only under adult supervision.
- Not recommended for infants.
- Dosage: 29 ml.

Other information:

- Do not store above 110°F (43°C).
- May discolor some fabrics and surfaces.

Inactive Ingredients:

Water, triethanolamine, glycerin, polysorbate, carbomer, fragrance.

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Made in Mexico by:
Gaza Proveedora De Servicios De
Hospedaje y Alimentos S.A. de C.V.




WARNING:
Cancer and Reproductive Harm
www.P65Warnings.ca.gov




www.pristinegel.com
1800-637-1006



500 mL NDC: 76938-001-03



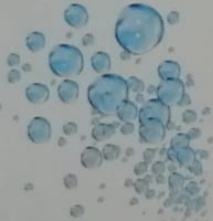
Hand Sanitizer Gel



Antibacterial Gel

KILLS 99.99%
OF MOST ILLNESS CAUSING GERMS

Moisturizing




16.907 Fl.Oz.(500ml.)

DRUG FACTS	
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WARNING:
 Cancer and Reproductive Harm
www.P01Warnings.gov



8 6015910024015

www.pristinegel.com
 1-800-637-1006



PRISTINE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76938-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	10 mL in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	3.33 mL in 100 mL
WATER (UNII: 059QF0K00R)	14.884 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.336 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.2 mL in 100 mL

CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				0.25 mL in 100 mL
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76938-001-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
2	NDC:76938-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
3	NDC:76938-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/14/2020	

Labeler - GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION (951577051)

Registrant - GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION (951577051)

Establishment				
Name			Address	ID/FEI
GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION				951577051
			Business Operations	
			manufacture(76938-001)	

Revised: 7/2020

GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION