

**HAND SANITIZER- alcohol gel**  
**Alta Pureza, Maquiladora, S.A. de C.V.**

*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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**Purity Gel 70% Alcohol**

**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.

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**

Water (aqua), carbomer, triethanolamine





Largo de etiqueta  
13 cm

**Drug Facts**  
**Información del medicamento**

**Active Ingredient(s)** / **Propósito**  
 Ingredientes Activos(s) / Propósito:  
 Ethyl Alcohol/Alcohol Etilico 70% / antiséptico/antibactericidas

**Use(s) / Usos(s):**  
 Use(s) / Usos(s):  
 Use(s) / Usos(s):

**Warnings / Advertencias:**  
 Warnings / Advertencias:  
 Warnings / Advertencias:

**Directions / Instrucciones:**  
 Directions / Instrucciones:  
 Directions / Instrucciones:

**Contains / Ingredientes:**  
 Contains / Ingredientes:  
 Contains / Ingredientes:

MANUFACTURED BY / HECHO POR: ALTA PUREZA MAQUILADORA, S.A. DE C.V. CALLE 10 No. 127 COL. GARCERAN SAN ANTONIO C.P. 06076, CD.MEX. MEXICO  
 HECHO EN MEXICO / HECHO EN MEXICO.



EXPIRATION DATE AND BATCH NUMBER ON THE BOTTLE  
 FECHA DE CADUCIDAD Y LOTE EN LA BOTELLA

**Purity Gel**

Hand Sanitizer | Sanitizante de Manos

ANTIBACTERIAL FORMULA | FORMULA ANTIBACTERIAL

BE SAFE & PROTECT YOURSELF  
 MANTENTE SEGURO & PROTEGETE

Net. Cont. Cont. Net.  
**1.05 gal | 4 L**

Scan Me For a Sample

15.7946 cm Ancho de etiqueta

Cliente: Purity Gel Fecha: 09 - 06 - 20 Producto: Gel sanitizante para manos	Materiales: BOPP Medidas: 15.7946 cm x 13cm Impresión: Exterior	Aprobación: Fotografía <input type="checkbox"/> Diseño Gráfico <input type="checkbox"/> Colores <input type="checkbox"/> Plano y Medidas <input type="checkbox"/> Textos / Legales <input type="checkbox"/>
<b>Colores:</b>  232a5d 005d36 70c1f2 17b0e7 3a8e0c fdc731 3e8e05 d12e2e 4d4d4d 010101		
NOTA: Con su firma en este documento se aprueba a totalidad de: los textos, códigos de barra, distribución de colores, imágenes, medidas y plano mecánico. Los colores impresos en este arte no son válidos como muestra exacta de color.		

3875 mL NDC: 77905-001-04

Largo de etiqueta  
13cm

**Drug Facts**  
**Información del medicamento**

**Activos/Ingredientes**      **Propósito**  
**Ingredientes/Activos**      **Propósito**  
Ethyl Alcohol/Alcohol (70%)      Antisepsia/Desinfectante

**Use(s) / Uso(s)**  
Hand sanitizer helps reduce bacteria that potentially can cause disease. It is not a disinfectant and does not sanitize. Use liberally on hands for up to 20 seconds to reduce the bacteria that potentially can cause disease. Do not use on cuts or open wounds.

**Warnings / Advertencias:**  
For external use only. Flammable. Keep away from heat or flame. 100 percent ethanol. Hand sanitizer is not for ingestion.  
When using, get product out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water. Avoid use on face, neck, or other sensitive areas. Do not use on cuts or open wounds. Do not use on children's hands.

**Directions / Instrucciones:**  
Place enough product on hands to cover all surfaces. Rub hands together until dry. Do not use on face. Do not use on children's hands. Do not use on cuts or open wounds. Do not use on children's hands.

**Contains / Ingredientes:**  
Water (Aqua), Ethanol, Methylparaben / Agua (Aqua), Etanol, Metilparabeno.

MANUFACTURED BY / HECHO POR: ALTA PUREZA MANUFACTURERA, S.A. DE C.V. CALLE 10 No. 127 COL. GRANJAS SAN ANTONIO C.P. 86700, CDMX. MEXICO / HECHO EN MEXICO.



7 502200 10147 5

EXPIRATION DATE AND BATCH NUMBER ON THE BOTTLE  
FECHA DE CADUCIDAD Y LOTE EN LA BOTELLA

Scan Me  
Escanéame



# Purity Gel

HAND SANITIZER | SANITIZANTE DE MANOS



ANTIBACTERIAL FORMULA | FORMULA ANTIBACTERIAL

**BE SAFE & PROTECT YOURSELF**  
MANTENTE SEGURO & PROTEGETE

Net. Cont.    Cont. Net.  
**1 gal | 3.78L**



15.7663 cm Ancho de etiqueta

Cliente: Purity Gel Fecha: 09 - 06 - 20 Producto: Gel sanitizante para manos	Materiales: BOPP Medidas: 15.7663 cm x 13cm Impresión: Exterior	Aprobación: Fotografía <input type="checkbox"/> Diseño Gráfico <input type="checkbox"/> Colores <input type="checkbox"/> Plano y Medidas <input type="checkbox"/> Textos / Legales <input type="checkbox"/>
<b>Colores:</b>  <p>232e5d    005d06    78cc72    17b0a7    3a8acc    f8c731    3a2a25    dc2a2a    d8d8d8    010101</p>		
NOTA: Con su firma en este documento se aprueba la totalidad de: los textos, códigos de barras, distribución de colores, imágenes, medidas y plano mecánico. Los colores impresos en esta arte no son válidos como muestra exacta de color.		

500 mL NDC: 77905-001-05





Largo de etiqueta  
12 cm

14.5329 cm Ancho de etiqueta

Cliente: Purity Gel Fecha: 09 - 06 - 20 Producto: Gel sanitizante para manos	Materiales: BOPP Medidas: 12.1429cm x 10cm Impresion: Exterior	Aprobacion: Fotografia <input type="checkbox"/> Diseño Gráfico <input type="checkbox"/> Colores <input type="checkbox"/> Plano y Medidas <input type="checkbox"/> Textos / Legales <input type="checkbox"/>
Colores: 		
NOTA: Con su firma en este documento se aprueba la totalidad de: los textos, códigos de barras, distribución de colores, imágenes, medidas y plano mecánico. Los colores impresos en esta arte no son válidos como muestra exacta de color.		

250 mL NDC: 77905-001-06



Cliente: Purity Gel Fecha: 09 - 06 - 20 Producto: Gel sanitizante para manos	Materiales: BOPP Medidas: 10.9286 cm x 9cm Impresion: Exterior	Aprobacion: Fotografia <input type="checkbox"/> Diseño Gráfico <input type="checkbox"/> Colores <input type="checkbox"/> Plano y Medidas <input type="checkbox"/> Textos / Legales <input type="checkbox"/>
Colores: 		
NOTA: Con su firma en este documento se aprueba la totalidad de: los textos, códigos de barras, distribución de colores, imágenes, medidas y plano mecánico. Los colores impresos en este arte no son válidos como muestra exacta de color.		

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77905-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.2 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.03 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77905-001-01	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77905-001-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77905-001-03	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77905-001-04	3875 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77905-001-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77905-001-06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

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

**Labeler** - Alta Pureza, Maquiladora, S.A. de C.V. (951577507)

**Registrant** - Alta Pureza, Maquiladora, S.A. de C.V. (951577507)

## Establishment

Name	Address	ID/FEI	Business Operations
Alta Pureza, Maquiladora, S.A. de C.V.		951577507	manufacture(77905-001) , pack(77905-001) , label(77905-001)

Revised: 6/2020

Alta Pureza, Maquiladora, S.A. de C.V.