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.

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.

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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 (aqua), carbomer, triethanolamine

Package Label - Principal Display Panel

600 mL NDC: 77905-001-01

Largo de etiqueta



Fecha	e: Purity : 09 - 06 icto: Gel mano:	- 20		Materiales: BOPP Medidas: 15.7663 cm x 13cm Impresion: Exterior						Aprobacion: Fotografía Diseño Gráfico Colores	
Colores:									Plano y Medidas Textos / Legales		
232e5d	005d%	78xcf2	17b0e7	Завесс	fdc73	3aaa35	dc2a2a	4Bd8d8	010101		



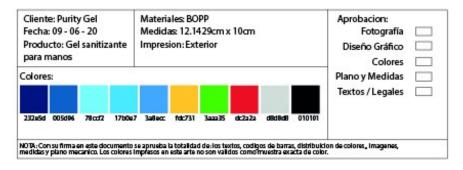














10.9286 cm Ancho de etiqueta

Cliente: Purity Gel Fecha: 09 - 06 - 20 Producto: Gel sanitizante para manos				Materiales: BOPP Medidas: 10.9286 cm x 9cm Impresion: Exterior					Aprobacion: Fotografía Diseño Gráfico Colores		
Colores:			ं							Plano y Medidas	
										Textos / Legales	
232a5d	005d96	78ccf2	17b0e7	328000	fdc731	322235	dc2a2a	dBd8d8	010101		

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: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER 940 (UNII: 4Q93RCW27E)	0.2 mL in 100 mL		
TROLAMINE (UNII: 903K93S3TK)	0.03 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

P	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.