

**PRISTINE- alcohol gel**  
**Transformaciones Del Caribe, Sociedad Anonima**

*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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**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, polyacrylic acid (Carbomer), triethanolamine (Trolamine), propylene glycol

Package Label - Principal Display Panel

**Pristine**  
Alcohol Antiseptic 70%  
Topical Solution



Hand Sanitizer  
Non-sterile Solution  
1 gal (3.78 L)

3780 mL NDC: 78167-002-01

<b>PRISTINE</b>				
alcohol gel				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78167-002	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)			0.4 mL in 100 mL	
TROLAMINE (UNII: 9O3K93S3TK)			0.2 mL in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			0.1 mL in 100 mL	
WATER (UNII: 059QF0KO0R)			29.3 mL in 100 mL	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78167-002-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	05/23/2020		

**Labeler** - Transformaciones Del Caribe, Sociedad Anonima (817531659)

**Registrant** - Transformaciones Del Caribe, Sociedad Anonima (817531659)

**Establishment**

Name	Address	ID/FEI	Business Operations
Transformaciones Del Caribe, Sociedad Anonima		817531659	manufacture(78167-002)

Revised: 5/2020

Transformaciones Del Caribe, Sociedad Anonima