

**HAND SANITIZER- 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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**Instant Hand Sanitizer Anti bacterial**

**Uses**

Uses

\* Helps eliminated bacterias on hand. This product is not a substitute of soap hand washing. Avoid contact with broken and damaged skin

**Active Ingredient**

Active Ingredient Purpose

- Ethyl Alcohol 70%.....Antiseptic

**Warnings**

- **For external use only**
- **When using this product** avoid contact with eyes. In case of contact, flush with water for several minutes.
- **Keep out of reach of children.** If swallowed, get medical help, or contact a Poison Control Center right away.
- **Stop use and ask Doctor:** if skin irritation develops when using this product
- **Flammable:** Keep away from heat and flame. Highly flammable liquid and vapor/

**Stop use and ask a doctor if**

**Stop use and ask a doctor if**

\* Irritation develops while using this product

**Keep out of reach of children**

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

**Directions**

**Directions:** Place enough product in your palm to thoroughly cover your hands.

- Rubs hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

**Inactive Ingredients**

water, carbomer, propylene glycol, triethanolamine

**Questions?**

QUESTIONS OR COMMENTS: Phone: (786) 871-6663

Uses

Uses

\* Helps eliminated bacteria on hand. This product is not a substitute of soap hand washing. Avoid contact with broken and damaged skin

Hand Sanitizer Gel

**Drug Facts**

**Active ingredient** Ethyl Alcohol 70.0%..... **Purpose** Anti-septic

**Uses**  
● Hand Sanitizer helps eliminate bacteria on hands. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin.

**Warnings**  
**For external use only.**  
**When using this product** avoid contact with eyes. In case of contact, flush with water for several minutes.  
**Keep out of reach of children,** except under adult supervision. If swallowed, get medical help, or contact a Poison Control Center right a way.  
**Flammable:** keep away from heat and flame. Highly flammable liquid and vapor.  
**Stop use and ask Doctor:** if skin irritation develops.

**Directions**  
Place enough product in your palm to thoroughly cover your hands.  
● Rub hands together briskly until dry.  
● Children under 6 years of age should be supervised when using this product.

**Other information**  
● store at 20°C to 25°C (68° to 77°F) ● may discolor certain fabrics

**Inactive ingredients** Aqua, Carbomer, Propylene Glycol, Triethanolamine.

**Drug Facts (Continued)**

**Questions or Comments** Phone (786) 871-6663

MADE IN GUATEMALA. Manufactured by: Transformaciones del Caribe S.A., 8ta. Ave. 1-17 zona 2, Colonia El Tesoro, Mixco, Guatemala. Phone: (502) 2378-7300 info@transcarsa.com.gt

**Distributed By Grumac LLC**  
300 Aragon Avenue suite 375 Coral Gables FL 33134 USA. Phone (786) 871-6663 info@grumacllc.com www.grumacllc.com

Net Wt. 16.90 Oz (500 mL)

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78 167-005
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
PROPANEDIOL (UNII: 5965N8 W85T)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78 167-005-	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	06/02/2020	

01	Product	06/02/2020	
<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	06/02/2020	

**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(78167-005)

Revised: 6/2020

Transformaciones Del Caribe, Sociedad Anonima