

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.

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/

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* Irritation develops while using this product

Keep out of reach of children

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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

70%


Simply
pure

**Instant
Hand Sanitizer
Anti-bacterial**

Kills more than
99.99 %
of many common germs
and bacteria

Fragrance Free

Net Wt. 770.73607 (21.85 kg)

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.	
Questions or Comments Phone (786) 871-6663	
MADE IN GUATEMALA. Manufactured by: Transformaciones del Caribe S.A. 6ta. 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	
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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 167-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78167-004-01	22700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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(78167-004)

Revised: 6/2020

Transformaciones Del Caribe, Sociedad Anonima