

HAND SANITIZER- alcohol gel
GRUPO PIRRETEAM SA DE CV

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.

Hand Sanitizer Anti bacterial Gel

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

isopropyl alcohol, water, carbomer, benzalkonium chloride

Questions?

QUESTIONS OR COMMENTS: Phone: (786) 599-2764. 24 hours a day, 7 days a week

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Hand Sanitizer Gel



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78797-004
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 COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0K00R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:78797-004-01	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/09/2020	

Labeler - GRUPO PIRRETEAM SA DE CV (951579014)

Registrant - GRUPO PIRRETEAM SA DE CV (951579014)

Establishment

Name	Address	ID/FEI	Business Operations
GRUPO PIRRETEAM SA DE CV		817531659	label(78797-004)

Establishment

Name	Address	ID/FEI	Business Operations
KUII PRODUCTOS DE LIMPIEZA SA DE CV		951578840	manufacture(78797-004)

Revised: 6/2020

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