

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/

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

isopropyl alcohol, water, carbomer, benzalkonium chloride

Questions?

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

Uses

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* 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 | Purpose |
| Ethyl Alcohol, 70% v/v | Antiseptic |
| USE: Hand Sanitizer helps eliminate bacteria on hands. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin. | |
| 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: Do not store above 110° F (43° C) | |
| 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. Flammable: Keep away from heat or flame. Stop use and ask doctor, if skin irritation develops. | |
| Inactive Ingredients: Carboner, Isopropyl Alcohol, Quaternary Ammonium, Water | |
| Questions or Comments? Call (786) 599-2764, 24 hours a day, 7 days a week. | |

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 55-85-30-08-38
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Keep away from children. For external use only, keep away from heat, in case of contact with eyes wash with abundant water.

EXP 05/2021
 (L) 00001

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78797-003 |
| 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 Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:78797-003-01 | 500 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(78797-003) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|------------------------|
| KUII PRODUCTOS DE LIMPIEZA SA DE CV | | 951578840 | manufacture(78797-003) |

Revised: 6/2020

GRUPO PIRRETEAM SA DE CV