# ALCOHOL- antiseptic liquid 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.

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## **Hand Soap Chlorexidine Gluconate**

#### Uses

Uses

\* Healthcare personnel Handwash. Significant reduce the amount of bacterias on the hands and forearms.

## **Active Ingredient**

Active Ingredient Purpose

• Isopropyl Alcohol 60%.....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

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\* 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 throughly cover your hands.

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

# **Inactive Ingredients**

sodium lauryl ether sulfate, cocamide DEA, EDTA disodium salt, ethylene glycol polymer, propylene glycol dicaprate, water

## Questions?

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

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# **Hand Soap**



## **ALCOHOL** antiseptic liquid **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:78797-007 **Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -ISOPROPYL ALCOHOL 60 mg in 1 mL UNII:ND2M416302)

Inactive Ingredients			
Ingredient Name	Strength		
EDETATE SO DIUM (UNII: MP1J8420LU)			
POLIDOCANOL (UNII: 0 AWH8 BFG9 A)			
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)			
COCO DIETHANOLAMIDE (UNII: 92005F972D)			
WATER (UNII: 059QF0KO0R)			
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)			
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	1 mg in 1 mL		

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1 N	NDC:78797-007- 1	$1000\ mL$ 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 PIRRET EAM SA DE CV (951579014)

# **Registrant -** GRUPO PIRRET EAM SA DE CV (951579014)

Establishment				
Name	Address	ID/FEI	Business Operations	
GRUPO PIRRETEAM SA DE CV		8 175316 59	label(78797-007)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
KUII PRODUCTOS DE LIMPIEZA SA DE CV		951578840	manufacture(78797-007)	

Revised: 6/2020 GRUPO PIRRETEAM SA DE CV