HAND SANITIZER- antis eptic 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.

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

Stop use and ask a doctor if

* 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 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



HAND SANITIZER antiseptic liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:78797-015 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

CHLORHEXIDINE

GLUCONATE

1 mg in 1 mL

CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -

UNII:R4KO0DY52L)

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	
UNII:ND2M416302)	

ISOPROPYL ALCOHOL

60 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
EDETATE SO DIUM (UNII: MP1J8420 LU)				
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)				

ı	Packaging				
	#	# Item Code Package Description Marketing Start Date		Marketing Start Date	Marketing End Date
	1	NDC:78797-015- 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 PIRRET EAM SA DE CV (951579014)

Establishment					
Name	Address	ID/FEI	Business Operations		
GRUPO PIRRETEAM SA DE CV		8 17531659	label(78797-015)		

Establishment				
Name	Address	ID/FEI	Business Operations	
KUII PRODUCTOS DE LIMPIEZA SA DE CV		951578840	manufacture(78797-015)	

Revised: 8/2020 GRUPO PIRRETEAM SA DE CV