

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.

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/

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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

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

Questions?

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

Uses

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

Hand Soap

KUIII M.R.

HAND SOAP

Chlorexidine Gluconate 0.5-1%

200,627 mL (6,784 fl oz)

Drug Facts	
Active Ingredient	Purpose
Chlorexidine Gluconate 0.5-1%	Antiseptic
Isopropyl Alcohol 60% v/v	Antiseptic
USE:	
Healthcare Personnel Handwash: Significant reduce the number of bacteria on the hands and forearms.	
Directions: Place enough product in your palm to thoroughly cover your hands.	
- Rub hands together briskly and wash.	
- Children under 6 years of age should be supervised when using this product.	
Other Information: Store at 88-77° F (20-25° 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. Stop use and ask Doctor, if skin irritation develops.	
Inactive Ingredients	
Sodium Lauryl Ether Sulfate, Cocamide DEA, EDTA Disodium Salt, Ethylene Glycol Polymer, Propylene Glycol Diacrylate, Water.	
Questions or Comments?	
Call (786) 599-2764, 24 hours a day, 7 days a week.	

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MX HECHO EN MÉXICO

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

60% Alcohol Kills 99% of Germs 53 Gallon

6 72975 50319 2

ALCOHOL

antiseptic liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 797-0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE SODIUM (UNII: MP1J8420LU)	
POLIDOCANOL (UNII: 0AWH8BFG9A)	
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78797-010-01	200627 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(78797-010)

Establishment

Name	Address	ID/FEI	Business Operations
KUII PRODUCTOS DE LIMPIEZA SA DE CV		951578840	manufacture(78797-010)

Revised: 6/2020

GRUPO PIRRETEAM SA DE CV