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
- Chlorhexidine gluconate 1%.....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

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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 T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:78797-013	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingredient Name			Basis of Strength		Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -			CHLORHEXIDINE		1 main 1 mT
			GILLOIGILLAIDIN		1 m a in 1

UNII:R4KO0DY52I	_)		GLUCONATE	1 mg m 11
ISOPROPYL ALC UNII:ND2M416302		UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL ALCO	OHOL 60 mg in 1 mL
Inactive Ingre	dients			
		Ingredient Name		Strength
EDETATE SODIU	M (UNII:	MP1J8420LU)		
POLIDOCANOL	(UNII: 0 A	WH8 BFG9 A)		
PROPYLENE GL	COL D	CAPRATE (UNII: U783H9JHWY)		
COCO DIETHAN	DLAMID	E (UNII: 92005F972D)		
WATER (UNII: 059	QF0KO	OR)		
		DR) ATE (UNII: BPV390UAP0)		
SODIUM LAURET Packaging			Marketing Start Date	Marketing End Date
SODIUM LAURET Packaging # Item Code	THSULF	ATE (UNII: BPV390UAP0) Package Description mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	-	<u> </u>
Packaging H Item Code	- 18927	ATE (UNII: BPV390UAP0) Package Description mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	Date	<u> </u>
SODIUM LAURET Packaging # Item Code 1 NDC:78797-013 01	- 18927 Produ	ATE (UNII: BPV390UAP0) Package Description T mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	Date	<u> </u>
SODIUM LAURET Packaging I Item Code NDC:78797-013 01	- 18927 Produ	ATE (UNII: BPV390UAP0) Package Description T mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct nation	Date 06/09/2020	Date
SODIUM LAURET Packaging # Item Code 1 NDC:78797-013 01	rH SULF - 18927 Produ Infori	ATE (UNII: BPV390UAP0) Package Description TmL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct mation Application Number or Monograph Citation	Date	<u> </u>

Labeler - GRUPO PIRRET EAM 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(78797-013)

Establishment

Name	Address	ID/FEI	Business Operations
KUII PRODUCTOS DE LIMPIEZA SA DE CV		951578840	manufacture(78797-013)

Revised: 8/2020

GRUPO PIRRETEAM SA DE CV