

HAND SANITIZER- alcohol gel
Pafer Foods & Beverages, S. de R.L de C.V.

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.

Ethyl alcohol 70% v/v

Antiseptic

- Hand Sanitizer to help reduce bacteria on the skin
- For use when soap and water are not available
- Recommended for repeated use

For external use only

Flammable. Keep away from heat or flame

Do not use:

- In children less than 2 months of age
- On open skin wounds

Keep out of reach of children.

If swallowed, get medical help or contact poison control center right away.

Directions:

Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years in the use of this product.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Aminoethyl Propanol, Acrylates Copolymer, Glycerin, Hydrogen Peroxide, Purified Water, Fragrance

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Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% w/w.....	Antiseptic
Uses	
■ Hand Sanitizer to help reduce bacteria on the skin	
■ For use when soap and water are not available	
■ Recommended for repeated use	
Warnings For external use only.	
Flammable. Keep away from heat or flame.	
Do not use:	
■ In children less than 2 months of age	
■ On open skin wounds	
When using this product keep out of eyes, ears and mouth.	
In case of contact rinse thoroughly with water.	
Keep out of reach of children.	
If swallowed, get medical help or contact poison control center right away.	
Directions:	
Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years in the use of this product.	
Other Information:	
Store between 15 -30 C (59 – 86F)	
Avoid freezing and excessive heat above 40C (104F)	
Inactive Ingredients:	
AMINOMETHYL PROPANOL, ACRYLATES COPOLYMER, GLYCERIN, HYDROGEN PEROXIDE, PURIFIED WATER.	

DISTRIBUTED BY: PRIGA, CO.
CORONADO, CA 92118
Info@prigaco.com www.SANI-T-AID.com

USA PRODUCT
USA Quality
USA PRODUCT

Product of USA

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78319-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPAS) (UNII: T967IEU43C)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78319-007-01	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - Pafer Foods & Beverages, S. de R.L de C.V. (812764102)

Registrant - Pafer Foods & Beverages, S. de R.L de C.V. (812764102)

Establishment

Name	Address	ID/FEI	Business Operations
Pafer Foods & Beverages, S. de R.L. de C.V.		812764102	pack(78319-007) , label(78319-007)

Revised: 7/2020

Pafer Foods & Beverages, S. de R.L de C.V.