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.

Unscented gel

Ethyl alcohol 70% w/w

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



HAND SANITIZER

Draduct Information

alcohol gel

r i duct illidi illatidii			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78319-009

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 MPA.S) (UNII: T967IEU43C)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Itam Cada	Dackage Description	Marketing Start	Marketing End

" Item code	Tuckage Description	Date	Date
	370 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
Marketing Information			
Marketing Catego	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not f	inal 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(78319-009), label(78319-009)

Revised: 7/2020 Pafer Foods & Beverages, S. de R.L de C.V.