HAND SANITIZER- ethyl alcohol 70% gel
Premium Printing Inc.

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.

Premium Gel Hand Sanitizer

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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 with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor.

If irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

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

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

Inactive Ingredients

Carbopol, Glycerin, Triethanolamine

Gel Hand Sanitizer

BIODEGRADABLE PRODUCT

Gel HAND SANITIZER

WITH 70% ETHYL ALCOHOL

Drug Facts

Active ingredient[s] ..... *Purpose*
Ethyl alcohol 70% v/v ..... Antiseptic

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*As seen in laboratory setting, actual results may vary.

0 664697 110192

Kills 99.99% of germs

135.25 FL OZ (4.22 QT) 4 L

Made in Mexico
Manufactured by: Foler Americas S.A. de C.V
Candido Aguilar 20 Col. San Andrés Atoto,
Naucalpan de Juárez Cp 53370 Estado de México
Questions or comments? +52 55 52553855

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0 664697 110215

Kills 99.99% of germs

8.45 FL OZ (0.26 QT) 250 mL

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HAND SANITIZER

ethyl alcohol 70% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78635-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	175 mL in 250 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TRIETHANOLAMINE ISOSTEARATE (UNII: T8OTU5ECY5)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78635-100-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78635-100-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:78635-100-04	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Premium Printing Inc. (035632750)

Registrant - Premium Printing Inc. (035632750)

Revised: 6/2020 Premium Printing Inc.