

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



Drug Facts	
Active ingredient(s).....	Purpose
Ethylalcohol 70% v/v.....	Antiseptic
Use (s)	
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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 below 15-30C (59-86F)	
• Avoid freezing and avoid overheating above 40C (104F)	
Inactive ingredients	
Carbopol, Glycerine, Triethanolamine.	
*As seen in laboratory setting, actual results may vary.	



Made in Mexico
Manufactured by: Faler Americas S.A. de C.V.
Candido Aguilar 20 Col. San Andrés Alata,
Naucaipan de Juárez Cp. 53370 Estado de México
Questions or comments? +525552653855



BIODEGRADABLE PRODUCT

Gel

HAND SANITIZER

WITH 70% ETHYLALCOHOL

Drug Facts

Active ingredient(s).....Purpose
Ethyl alcohol 70% v/v.....Antiseptic

Use(s)
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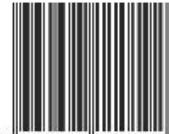
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0 664697 110192

Kills 99.99% of germs 

135.25 FL OZ (4.22 QT) 4 L



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Gel

HAND SANITIZER

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0 664697 110215

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Nauyaplan de Juárez Cp 63370 Estado de México
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Kills 99.99% of germs 

8.45 FL OZ (0.26 QT) 250 mL



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.