

HYGEIA EFFECT HAND SANITIZER- alcohol 70% gel
Pecan Bayou Enterprises, LLC

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.

Purpose

Antiseptic, Hand Sanitizer

Use

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

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Warnings

For external use only. Flammable. Keep away from heat or flame.

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

When using this product keep out of the eyes, ears and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if rash or irritation occurs. These may be signs of a serious condition.

Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center right away.

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

Other Information

Store between 15-50C (59-86F)

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

Inactive Ingredients

Water, Glycerine USP, Carbomer, TEA

Package Label Principal Display Panel



HYGEIA EFFECT

Hand Sanitizer

32 Oz (946.4ml)

Drug Facts	
Active Ingredient [s]	Purpose
Ethanol 70% v/v	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> on 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.	
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Directions	
<ul style="list-style-type: none"> 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. 	
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<ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, carbomer,, purified water USP	

Alcohol Antiseptic 70% Topical Solution
Hand Sanitizer Non-sterile Solution

HYGEIA EFFECT HAND SANITIZER

alcohol 70% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76605-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	662 mL in 946 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 946 mL
GLYCERIN (UNII: PDC6A3C0OX)	84 mL in 946 mL

WATER (UNII: 059QF0KO0R)

199 mL in 946 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76605-119-01	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2021	



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/2021	

Labeler - Pecan Bayou Enterprises, LLC (117491868)

Registrant - Pecan Bayou Enterprises, LLC (117491868)

Establishment

Name	Address	ID/FEI	Business Operations
Pecan Bayou Enterprises, LLC		117491868	manufacture(76605-119)

Revised: 3/2021

Pecan Bayou Enterprises, LLC