

AP HAND SANITIZER- alcohol gel
International Grocers of America 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.

Hand Sanitizer Gel

70% Alcohol

1 Gallon (3.8L)

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer Gel

Use

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 right away.

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 right away.

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

CARBOMER, TROLAMINE, WATER

Package Label - Principal Display Panel

Hand Sanitizer Gel

Eliminates 99.99% of Germs

1 Gallon (3.8L)



The image shows a product label for Hand Sanitizer Gel. The background is blue with a molecular structure pattern. The text on the label includes: 'HAND SANITIZER GEL' in large bold letters, 'Kills 99.9% of Germs' below it, and 'FRAGRANCE FREE 1 Gallon 128 oz. (3.8L)' at the bottom. On the right side, there is a white box containing detailed product information.

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial
Use 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"> • in children less than 2 months of age • on open skin wounds 	
When Using Section	
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 right away.	
Stop Use Section	
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 Section	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Dosage And Administration Section	
<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. 	
Storage And Handling Section	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive Ingredients.	
Carbomer, Trolamine, Water	

You May Report adverse events to 1-800-FDA-1088

Expiration Date July 2022

Distributed By / Distribuido Por International Grocers of America LLC Houston, Texas 77057 U.S.A

Questions About this product email to intergrocerstx@gmail.com

Made in an FDA Registered Facility



3 73755 00006 0

AP HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77287-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.0025 mL in 1 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.004 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.289 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77287-200-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - International Grocers of America LLC (116942703)

Revised: 7/2020

International Grocers of America LLC