

HAND SANITIZER- alcohol gel
COMERCIAL GOURA,S. DE R.L.

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

DIRECTION

Place enough product on hands to cover all surfaces. Rub hands together until dry.

INACTIVE INGREDIENT SECTION

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

INDICATIONS AND USAGE

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.

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

KEEP OUT OF REACH OF CHILDREN

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

PURPOSE SECTION

Purpose

Antmicrobial

WARNINGS AND PRECAUTIONS

Warnings

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

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

Store below 110°F (43°C)

ACTIVE INGREDIENT

Active ingredient. Ethyl Alcohol 70% v/v

ASK A DOCTOR

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

ASK A DOCTOR

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

STOP USE

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

WARNING

Warnings

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

PACKAGE LABELS





MEDICALLY MINDED™

Hand Sanitizer Gel

ANTIMICROBIAL FORMULA

(110 mm)

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Use: Hand sanitizer to help reduce bacteria on skin.	
Warnings:	
Flammable. Keep away from fire or flame.	
For external use only.	
When using this product do not use in or near the eyes. In case of contact, flush thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.	
Other Information: Store below 110°F (43°C)	
Inactive Ingredients: Water (Aqua), Glycerin, Carbomer, Triethanolamine	

16.9 FL OZ (500 mL)

500.358MMC1

Distributed by
SBI Brands, LLC
Las Vegas, NV 89119
MedicallyMinded.us



MADE IN MEXICO

LOTE Y FECHA DE EXPIRACION IMPRESAS EN EL ENVASE

6.75"
(171 mm)



Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer Gel Non-sterile Solution
1000 mL (33.8 fl. oz.)



Drug Facts	
Active ingredient. Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
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	
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.	
Directions <ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Children under 6 years of age should be supervised when using. 	
Other information <ul style="list-style-type: none"> Store below 110°F (43°C) 	
Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine	

Distributed by
SBL Brands, LLC
MedicallyMinded.us
MADE IN MEXICO

NET CONTENTS
1000 mL
(33.8 fl. oz.)



MEDICALLY MINDED™

Drug Facts
Active Ingredients Ethyl Alcohol 70% v/v.....Antimicrobial
Use: Hand sanitizer to help reduce bacteria on skin.
Warnings: Flammable. Keep away from fire or flame. For external use only. When using this product do not use in or near the eyes. In case of contact, flush thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.
Other information: Store below 110°F (43°C)
Inactive Ingredients: Water (Aqua), Glycerin, Carbomer, Triethanolamine.

Hand Sanitizer Gel
ANTIMICROBIAL FORMULA



Distributed by
SBL Brands, LLC
Las Vegas, NV 89119
MedicallyMinded.us
MADE IN MEXICO

Lot: E132020
Best Before: 05/13/22

1.05 US GALLON (4 L)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78501-1000
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 940 (UNII: 4Q93RCW27E)	0.002 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.0375 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.2585 mL in 1 mL
TRIETHANOLAMINE CAPROYL GLUTAMATE (UNII: 0F2FO57253)	0.002 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78501-1000-4	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2020	
2	NDC:78501-1000-5	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2020	
3	NDC:78501-1000-6	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2020	
4	NDC:78501-1000-7	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/26/2020	

Labeler - COMERCIAL GOURA,S. DE R.L. (951578628)

Registrant - COMERCIAL GOURA,S. DE R.L. (951578628)

Establishment

Name	Address	ID/FEI	Business Operations
COMERCIAL GOURA,S. DE R.L.		951578628	manufacture(78501-1000)