

**GELCOHOL 1L- alcohol gel**  
**Fulfilment, S.A. de C.V.**

*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.*

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**Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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.

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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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

glycerin, water, alcohol, triethanolamine, carbomer

**Package Label - Principal Display Panel**

1L NDC: 77483-002-01



# Hand Sanitizer

## Drug Facts

### Active Ingredient

Ethyl Alcohol 70%

### Purpose

Antiseptic

### Use(s)

• For handwashing to decrease bacteria on the skin • For use when soap and water are not available. • Recommended for repeated use.

### Warnings

Flammable, keep away from fire and flame

For external use only

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

### 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 59°-86°F (15°-30°C) • Avoid freezing and excessive heat above 104°F (40°C) • May discolor certain fabrics

### Inactive ingredients

Aqua, Carbomer, Triethanolamine, Glycerin.



MANUFACTURED BY:  
FULFILMENT SA DE CV  
CALLE DELA A. BUSTOS 140



PADEP DE LA REFORMA 190  
PISO 6 INT 602, CUAUHTÉMOC,  
CUAUHTÉMOC, CIUDAD DE MÉXICO.  
MADE IN MEXICO



# Hand Sanitizer

## 70% Alcohol formula

SOFT WITH YOUR HANDS



Antibacterial

### Protection for your skin



With moisturizers

**KILLS**  
**99.99%**  
**OF MOST ILLNESS**  
**CAUSING GERMS**

  
**0%****Triclosan Parabens  
Sticky feeling  
Fragrance****33.81 FL OZ (1000 ML)****GELCOHOL 1L**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77483-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	700 mL in 1 L

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0K00R)	
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77483-002-01	1 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

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

**Labeler** - Fulfilment, S.A. de C.V. (815113642)

**Registrant** - Fulfilment, S.A. de C.V. (815113642)

**Establishment**

Name	Address	ID/FEI	Business Operations
Fulfilment, S.A. de C.V.		815113642	manufacture(77483-002)

Revised: 5/2020

Fulfilment, S.A. de C.V.