

**HAND SANITIZER- alcohol gel**  
**Amenidades Flo, 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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**Alcohol 70% - Botella 60 mL**  
**Manufacturer SIESA**

**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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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**

glycerin, triethanolamine, carbomer, purified water USP

**Package Label - Principal Display Panel**

60 mL NDC: 79614-070-60



**HAND  
SANITIZER**

CONTAINS  
**ETHYL  
ALCOHOL  
70%**



**TOPICAL  
SOLUTION**

08337460216

2 FL. OZ. (60 ml)

**Drug Facts**

**Active Ingredient** Ethyl Alcohol 70% v/v. **Purpose** Antiseptic.

**Uses** To decrease bacteria on the skin when you wash, soap & towel and not suitable for use on wounds or open sores.

**Warnings** — For external use only.

**Directions** — Keep away from fire or flames. Rub on the skin until the product feels dry. Do not use on open sores or irritated skin.

**Keep out of reach of children.**

**Other information** — Do not use on children 2 years of age or younger. If you have a rash or contact a health care provider. If you have a rash or contact a health care provider. If you have a rash or contact a health care provider.

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Made in Mexico. Distributed by: **First Aid Antiseptics, Inc.**, 12000 E. 1st Ave., Denver, CO 80231. **Customer Support** 1-800-878-8888.



alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79614-070
<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	70 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
TROLAMINE (UNII: 9O3K93S3TK)	0.3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.35 g in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79614-070-60	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

**Labeler** - Amenidades Flo, S.A. de C.V. (816732572)

**Registrant** - Amenidades Flo, S.A. de C.V. (816732572)

### Establishment

Name	Address	ID/FEI	Business Operations
Amenidades Flo, S.A. de C.V.		816732572	pack(79614-070) , label(79614-070)

Revised: 7/2020

Amenidades Flo, S.A. de C.V.