

## **HAND SANITIZER- alcohol gel**

### **Sistela Corporation**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 80% 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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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, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

**Sistela**  
**hand sanitizer**  
non-sterile solution

**ALCOHOL ANTISEPTIC**

Kills  
**99%**  
of germs

**500 ml | 16.9 FLOZ**

Made in Mexico by:  
Paego Envasado S.A. de C.V.  
Distributed by Sistela Corporation  
73 East Lake, Chicago, IL 60601  
sales@sistela.com  
+52 55 3032 2112  
#SKU XGS-002



### Drug Facts

Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

### Use(s)

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**Inactive ingredients** glycerin, purified water USP, aminomethyl propanol, carbomer.

\* NATURAL: Ethanol based on sugar cane and / or corn.

500 mL NDC: 78526-105-01

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78526-105
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	1.265 mL in 500 mL
GLYCERIN (UNII: PDC6A3C0OX)	7.25 mL in 500 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	1.5 mL in 500 mL
WATER (UNII: 059QF0K00R)	139.985 mL in 500 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78526-105-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/04/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/04/2020	

**Labeler** - Sistela Corporation (117483390)**Registrant** - Sistela Corporation (117483390)**Establishment**

Name	Address	ID/FEI	Business Operations
Fuego Envasado		812932655	manufacture(78526-105)

Revised: 6/2020

Sistela Corporation