

## **HAND SANITIZER- alcohol gel**

### **Green Solution de Centroamerica Export (Usuario Zona Franca)**

*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 Gel Hand Sanitizer**

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.

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**

glycerin, hydrogen peroxide, purified water USP

### **Package Label - Principal Display Panel**



**HAND *gel*  
SANITIZER**

**70%**



**1 gallon  
(128 FL OZ)**

Alcohol Antiseptic 70%

**Topical Solution  
Non sterile Solution**

## Drug Facts

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

### Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  
For general disinfection of surfaces

**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 a rash occurs. These may be signs of a serious condition.

**Keep away from children.** In 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.
- Apply a small amount in paper towel and clean surface as needed.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

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

**Inactive ingredients:** Glycerin, Polycrylic Acid (Carbomer), Hydrogen Peroxide, Water.

**Made in Guatemala By:**  
**Green Solution de Centroamérica S.A.**

ALCOHOL 1 GALLON



**Labeler package code xxxxxxxxxx**



Preserving your baby's umbilical cord blood is a once-in-a-lifetime opportunity to protect your family's health. These stem cells are currently treating nearly 80 diseases, and numerous clinical trials are underway for the treatment of diseases such as autism, cerebral palsy, diabetes, and certain cancers.

Contact Us  
800.781.7253 | Cryo-Cell.com

Drug Facts	
ACTIVE INGREDIENTS:	Ethyl Alcohol (70%)
PURPOSE:	Hand Sanitizer
USES: Decreases bacteria on the hands.	
<b>WARNINGS:</b>	
For External Use Only. Flammable. Keep away from heat or flame.	
Do not use on burns or open wounds.	
Do not store where temperature exceeds 105°F.	
Do not get in eyes. In case of eye contact: flush with water.	
Do not inhale or ingest. If swallowed, get medical help or contact poison control immediately.	
Stop use and ask a doctor if skin irritation develops.	
<b>KEEP OUT OF REACH OF CHILDREN.</b>	
DIRECTIONS: Put small amount into palm of hand. Rub together until dry.	
INACTIVE INGREDIENTS: Polyacrylic Acid, Diphenyl, Hydrogen Peroxide, Water.	
Made in Guatemala. Distributed by: Cryo-Cell LOT: xxxxxxxx	

Hand Sanitizer  
8 fl oz. (236 mL.)

236ml NDC 81448-001-01

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81448-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	1.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81448-001-01	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/31/2021	
2	NDC:81448-001-02	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/31/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	01/30/2021	
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**Labeler** - Green Solution de Centroamerica Export (Usuario Zona Franca) (817601459)

**Establishment**

Name	Address	ID/FEI	Business Operations
Green Solution De Centroamerica Export (Usuario Zona Franca)		817601459	manufacture(81448-001)

Revised: 4/2021

Green Solution de Centroamerica Export (Usuario Zona Franca)