

## **HAND SANITIZER- antiseptic foam solution**

### **Innovaciones Tecnologicas Concar SA de CV**

*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**

1 L NDC: 79279-421-06

## PROPERTIES

- Alcohol, fragrance and dye-free
- Contains emollients



## ANTISEPTIC HAND SANITIZER FOAM

*Benzalkonium  
Chloride 0.13%*

**33.8 fl oz (1 L)**



## Drug Facts

**Active ingredient Purpose**  
Benzalkonium chloride 0.13% ....Antiseptic

### Use

■ for hand washing to decrease bacteria on the skin

### Warnings

**For external use only.**

**Do not use** in the eyes

**Stop use and ask a doctor if**

■ irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

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

### Directions

wet hands thoroughly with product and allow to dry without wiping

### Other information

avoid use in case of hypersensitivity to benzalkonium chloride

### Inactive ingredients

Citric Acid, Hydroxyethylcellulose, Lanolin Ethoxylated, Povidone, Propylene Glycol, Water

### Questions or Comments?

818-619-2735

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*It is not medicine  
Only for external use*

## HAND SANITIZER

antiseptic foam solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79279-421
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 kg in 100 L

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1.45 L in 100 L
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79279-421-06	1 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

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

**Labeler** - Innovaciones Tecnologicas Concar SA de CV (951578588)

## Establishment

Name	Address	ID/FEI	Business Operations
Innovaciones Tecnologicas Concar SA de CV		951578588	manufacture(79279-421)

Revised: 6/2020

Innovaciones Tecnologicas Concar SA de CV