

**HAND SANITIZER- alcohol gel**  
**BIO SYSTEMS DE MEXICO 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**

20 L NDC: 75772-421-01



**FRAGRANCE FREE**

# HAND SANITIZER

FORMULATED WITH

**70%**  
OF ALCOHOL

**RINSE  
FREE**

**ANTIMICROBIAL ACTION**

## DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 70% v/v .....	Antimicrobial

**Use:** Hand sanitizer to help reduce bacteria on the skin.

**Warnings:** Flammable. Keep away from fire or flame. For external use only. Do not ingest, if swallowed seek medical help. Avoid contact with eyes. Keep out of reach of children. Children under 6 years old to use under adult supervision. In case of irritation, discontinue use and consult your doctor.

**Directions:** Apply the Gel on the hands and rub gently for 20 seconds until the product evaporates.

**Other information:** Store below 106°F (41°C). May discolor certain fabrics or surfaces.

**Inactive ingredients:** demineralized water, glycerin, carbomer, triethanolamine, dmdm hydantoin, aloe barbadensis extract, iodopropynyl butylcarbamate, butylene glycol.

NDC code ??????????????

**5.28 GAL (20 L)**

Made in Mexico by  
Biosystems S.A. de  
C.V.



alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75772-421
<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	80 L in 100 L

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75772-421-01	20 L in 1 CONTAINER; 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** - BIO SYSTEMS DE MEXICO SA DE CV (589751791)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
BIO SYSTEMS DE MEXICO SA DE CV		589751791	manufacture(75772-421)

Revised: 5/2020

BIO SYSTEMS DE MEXICO SA DE CV