

**HAND SANITIZER- isopropyl alcohol liquid**  
**Soluciones Cosméticas 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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**Hand Sanitizer Bershi**

**Active Ingredient(s)**

Isopropyl 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.

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**

Water, Propylene Glycol, Carbomer, Aminomethyl Propanol

## Package Label - Principal Display Panel

### Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Ethyl alcohol 70%.....	Antiseptic

**Use** to help reduce bacteria on the skin.

#### **Warnings**

For external use only.

**FLAMMABLE:** Keep away from source of heat or fire.

#### **When using this product:**

Avoid contact with eyes. In case of accidental contact, flush eyes thoroughly with water for 15 minutes. Avoid contact with broken skin or if you have allergies to any ingredients.

#### **Stop use and consult a doctor if skin irritation occurs.**

Keep out of reach of children. If swallowed get medical help at a Poison Control Center immediately.

#### **Directions:**

- Place a small amount of product in your hand.
- Rub hands together briskly for at least 30 seconds until dry.
- Children under 6 years of age should use adult supervision

#### **Other information:**

- Store at temperature below 110° (43°C)
- May discolor certain fabrics or surfaces

#### **Inactive ingredients**

Water, Propylene Glycol, Carbomer, Aminomethyl Propanol

**QUESTIONS:** 800-517-2247



**MADE IN MEXICO**

DISTRIBUTED BY:  
RediBag USA  
135 Fulton Ave  
New Hyde Park, NY 11040

500 ML - NDC 75165-250-01



## HAND SANITIZER

isopropyl alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75165-250
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		2 mL in 100 mL		
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		0.8 mL in 100 mL		
WATER (UNII: 059QF0K00R)		27 mL in 100 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		0.2 mL in 100 mL		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75165-250-01	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - Soluciones Cosmeticas SA de CV (814818001)

**Registrant** - Soluciones Cosmeticas SA de CV (814818001)

### Establishment

Name	Address	ID/FEI	Business Operations
Soluciones Cosmeticas SA de CV		814818001	manufacture(75165-250)

Revised: 5/2020

Soluciones Cosmeticas SA de CV