### HAND SANITIZER- is opropyl alcohol liquid Soluciones Cosmeticas 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.

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#### **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, Aminomthyl Propanol

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

# **Drug Facts**

#### Active Ingredient

Purpose

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

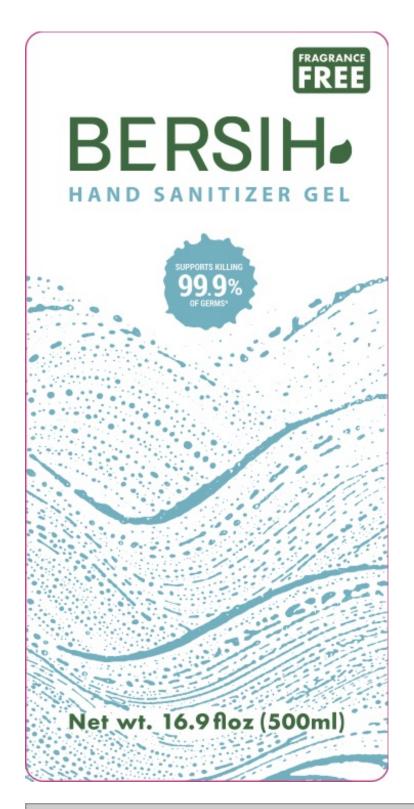
QUESTIONS: 800-517-2247



#### 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

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	2 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.8 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.2 mL in 100 mL

P	ackaging			
# 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	

Marketing Information			
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		8 148 18 0 0 1	manufacture(75165-250)

Revised: 5/2020 Soluciones Cosmeticas SA de CV