

## **HAND SANITIZER RINSE FREE- alcohol gel**

**Absara Cosmetics, S.A.P.I. de C.V.**

*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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% 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**

500 ml NDC: 70956-420-10

# Bextera

## HEALTH

# HAND SANITIZER

SEVENTYPERCENT  
ETHYL ALCOHOL  
ANTIBACTERIAL  
AND VIRAL 70%  
KILLS MOST GERMS

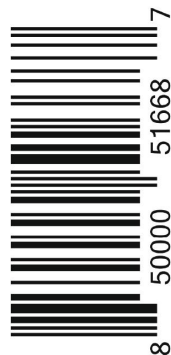


Manufactured in a  
**FDA**  
Registered Facility



NET WT 16.9oz (500ml)

Distributed by: **Bextra Nutrition®**  
7955 Airport Pulling Road Suite 205  
Naples, FL 34109  
[www.bextranutrition.com](http://www.bextranutrition.com)



### 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.

**When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash appears and lasts.

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

**Directions** • Put enough product in your palm to cover hands and rub hands together briskly until dry

• Children under 6 years old should be supervised when using this product

**Other information** • Store below 110°F (43°C)

• May discolor certain fabrics or surfaces

**Inactive ingredients** Deionized water, carbomer, glycerin, propylene glycol, triethanolamine, methylisothiazolinone, hydroxycitronellal

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

HAND SANITIZER RINSE FREE

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70956-420
<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	70 mL in 100 mL

### Inactive Ingredients

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

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70956-420-10	500 mL in 1 BOTTLE; 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** - Absara Cosmetics, S.A.P.I de C.V. (816161236)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Absara Cosmetics, S.A.P.I de C.V.		816161236	manufacture(70956-420)

Revised: 4/2020

Absara Cosmetics, S.A.P.I de C.V.