

**IBARRA- alcohol gel**  
**PROMAQUILA DE COCULA, S.A. 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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**MENTHOL SCENTED HAND SANITIZER**

**ACTIVE INGREDIENT**

**ACTIVE INGREDIENT**

Active ingredient. Ethyl Alcohol 70%

**PURPOSE**

Purpose Antmicrobial

**INDICATIONS AND USAGE**

Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

**DOSAGE AND ADMINISTRATION**

Place enough product on hands to cover all surfaces. Rub hands together until dry.

**WARNINGS AND PRECAUTIONS**

Store below 110°F (43°C)

Children under 6 years of age should be supervised when using.

**WARNINGS**

Warnings

For external use only. Flammable. Keep away from heat or flame

**STOP USE SECTION**

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**

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

## INACTIVE INGREDIENTS

Inactive ingredients Water, Glycerin, Carbomer, Triethanolamine, Aloe Vera Leaf, Menthol

## PACKAGE LABEL

**Alcohol Antiseptic 70%**  
**Topical Solution**  
**Hand Sanitizer Gel Non-sterile Solution**  
**250 mL (8.45 fl. oz.)**

<b>Drug Facts</b>	
<b>Active ingredient.</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v.....	Antimicrobial
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>When using this product</b> 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.	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces. Rub hands together untildry. • Children under 6 years of age should be supervised when using.	
<b>Other information</b>	
• Store below 110°F (43°C)	
<b>Inactive ingredients</b> Water, Glycerin, Carbomer, Triethanolamine, Aloe Vera Leaf, Menthol	

MANUFACTURED BY:  
PROMAQUILA DE COCULA, S.A. DE C.V.  
JOSE RAYMUNDO IBARRA 8, BARRIO LA CRUZ,  
48500, COCULA, JALISCO  
MADE IN MEXICO

NET  
CONTENTS  
**250**  
**mL**  
(8.45 fl. oz.)

**Alcohol Antiseptic 70%**  
**Topical Solution**  
**Hand Sanitizer Gel Non-sterile Solution**  
**500 mL (16.9 fl. oz.)**

<b>Drug Facts</b>	
<b>Active ingredient.</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v.....	Antimicrobial
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
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• Store below 110°F (43°C)	
<b>Inactive ingredients</b> Water, Glycerin, Carbomer, Triethanolamine, Aloe Vera Leaf, Menthol	

NET  
CONTENTS  
**500 mL**  
(16.9 fl. oz.)

**Alcohol Antiseptic 70%**  
**Topical Solution**  
**Hand Sanitizer Gel Non-sterile Solution**  
**1000 mL (33.8 fl. oz.)**

<b>Drug Facts</b>	
<b>Active ingredient.</b> Ethyl Alcohol 70% v/v	<b>Purpose</b> Antimicrobial
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
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.	
<b>Directions</b> • Place enough product on hands to cover all surfaces. Rub hands together untildry. • Children under 6 years of age should be supervised when using.	
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 48500, COCULA, JALISCO  
 MADE IN MEXICO

NET CONTENTS  
**1000 mL**  
 (33.8 fl. oz.)

**IBARRA**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79577-0003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.28511 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.00302 mL in 1 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.00279 mL in 1 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.00278 mL in 1 mL
MENTHOL (UNII: L7T10EIP3A)	0.002 mL in 1 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.0043 mL in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79577-0003-3	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	

2	NDC:79577-0003-4	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	
3	NDC:79577-0003-5	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/04/2020	

**Labeler** - PROMAQUILA DE COCULA, S.A. DE C.V. (812760470)

**Registrant** - PROMAQUILA DE COCULA, S.A. DE C.V. (812760470)

## Establishment

Name	Address	ID/FEI	Business Operations
PROMAQUILA DE COCULA, S.A. DE C.V.		812760470	manufacture(79577-0003)

Revised: 8/2020

PROMAQUILA DE COCULA, S.A. DE C.V.