

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.

LAVENDER SCENTED HAND SANITIZER

ACTIVE INGREDIENTS

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

WARNINGS AND PRECAUTIONS

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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

STOP USE

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,

PACKAGE LABELS

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

Drug Facts	
Active ingredient.	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Use[s] 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	
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.	
Directions <ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Children under 6 years of age should be supervised when using. 	
Other information <ul style="list-style-type: none"> Store below 110°F (43°C) 	
Inactive ingredients Water, Glycerin, Carbomer, Aminomethylpropanol, Aloe Vera Leaf	

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.)

Drug Facts	
Active ingredient.	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Use[s] 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	
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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.)

Drug Facts	
Active ingredient. Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
Use[s] 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	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Children under 6 years of age should be supervised when using.	
Other information • Store below 110°F (43°C)	
Inactive ingredients Water, Glycerin, Carbomer, Aminomethylpropanol, Aloe Vera Leaf	

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NET CONTENTS
1000 mL
 (33.8 fl. oz.)

IBARRA
 alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79577-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.0043 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.28711 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.00302 mL in 1 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.00278 mL in 1 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.00279 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79577-0004-4	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	
2	NDC:79577-0004-5	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	

3	NDC:79577-0004-6	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2020	
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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(79577-0004)

Revised: 8/2020

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