

HAND SANITIZER- alcohol gel
Articulos Medicos Brooks, 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.

Active Ingredient(s)

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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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, carbomer, glycerin and triethanolamine.

Package Label - Principal Display Panel

PDP 60 mL NDC: 79078-002-01

Hand Sanitizer

70%

ALCOHOL

60 mL (2.02 fl oz)

PI 60 mL NDC: 79078-002-01

Drug Facts

<i>Active Ingredient [s]</i>	<i>Purpose</i>
Ethyl alcohol 70% v/v	Antiseptic

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 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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

■ Store below 110°F (43 °C)

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

MANUFACTURED BY: Artículos Médicos Brooks, S.A. de C.V.
Ecuario López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.

PRODUCT OF MEXICO.

EXPIRATION DATE:

BATCH NUMBER:

PDP 236.58 mL NDC: 79078-002-02

Hand Sanitizer

70%

ALCOHOL

236.58 mL (8 fl oz)

PI 236.58 mL NDC: 79078-002-02

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store below 110°F (43 °C)

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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PRODUCT OF MEXICO.

EXPIRATION DATE:

BATCH NUMBER:

Hand Sanitizer

70%

ALCOHOL

250 mL (8.5 fl oz)

Drug Facts

Active Ingredient [s] P

Ethyl alcohol 70% v/v A

Use [s]

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

Warnings

For external use only. Flammable. Keep away from heat

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 mucous
contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if redness or irritation develop
more than 72 hours.

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

Directions

- Place enough product on hands to cover all surfaces. Rub
until dry.
- Supervise children under 6 years of age when using this product
swallowing.

Other information

- Store between 110 °F (43 °C)
- May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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PRODUCT OF MEXICO.
EXPIRATION DATE: **BATCH NUMBER:**

PDP 473.1 mL NDC: 79078-002-04

Hand Sanitizer

70%
ALCOHOL

473.1 mL
(16 fl oz)

BATCH NUMBER:

EXPIRATION DATE:

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 thoroughly with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.
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 110°F (43 °C)
■ May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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Ecuario López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.
PRODUCT OF MEXICO.

PDP 500 mL NDC: 79078-002-05

Hand Sanitizer

70%
ALCOHOL

500 mL
(16.9 fl oz)

PDP 1000 mL NDC: 79078-002-06

EXPIRATION DATE: BATCH NUMBER:

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 thoroughly with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.
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 110°F (43 °C)
■ May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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Ecuatio López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.
PRODUCT OF MEXICO.

Hand Sanitizer

70%
ALCOHOL

1000 mL
(33.8 fl oz)

PDP 3785 mL NDC: 79078-002-07

EXPIRATION DATE: BATCH NUMBER:

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 thoroughly with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.
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 110°F (43 °C)
■ May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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PRODUCT OF MEXICO.

Hand Sanitizer

70% **ALCOHOL**

Drug Facts

Active Ingredient [s]

Purpose

Ethyl alcohol 70% v/v Antiseptic

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 thoroughly with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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 110°F (43 °C)
- May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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Ecuario López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.

MADE IN MEXICO.

EXPIRATION DATE: **BATCH NUMBER:**

3.785 L (1 gal)

PDP 5000 mL NDC: 79078-002-08

Hand Sanitizer

70% **ALCOHOL**

Drug Facts

Active Ingredient(s)

Purpose(s)

Active ingredient [s]

Ethyl alcohol 70% v/v Antiseptic

Purpose**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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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 110°F (43 °C)
- May discolor certain fabrics or surfaces.

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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Ecuario López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.

MADE IN MEXICO.

EXPIRATION DATE:

BATCH NUMBER:

5 L(1 gal 1 qt)

PDP 200000 mL NDC: 79078-002-09

Hand Sanitizer

70%
ALCOHOL

200 L

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store below 110°F (43°C).

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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PRODUCT OF MEXICO.

EXPIRATION DATE: BATCH NUMBER:

PDP 1000000 mL NDC: 79078-002-10

Hand Sanitizer

70%
ALCOHOL

1000 L

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 70% v/v	Antiseptic

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 thoroughly with water.

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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 below 110°F (43°C).

Inactive ingredients: Water, carbomer, glycerin and triethanolamine.

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Ecuaro López 35 MZ 92. Granjas Valle de Guadalupe Sección A, Ecatepec de Morelos.

PRODUCT OF MEXICO.

EXPIRATION DATE: BATCH NUMBER:

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79078-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL
TRIETHANOLAMINE HYDRIOXIDE (UNII: DT98IT03JK)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 1342 (UNII: 809Y72KV36)	0.49 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79078-002-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79078-002-02	236.58 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79078-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79078-002-04	473.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79078-002-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79078-002-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:79078-002-07	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:79078-002-08	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:79078-002-09	200000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
10	NDC:79078-002-10	1000000 mL in 1 CONTAINER; 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 - Articulos Medicos Brooks, S.A. de C.V. (951579414)

Establishment

Name	Address	ID/FEI	Business Operations
Articulos Medicos Brooks, S.A. de C.V.		951579414	manufacture(79078-002) , pack(79078-002) , label(79078-002)

Revised: 6/2020

Articulos Medicos Brooks, S.A. de C.V.