

CLEAN SEPT ALCOHOL ANTISEPTIC 70% - TOPICAL HAND SANITIZER NON-STERILE GEL- ethyl alcohol gel
BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E EXPORTACAO LTDA

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.

NO CHANGES NOTIFICATION

Drug Facts Panel - Active Ingredients

Denatured Ethyl Alcohol 70% v/v. Purpose: Antiseptic.

Drug Facts Panel - Purpose

Purpose: Antiseptic.

Drug Facts Panel - Use

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

Drug Facts Panel - 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.

Do not use

- in children less than 2 months of age
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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Drug Facts Panel - 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.

Drug Facts Panel - Other Information

Store between 15-30 °C (59-86 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)

Drug Facts Panel - Inactive Ingredients

Carbomer, Glycerin, Triethanolamine, Water.

Package Label - Principal Display Panel

200 ml, NDC 79916-001-01



**KILLS
99,99%
OF GERMS**

**Alcohol Antiseptic 70% - Topical
Hand Sanitizer - Non-Sterile
Physical form: Gel**

6.7 fl. oz. / 200 ml

Drug Facts

Active ingredients	Purpose
Denatured Ethyl Alcohol 70% v/v	Antiseptic

Uses

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

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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°- 30°C (59°- 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Carbomer, Glycerin, Triethanolamine, Water.

Manufactured by:
Be Factory Laboratories Industria Comercio
Importacao e Exportacao Ltda
Av. Forte do Leme 205, Parque Sao Lourenco,
Sao Paulo, 08340-010, Brazil

MADE IN BRAZIL



7 898584 623004

LOT / EXPIRATION DATE: Printed on the packaging



QUESTIONS OR REPORTING OF ADVERSE EVENTS? CONTACT WEEKDAYS FROM 9AM TO 5PM AT 1-786-272-5677

500 ml, NDC 79916-001-02

Drug Facts (continued)
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°- 30°C (59°- 86°F) • Avoid freezing and excessive heat above 40°C (104°F)
Inactive ingredients Carbomer, Glycerin, Triethanolamine, Water.
Questions or reporting of adverse events? Contact weekdays from 9AM to 5PM at 1-786-272-5677

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Importacao e Exportacao Ltda
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Sao Paulo, 08340-010, Brazil

MADE IN BRAZIL



7 898584 623011

LOT / EXPIRATION DATE:
Printed on the packaging




Alcohol Antiseptic 70% - Topical
Hand Sanitizer - Non-Sterile
Physical form: Gel
16.9 fl. oz. / 500 ml

Drug Facts	
Active ingredients Denatured Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Uses 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.	

1500 ml, NDC 79916-001-03

Clean SEPT



**Alcohol Antiseptic 70% - Topical
Hand Sanitizer - Non-Sterile
Physical form: Gel**

50.7 fl. oz. / 1,5 L

Drug Facts

Active ingredients

Denatured Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

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.

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°- 30°C (59°- 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Carbomer, Glycerin, Triethanolamine, Water.

Questions or reporting of adverse events?

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Importacao e Exportacao Ltda
Av. Forte do Leme 205, Parque Sao Lourenco,
Sao Paulo, 08340-010, Brazil



MADE IN BRAZIL



LOT / EXPIRATION DATE: Printed on the packaging

Clean SEPT



**Alcohol Antiseptic 70% - Topical
Hand Sanitizer - Non-Sterile
Physical form: Gel**

Drug Facts

Active ingredients

Denatured Ethyl Alcohol 70% v/v.....

Purpose

Antiseptic

Uses

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.

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Directions

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

- Store between 15°- 30°C (59°- 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Carbomer, Glycerin, Triethanolamine, Water.

Questions or reporting of adverse events?

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Manufactured by:

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Av. Forte do Leme 205, Parque Sao Lourenco, Sao Paulo, 08340-010, Brazil



1.3 gal / 5 L

MADE IN BRAZIL



LOT / EXPIRATION DATE: Printed on the packaging

3 ml, NDC 79916-001-05

Clean SEPT



Alcohol Antiseptic 70% - Topical Hand Sanitizer - Non-Sterile Physical form: Gel

Drug Facts

Active ingredients

Denatured Ethyl Alcohol 70% v/v.....Antiseptic

Purpose

Uses

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.

0.1 fl. oz. / 3 ml

Drug Facts (continued)

Do not use

- in children less than 2 months of age • on open skin wounds

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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°- 30°C (59°- 86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Carbomer, Glycerin, Triethanolamine, Water.

Questions or reporting of adverse events?

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Manufactured by:

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Comercio Importacao e Exportacao Ltda
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Lourenco, Sao Paulo, 08340-010, Brazil

MADE IN BRAZIL



LOT / EXPIRATION DATE: Printed on the packaging

CLEAN SEPT ALCOHOL ANTISEPTIC 70% - TOPICAL HAND SANITIZER NON-STERILE GEL

ethyl alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79916-001

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
TROLAMINE (UNII: 9O3K93S3TK)	0.18 mL in 100 mL

WATER (UNII: 059QF0KO0R)			20.22 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)			1 mL in 100 mL	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)			0.6 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79916-001-01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2020	
2	NDC:79916-001-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2020	
3	NDC:79916-001-03	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2020	
4	NDC:79916-001-04	5000 mL in 1 JUG; Type 0: Not a Combination Product	08/06/2020	
5	NDC:79916-001-05	3 mL in 1 POUCH; Type 0: Not a Combination Product	08/06/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/06/2020	

Labeler - BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORT ACAA E EXPORT ACAA LTDA (900786538)

Establishment

Name	Address	ID/FEI	Business Operations
BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E EXPORTACAO LTDA		900786538	manufacture(79916-001) , pack(79916-001) , label(79916-001)

Revised: 12/2020 BE FACTORY LABORATORIES INDUSTRIA COMERCIO IMPORTACAO E EXPORTACAO LTDA