

FASHION ANTISEPTIC GEL HAND SANITIZER- ethyl alcohol gel
JOAO HENRIQUE SILVA BESSA E CIA 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 CHANGE NOTIFICATION

Drug Facts Panel - Active Ingredients

Denatured Ethyl Alcohol 70%. Purpose: Antiseptic

Drug Facts Panel - Purpose

Purpose: Antiseptic.

Drug Facts Panel - Uses

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

Drug Facts Panel - Directions

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

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

Inactive ingredients:

Aminomethyl Propanol, Carbomer, Glycerin, Water.

Drug Facts Panel - Question and reporting of adverse events

Questions or reporting of adverse events?

Contact weekdays from 9AM to 5PM at 1-786-272-5677

Package Label - Principal Display Panel

60 ml NDC 78904-001-01



MANUFACTURED BY: JOÃO HENRIQUE SILVA BESSA E CIA LTDA
 Rua Francisco Andrade Borges, 125 - Lagoa da Prata/MG
 CEP: 35590-000 - Brazil. Phone Number: +55 37 3281-8300
 www.fashioncosmeticos.com.br • sac@fashioncosmeticos.com.br
 Lot/Expiration Date: See marking. MADE IN BRAZIL



Drug Facts

Active ingredients **Purpose**
 Denatured Ethyl Alcohol 70% 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

Lift here for more **DRUG FACTS**

Drug Facts (continued)

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

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- 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)

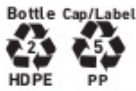
Inactive ingredients

Aminomethyl Propanol, Carbomer, Glycerin, Water.

Questions or reporting of adverse events?

Contact weekdays from 9AM to 5PM at 1-786-272-5677

200 ml NDC 78904-001-02



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 Lot/Expiration Date: See marking. MADE IN BRAZIL

| Drug Facts | |
|--|----------------|
| Active ingredients | Purpose |
| Denatured Ethyl Alcohol 70% | Antiseptic |
| Uses | |
| <ul style="list-style-type: none"> • Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Warnings | |
| <p>For external use only. Flammable. Keep away from heat or flame.</p> <p>Do not use</p> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. ▶</p> | |

Lift here for more **DRUG FACTS**

| |
|--|
| Drug Facts (continued) |
| <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> |
| Directions |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • Store between 15-30 °C (59-86 °F) • Avoid freezing and excessive heat above 40 °C (104 °F) |
| Inactive ingredients |
| Aminomethyl Propanol, Carbomer, Glycerin, Water. |
| Questions or reporting of adverse events? |
| Contact weekdays from 9AM to 5PM at 1-786-272-5677 |

400 ml NDC 78904-001-03



FASHION

ANTISEPTIC GEL

HAND SANITIZER
WITH GLYCERIN

ETHYL ALCOHOL
70%

13.5 fl.oz
400ml

KILLS
99.99%
OF GERMS

Drug Facts

| Active ingredients | Purpose |
|-----------------------------|------------|
| Denatured Ethyl Alcohol 70% | 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
Aminomethyl Propanol, Carbomer, Glycerin, Water.

Questions or reporting of adverse events?
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Lot/Expiration Date: See marking. MADE IN BRAZIL

500 ml NDC 78904-001-04

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Lot/Expiration Date: See marking. MADE IN BRAZIL



FASHION

ANTISEPTIC GEL

HAND SANITIZER
WITH GLYCERIN

ETHYL ALCOHOL
70%

16.9 fl.oz
500ml

KILLS
99.99%
OF GERMS

Drug Facts

| Active ingredients | Purpose |
|-----------------------------|------------|
| Denatured Ethyl Alcohol 70% | 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
Aminomethyl Propanol, Carbomer, Glycerin, Water.

Questions or reporting of adverse events?
Contact weekdays from 9AM to 5PM at 1-786-272-5677



Drug Facts

Active ingredients

Denatured Ethyl Alcohol 70% 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.

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

Aminomethyl Propanol, Carbomer, Glycerin, Water.

Questions or reporting of adverse events?

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5000 ml NDC 78904-001-06

FASHION

ANTISEPTIC GEL

HAND SANITIZER
WITH GLYCERIN

**ETHYL ALCOHOL
70%**

**KILLS
99.99%
OF GERMS**

**1.3 gal
5L**

Drug Facts

| Active ingredients | Purpose |
|-----------------------------------|------------|
| Denatured Ethyl Alcohol 70% | 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.
- 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
Aminomethyl Propanol, Carbomer, Glycerin, Water.

Questions or reporting of adverse events?
Contact weekdays from 9AM to 5PM at 1-786-272-5677



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5 ml NDC 78904-001-07

Level 1

FASHION

ANTISEPTIC GEL
HAND SANITIZER
WITH GLYCERIN

KILLS
99.99%
OF GERMS

ETHYL ALCOHOL
70%

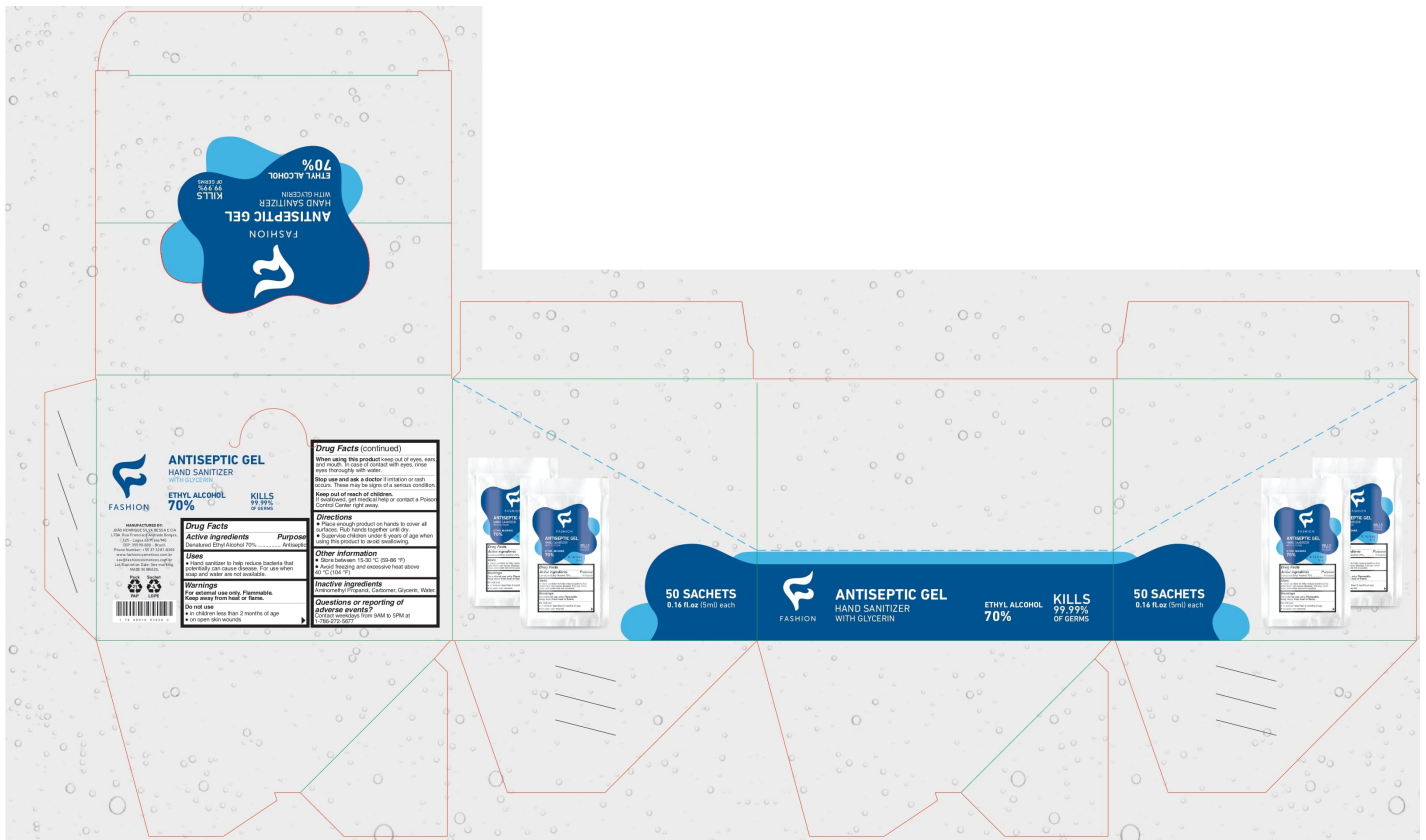
0.16 fl.oz
5ml

| Drug Facts | |
|---|----------------|
| Active ingredients | Purpose |
| Denatured Ethyl Alcohol 70% | Antiseptic |
| Uses | |
| <ul style="list-style-type: none"> 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 | |
| <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds | |

50x5 ml NDC 78904-001-07

Level 2

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| Drug Facts (continued) |
| <p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> |
| Directions |
| <ul style="list-style-type: none"> 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 |
| <ul style="list-style-type: none"> Store between 15-30 °C (59-86 °F) Avoid freezing and excessive heat above 40 °C (104 °F) |
| Inactive ingredients |
| Aminomethyl Propanol, Carbomer, Glycerin, Water. |
| Questions or reporting of adverse events? |
| Contact weekdays from 9AM to 5PM at 1-786-272-5677 |
| <p>MANUFACTURED BY: JOÃO HENRIQUE SILVA BESSA E CIA LTDA Rua Francisco Andrade Borges, 125 - Lagoa da Prata/MG CEP: 35590-000 - Brazil. Phone Number: +55 37 3281-8300 www.fashioncosmeticos.com.br • sac@fashioncosmeticos.com.br Lot/Expiration Date: See marking. MADE IN BRAZIL</p> |
| |



FASHION ANTISEPTIC GEL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78904-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------------|
| WATER (UNII: 059QF0K00R) | 26.35 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 3 mL in 100 mL |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | 0.3 mL in 100 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.35 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78904-001-01 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 2 | NDC:78904-001-02 | 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |

| | | | | |
|---|------------------|--|------------|--|
| 3 | NDC:78904-001-03 | 400 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 4 | NDC:78904-001-04 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 5 | NDC:78904-001-05 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 6 | NDC:78904-001-06 | 5000 mL in 1 JUG; Type 0: Not a Combination Product | 07/14/2020 | |
| 7 | NDC:78904-001-07 | 50 in 1 CARTON | 07/14/2020 | |
| 7 | | 5 mL in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/14/2020 | |

Labeler - JOAO HENRIQUE SILVA BESSA E CIA LTDA (899478850)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------------|---------|-----------|---|
| JOAO HENRIQUE SILVA BESSA E CIA LTDA | | 899478850 | manufacture(78904-001) , pack(78904-001) , label(78904-001) |

Revised: 12/2020

JOAO HENRIQUE SILVA BESSA E CIA LTDA