

HAND SANITIZER- alcohol gel
NATURATLALI S DE RL DE CV

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.

ProteX NDC: 77143-005
Antibacterial 80% Alcohol

Active Ingredient(s)

Alcohol 80% 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

Flammable, keep away from fire or flame.

For external use only.

Do not use

- on open 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.

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

Inactive ingredients

Purified water USP, glycerin, carbomer, triethanolamine.

Package Label - Principal Display Panel

200000 mL NDC: 77143-005-01

PROTEX™

ADVANCED
Alcohol Antiseptic 80%
Hand Sanitizer Gel Non-sterile

55 Gal (200 L)

Lot and expiration date on bottle

| Drugs Facts | |
|---|----------------|
| Active ingredient | Purpose |
| Ethyl alcohol 80% v/v | Antiseptic |
| Uses [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. | |
| Do not use <ul style="list-style-type: none">• 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 thoroughly with water. | |
| Stop use and consult 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 and 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.• 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: Water, EDTA, Carbomer, Glycerin, TEA | |

www.pftradingllc.com
MADE IN MEXICO.
DISTRIBUTED BY:
PF TRADING, LLC
ATTN: MEL PERAZA
5400 SUNCREST A-1
EL PASO, TX 79911

info@pftradingllc.com
Questions? (915) 500 4042
NDC 77143-005-01

8 50020 86807 0

3785 mL NDC: 77143-005-02

PROTEX™

ADVANCED
Alcohol Antiseptic 80%
Hand Sanitizer Gel Non-sterile

1 Gal (3.78 L)

Lot and expiration date on bottle

| Drugs Facts | |
|---|----------------|
| Active ingredient | Purpose |
| Ethyl alcohol 80% v/v | Antiseptic |
| Uses [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. | |
| Do not use <ul style="list-style-type: none">• 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 thoroughly with water. | |
| Stop use and consult 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 and 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.• 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: Water, EDTA, Carbomer, Glycerin, TEA | |

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NDC 77143-005-02

8 50020 86804 9

1000 mL NDC: 77143-005-03

PROTEX™

ADVANCED Alcohol Antiseptic 80% Hand Sanitizer Gel Non-sterile

33.8 FL OZ (1 L)

Drugs Facts

| Active Ingredient | Purpose |
|-----------------------|------------|
| Ethyl alcohol 80% v/v | Antiseptic |

Uses [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.

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 thoroughly with water.

Stop use and consult a doctor if redness or irritation develops and persists for more than 72 hours.

Keep out of reach of children if swallowed get medical help and 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)
- May discolor certain fabrics or surfaces.

Inactive Ingredients:
Water, EDTA, Carbomer, Glycerin, TEA

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Questions? (915) 500 4942
NDC 77143-005-03

8 50020 86803 2

Lot and expiration date on bottle.

500 mL NDC: 77143-005-04

PROTEX™

ADVANCED Alcohol Antiseptic 80% Hand Sanitizer Gel Non-sterile

16.9 FL OZ (500 ML)

Drugs Facts

| Active Ingredient | Purpose |
|-----------------------|------------|
| Ethyl alcohol 80% v/v | Antiseptic |

Uses [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.

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 thoroughly with water.

Stop use and consult a doctor if redness or irritation develops and persists for more than 72 hours.

Keep out of reach of children if swallowed get medical help and 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)
- May discolor certain fabrics or surfaces.

Inactive Ingredients:
Water, EDTA, Carbomer, Glycerin, TEA


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Questions? (915) 500 4942
NDC 77143-005-04

8 50020 86800 1

Lot and expiration date on bottle.

19000 mL NDC: 77143-005-05



PROTEX™
ADVANCED
Alcohol Antiseptic 80%
Hand Sanitizer Gel Non-sterile

5 Gal (19 L)

Lot and expiration date on bottle

| Drugs Facts | |
|---|------------------------------|
| Active ingredient Ethyl alcohol 80% v/v..... | Purpose Antiseptic |
| Uses [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. | |
| 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 thoroughly with water. | |
| Stop use and consult 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 and 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: Water, EDTA, Carbomer, Glycerin, TEA | |

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 Questions? (915) 500 4042
 NDC 77143-005-05

118 mL NDC: 77143-005-06



PROTEX™
ADVANCED
Alcohol Antiseptic 80%
Hand Sanitizer Gel Non-sterile

4 FL OZ (118 ML)

Lot and expiration date on bottle


| Drugs Facts | |
|---|------------------------------|
| Active ingredient Ethyl alcohol 80% v/v..... | Purpose Antiseptic |
| Uses [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 consult 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 and 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. | |
| Inactive ingredients: Water, EDTA, Carbomer, Glycerin, TEA | |

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 Questions? (915) 500 4042
 NDC 77143-005-06

250 mL NDC: 77143-005-07



PROTEX™

ADVANCED
Alcohol Antiseptic 80%
Hand Sanitizer Gel Non-sterile

8.3 FL OZ (250 ML)

Lot and expiration date on bottle

| Drugs Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Ethyl alcohol 80% v/v..... | Antiseptic |
| Uses [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 consult 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 and 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. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Inactive Ingredients: | |
| Water, EDTA, Carbomer, Glycerin, TEA | |

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Questions? (915) 500 4042

NDC 77143-005-07

350 mL NDC: 77143-005-09



PROTEX™

ADVANCED
Alcohol Antiseptic 70%
Hand Sanitizer Gel Non-sterile

11.8 FL OZ (350 ML)

Lot and expiration date on bottle

| Drugs Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Ethyl alcohol 70% v/v..... | Antiseptic |
| Uses [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. | |
| Do not use | |
| <ul style="list-style-type: none"> • 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 thoroughly with water. | |
| Stop use and consult 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 and 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. • 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) • May discolor certain fabrics or surfaces. | |
| Inactive Ingredients: | |
| Water, EDTA, Carbomer, Glycerin, TEA | |

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Questions? (915) 500 4042

NDC 77143-004-09

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77143-005 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 0.5 mL in 100 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.8 g in 100 mL |
| WATER (UNII: 059QF0K00R) | |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.5 g in 100 mL |
| EDETIC ACID (UNII: 9G34HU7RV0) | 0.5 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77143-005-05 | 19000 mL in 1 CONTAINER; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:77143-005-04 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:77143-005-03 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:77143-005-02 | 3785 mL in 1 CONTAINER; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:77143-005-01 | 200000 mL in 1 DRUM; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:77143-005-06 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 7 | NDC:77143-005-07 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |
| 8 | NDC:77143-005-09 | 350 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/14/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - NATURATLALIS DE RL DE CV (951577202)

Registrant - NATURATLALIS DE RL DE CV (951577202)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---|
| NATURATLALIS DE RL DE CV | | 951577202 | pack(77143-005) , manufacture(77143-005) , label(77143-005) |

Revised: 11/2020

NATURATLALI S DE RL DE CV