

HAND SANITIZER- alcohol gel

Streamline Polymers LLC

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.

Gel Hand Sanitizer - Carbomer Formula

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product.

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

- a. Glycerol (0.63% v/v).
- b. Carbomer 940 (6.27% v/v).
- c. PEG-8 Dimethicone (0.45% v/v)
- d. Trolamine (0.22% v/v)
- e. East Indian Lemon Grass Oil (0.14% v/v)
- f. Sterile distilled water or boiled cold water.

The firm does not add other active ingredients.

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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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 940, Glycerin, PEG-8 Dimethicone, Trolamine, Fragrance

Package Label - Principal Display Panel

Drug Facts [Cont.]
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 940, Fragrance, Glycerin, PEG - 8 Dimethicone, Trolamine, Water

Drug Facts
Active Ingredient & 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
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

*Kills 99.99% of most common germs that may cause illness.

Manufactured and Distributed by Streamline Polymers
16950 Wallisville Rd., Houston, TX 77049
For Questions, please call 888.770.4905

R 51910.1200



- GEL - HAND SANITIZER

KILLS 99.99% OF GERMS*

} made with
lemon scented
essential oils
}

Net Contents 16.9 fl. oz. • 70% Alcohol

STREAMLINE

Manufactured and Distributed by Streamline Polymers
15250 Westville Rd. Houston, TX 77049
For Questions, please call 888.770.4805

Drug Facts

[Cont.]

- 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 940, Fragrance, Glycerin, PEG - 8 Dimethicone, Trolamine, Water

Drug Facts

Active Ingredient & 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.

Do not use

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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.

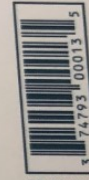
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

*Kills 99.99% of most common germs that may cause illness.



STREAMLINE



PD-341rev0



Drug Facts

Active Ingredient & 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.

Do not use

- on children less than two 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.

*Kills 99.99% of most common germs that may cause illness.

gel hand sanitizer

kills 99.99% of all germs*

made with
essential oils
lemon scented

Drug Facts [Cont.]

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 940, Fragrance, Glycerin, PEG - 8, Dimethicone, Trolamine, Water

Manufactured and Distributed by Streamline Polymers
10650 Wallville Rd. Houston, TX 77045

16.9 oz • 70% Alcohol



STREAMLINE



PD-304rev1

Drug Facts

Active Ingredient & 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.

Do not use

- on children less than two 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.

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*Kills 99.99% of most common germs that may cause illness.

gel hand sanitizer

kills 99.99% of all germs*

made with
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Drug Facts [Cont.]

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 940, Fragrance, Glycerin, PEG - 8, Dimethicone, Trolamine, Water

Manufactured and Distributed by Streamline Polymers
16650 Waterville Rd Houston, TX 77048

8.5 oz • 70% Alcohol

| | | | |
|---|--|---|--|
| <p>Drug Facts</p> <p>Active Ingredient Ethyl Alcohol 70% v/v</p> <p>Purpose Antiseptic</p> |  <p>60 TEXAS</p> |  <p>STREAMLINE</p> <p>gel hand sanitizer</p> <p><i>kills 99.99% of all germs*</i></p> <p>made with essential oils <small>reminiscent of nature</small></p> | <p>Drug Facts [Cont.]</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> |
| <p>Use[s]</p> <p>Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> |  <p>74793 1 0006 1</p> | | <p>Directions</p> <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. |
| <p>Warnings</p> <p>For external use only. Flammable. Keep away from heat or flame.</p> | <p>PD-302497</p> | <p>16.9 oz • 70% Alcohol</p> | <p>Other information</p> <ul style="list-style-type: none"> Store between 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) |
| <p>Do not use</p> <ul style="list-style-type: none"> on children less than two months of age on open skin wounds | <p>Inactive ingredients</p> <p>Carbomer 940, Fragrance, Glycerin, PEG - 8, Dimethicone, Triolamine, Water</p> | | |
| <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><small>Manufactured and Distributed by Streamline Products, 11000 Hollister Rd., Houston, TX 77060</small></p> | | |

8.5 oz NDC: 74793-0006-1

16.9 oz NDC: 74793-0006-2



STREAMLINE

gel hand sanitizer

kills 99.99% of all germs*

made with
essential oils
lemon scented

1 Gallon / 3.78 L • 70% Alcohol

*Kills 99.99% of most common germs that may cause illness.

Drug Facts

| Active Ingredient | 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.

Do not use

- on children less than two months of age
- on open skin wounds

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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 940, Fragrance, Glycerin, PEG-8 Dimethicone, Triethylamine, Water

Manufactured and Distributed by Streamline Polymers
1690 Wauville Rd., Houston, TX 77049

PD-305rev1





HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74793-0006 |
| 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 |
|---|-------------------|
| CARBOMER 940 (UNII: 4Q93RCW27E) | 6.27 mL in 100 mL |
| EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW) | 0.14 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.63 mL in 100 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 0.22 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |

PEG-8 DIMETHICONE (UNII: GIA7T764OD)

0.45 mL in 100 mL

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:74793-0006-1 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| 2 | NDC:74793-0006-2 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| 3 | NDC:74793-0006-3 | 3780 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| 4 | NDC:74793-0006-5 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| 5 | NDC:74793-0006-6 | 479 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |
| 6 | NDC:74793-0006-7 | 241 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/06/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/06/2020 | |

Labeler - Streamline Polymers LLC (117054225)

Registrant - Streamline Polymers LLC (117054225)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| Streamline Polymers LLC | | 117054225 | manufacture(74793-0006) |

Revised: 2/2021

Streamline Polymers LLC