

## **HAND SANITIZER- isopropyl alcohol gel**

### **KARSOF SYSTEMS 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.*

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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 (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Isopropyl Alcohol 75% 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.

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

elettaria cardamomum, azadirachta indica, syzygium aromaticum, cinnamomum camphora, aloe vera, phyllanthus emblica, carbomer, glycerin, hydrogen peroxide, purified water USP, rosa gallica, crocus sativus


## Package Label - Principal Display Panel


3785.41ml NDC 77160-307-01

**Dr**

**GermCleaner**

**Hand Sanitizer**

**Ascend Herbs**  
<https://ascend-herbs.com>

**MADE IN USA**

**Gel**  
**Rose Petals**

**Isopropyl Alcohol**  
**Antiseptic 80%**  
  
Topical Gel

**1 Gallon**  
**3.78 L**

**NDC 77160-307-01**

| Drug Facts  |            |
|---|------------|
| Active Ingredient(s)  | Purpose    |
| Isopropyl alcohol 80% .....   | Antiseptic |
| Use(s)  |            |
| Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |            |
| Warnings  |            |
| <b>For external use only. Flammable. Keep away from heat or flame.</b>  |            |
| Do not use  |            |
| • in children less than 2 months of age<br>• 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.  |            |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |            |
| <b>Keep out of reach of children.</b> 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.<br>• Supervise children under 6 years of age when using this product to avoid swallowing.                              |            |
| Other information   |            |
| • Store between 15-30C (59-86F)<br>• Avoid freezing and excessive heat above 40C (104F)   |            |
| Inactive ingredients  |            |
| Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera |            |



946.353ml NDC 77160-307-02

**Dr GermCleaner™**

# Isopropyl Alcohol Antiseptic 80%

Topical Gel

NDC 77160-307-02

## Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



**Gel**  
**Rose Petals**

**32 FL. OZ.**  
946.353 ml

### Drug Facts

| Active Ingredient[s]        | Purpose    |
|-----------------------------|------------|
| Isopropyl alcohol 80% ..... | 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

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

### Inactive ingredients

Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera



473.176ml NDC 77160-307-03

Dr **GermCleaner**™

# Isopropyl Alcohol Antiseptic 80%

Topical Gel

## Hand Sanitizer

NDC 77160-307-03



Ascend Herbs  
<https://ascend-herbs.com>



**Gel**  
**Rose Petals**

**16 FL. OZ.**  
**473 ml**

### Drug Facts

| Active Ingredient[s]        | Purpose    |
|-----------------------------|------------|
| Isopropyl alcohol 80% ..... | 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

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

### Inactive ingredients

Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera



236.588ml NDC 77160-307-05

# Dr <sup>TM</sup> GermCleaner

Isopropyl Alcohol Antiseptic 80%

Topical Gel

## Hand Sanitizer



**Ascend Herbs**

<https://ascend-herbs.com>



**Gel**  
Rose Petals

8 fl. oz.  
(236.59 ml)

NDC 77160-307-05

| Drug Facts  |            |
|---|------------|
| Active Ingredient(s)  | Purpose    |
| Isopropyl alcohol 80%   | Antiseptic |
| <b>Use(s)</b><br>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |            |
| <b>Warnings</b><br><b>For external use only. Flammable. Keep away from heat or flame.</b>   |            |
| <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>   |            |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |            |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |            |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |            |
| <b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> |            |
| <b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-85F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>   |            |
| <b>Inactive ingredients</b><br>Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera            |            |



118.294ml NDC 77160-307-06

# Dr <sup>TM</sup> GermCleaner

Isopropyl Alcohol Antiseptic 80%

Topical Gel

## Hand Sanitizer



**Ascend Herbs**

<https://ascend-herbs.com>



**Gel**  
Rose Petals

4 fl oz

NDC 77160-307-06

| Drug Facts  |            |
|---|------------|
| Active Ingredient(s)  | Purpose    |
| Isopropyl alcohol 80%   | Antiseptic |
| <b>Use(s)</b><br>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |            |
| <b>Warnings</b><br><b>For external use only. Flammable. Keep away from heat or flame.</b>   |            |
| <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>   |            |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |            |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |            |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |            |
| <b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> |            |
| <b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>   |            |
| <b>Inactive ingredients</b><br>Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera            |            |



59.1471ml NDC 77160-307-07



# Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

## Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



**Gel**  
Rose Petals

2 fl oz



NDC 77160-307-07

| Drug Facts  |            |
|---|------------|
| Active Ingredient(s)  | Purpose    |
| Isopropyl alcohol 80%   | Antiseptic |
| <b>Use(s)</b><br>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |            |
| <b>Warnings</b><br><b>For external use only. Flammable. Keep away from heat or flame.</b>   |            |
| <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>   |            |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |            |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |            |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |            |
| <b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> |            |
| <b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>   |            |
| <b>Inactive ingredients</b><br>Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera            |            |

59.1471ml NDC 77160-307-08

# Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

## Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



**Gel**  
Rose Petals

2 fl oz



NDC 77160-307-08

| Drug Facts  |            |
|---|------------|
| Active Ingredient(s)  | Purpose    |
| Isopropyl alcohol 80%   | Antiseptic |
| <b>Use(s)</b><br>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |            |
| <b>Warnings</b><br><b>For external use only. Flammable. Keep away from heat or flame.</b>   |            |
| <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>   |            |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |            |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |            |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |            |
| <b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> |            |
| <b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>   |            |
| <b>Inactive ingredients</b><br>Rosa gallica, Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP, Syzygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera            |            |

## HAND SANITIZER

isopropyl alcohol gel

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:77160-307 |
| Route of Administration | TOPICAL        |                    |               |

Active Ingredient/Active Moiety

| Ingredient Name  |                  | Basis of Strength   | Strength             |                    |
|--|------------------|---|----------------------|--------------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) |                  | ISOPROPYL ALCOHOL   | 80 mL in 100 mL      |                    |
|  |                  |   |                      |                    |
| Inactive Ingredients   |                  |   |                      |                    |
| Ingredient Name  |                  | Strength  |                      |                    |
| ROSA GALLICA FLOWER OIL (UNII: B3Y66352HF)                                 |                  |   |                      |                    |
| ELETTARIA CARDAMOMUM WHOLE (UNII: KH2S76267N)                              |                  |   |                      |                    |
| AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)                             |                  |   |                      |                    |
| SYZYGIUM AROMATICUM WHOLE (UNII: EY9MMA0P6Y)                               |                  |   |                      |                    |
| CINNAMOMUM CAMPHORA WHOLE (UNII: 0B27814T7X)                               |                  |   |                      |                    |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)  |                  |   |                      |                    |
| CROCUS SATIVUS FLOWER (UNII: 00IF91KFKQ)                                   |                  |   |                      |                    |
| PHYLLANTHUS EMBLICA WHOLE (UNII: 9B45E1E94Z)                               |                  |   |                      |                    |
| CARBOMER 940 (UNII: 4Q93RCW27E)  |                  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)  |                  | 1.45 mL in 100 mL   |                      |                    |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V)                                       |                  | 0.125 mL in 100 mL  |                      |                    |
| WATER (UNII: 059QF0KO0R)   |                  |   |                      |                    |
|  |                  |   |                      |                    |
| Packaging  |                  |   |                      |                    |
| #  | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
| 1  | NDC:77160-307-01 | 3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 2  | NDC:77160-307-02 | 946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 3  | NDC:77160-307-03 | 473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 4  | NDC:77160-307-05 | 236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 5  | NDC:77160-307-06 | 118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 6  | NDC:77160-307-07 | 59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
| 7  | NDC:77160-307-08 | 59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2020           |                    |
|  |                  |   |                      |                    |
| Marketing Information  |                  |   |                      |                    |
| Marketing Category   |                  | Application Number or Monograph Citation                  | Marketing Start Date | Marketing End Date |
| OTC monograph not final  |                  | part333A  | 05/11/2020           |                    |

**Labeler** - KARSOFT SYSTEMS LLC (049125501)

**Registrant** - KARSOFT SYSTEMS LLC (049125501)

**Establishment**

| Name               | Address | ID/FEI     | Business Operations    |
|--------------------|---------|------------|------------------------|
| KARSOF SYSTEMS LLC |         | 049 125501 | manufacture(77160-307) |

Revised: 7/2020

KARSOF SYSTEMS LLC