

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.

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.

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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

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

Package Label - Principal Display Panel

3785.41ml NDC 77160-308-01

Dr GermCleaner™

**Isopropyl Alcohol
Antiseptic 80%**

Hand Sanitizer

Topical Gel



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

**Dry & Sensitive Skin
Gel
Rose Petals
Clove**



**1 Gallon
3.78 L**

NDC 77160-308-01

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	
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Other information	
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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, Coconut Oil, Olive Oil	



946.353ml NDC 77160-308-02

Dr *GermCleaner*

Isopropyl Alcohol Antiseptic 80%

Topical Gel

NDC 77160-308-02

Hand Sanitizer



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

Dry & Sensitive Skin



Gel
**Rose Petals
Clove**

32 FL. OZ.
946.353 ml

473.176ml NDC 77160-308-03

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

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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, Coconut Oil, Olive Oil



Dr **GermCleaner**TM

Isopropyl Alcohol Antiseptic 80%

Topical Gel

Hand Sanitizer



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

Dry & Sensitive Skin



Gel
Rose Petals
Clove

16 FL. OZ.
473 ml

NDC 77160-308-03

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

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Do not use

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Other information

- Store between 15-30C (59-86F)
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Inactive ingredients

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236.588ml NDC 77160-308-05

Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

Hand Sanitizer



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

Dry & Sensitive Skin

Gel

Rose Petals
Clove

8 fl. oz.
(236.59 ml)



NDC 77160-308-05

Drug Facts	
Active Ingredient[s] Isopropyl alcohol 80%	Purpose 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.	
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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, Coconut Oil, Olive Oil	



118.294ml NDC 77160-308-06

Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

Hand Sanitizer



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

Dry & Sensitive Skin

Gel

Rose Petals
Clove

4 fl oz



NDC 77160-308-06

Drug Facts	
Active Ingredient[s] Isopropyl alcohol 80%	Purpose 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.	
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59.1471ml NDC 77160-308-07

Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

Hand Sanitizer



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

Dry & Sensitive Skin

Gel

Rose Petals
 Clove

2 fl oz



NDC 77160-308-07

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	
<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 eyes thoroughly with water.	
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Directions	
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Other information	
<ul style="list-style-type: none"> 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, Szygium aromaticum, Crocus sativus, Elettaria cardamomum, Azadirachta indica, Phyllanthus emblica, Cinnamomum camphora, Aloe vera, Coconut Oil, Olive Oil	

59.1471ml NDC 77160-308-08

Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Gel

Hand Sanitizer



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

Dry & Sensitive Skin

Gel

Rose Petals
 Clove

2 fl oz



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.	
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HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77160-308
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)				
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)				
PHYLLANTHUS EMBLICA WHOLE (UNII: 9B45E1E94Z)				
CINNAMOMUM CAMPHORA WHOLE (UNII: 0B27814T7X)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CROCUS SATIVUS FLOWER (UNII: 00IF91KFKQ)				
COCONUT OIL (UNII: Q9L0O73W7L)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77160-308-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77160-308-02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77160-308-03	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
4	NDC:77160-308-05	236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
5	NDC:77160-308-06	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
6	NDC:77160-308-07	59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
7	NDC:77160-308-08	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 - KARSO SYSTEMS LLC (049125501)

Registrant - KARSO SYSTEMS LLC (049125501)

Establishment

Name	Address	ID/FEI	Business Operations
KARSOF SYSTEMS LLC		049125501	manufacture(77160-308)

Revised: 7/2020

KARSOF SYSTEMS LLC