

HAND SANITIZER- isopropyl alcohol liquid
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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3785.41ml NDC 77160-309-01

	<p>Isopropyl Alcohol Antiseptic 80%</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">NDC 77160-309-01</p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active Ingredient(s)</th> <th>Purpose</th> </tr> <tr> <td>Isopropyl alcohol 80%</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Use(s)</td> </tr> <tr> <td colspan="2">Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds </td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <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. </td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) </td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">Glycerin, Hydrogen peroxide, Purified water USP</td> </tr> </table>	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.		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		<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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 		Inactive ingredients		Glycerin, Hydrogen peroxide, Purified water USP	
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	<p>Ascend Herbs https://ascend-herbs.com</p>																																						
	<p>Liquid Unscented</p>	<p>1 Gallon 3.78 L</p>																																					

946.353ml NDC 77160-309-02



Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Solution

NDC 77 160-309-02

Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



Liquid
Unscented

32 FL. OZ.
946.353 ml

Drug Facts	
Active Ingredient[s]	Purpose
Isopropyl alcohol 80%.....	Antiseptic
Use[s]	
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Inactive ingredients	
Glycerin, Hydrogen Peroxide, Purified water USP	



473.176ml NDC 77160-309-03

Dr **GermCleaner**™

Isopropyl Alcohol Antiseptic 80%

Topical Solution

NDC 77160-309-03

Hand Sanitizer



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



Liquid
Unscented

16 FL. OZ.
473 ml

236.588ml NDC 77160-309-05

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

Glycerin, Hydrogen Peroxide, Purified water USP



Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



Liquid
Unscented

8 fl. oz.
(236.59 ml)

NDC 77160-309-05

118.294ml NDC 77160-309-06

Dr GermCleaner™

Isopropyl Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer



Ascend Herbs

<https://ascend-herbs.com>



Liquid
Unscented

4 fl oz.

NDC 77160-309-06

59.1471ml NDC 77160-309-07

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.	
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Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Glycerin, Hydrogen Peroxide, Purified water USP	





Drug Facts	
Active Ingredient[s] Isopropyl alcohol 80%	Purpose Antiseptic
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Inactive ingredients Glycerin, Hydrogen Peroxide, Purified water USP	



Dr GermCleanerTM
Isopropyl Alcohol Antiseptic 80%
 Topical Gel
Hand Sanitizer
 NDC 77160-309-07
 **Ascend Herbs**
<https://ascend-herbs.com>
 **Liquid** Unscented 2 fl oz

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.	
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Inactive ingredients Glycerin, Hydrogen Peroxide, Purified water USP	

384927 538052  

59.1471ml NDC 77160-309-08

Dr GermCleanerTM
Isopropyl Alcohol Antiseptic 80%
 Topical Gel
Hand Sanitizer
 NDC 77160-309-08
 **Ascend Herbs**
<https://ascend-herbs.com>
 **Liquid** Unscented 2 fl oz

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.	
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384927 538045  

HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77160-309
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
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Inactive Ingredients

Ingredient Name	Strength
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:77160-309-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:77160-309-02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:77160-309-03	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
4	NDC:77160-309-05	236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
5	NDC:77160-309-06	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
6	NDC:77160-309-07	59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
7	NDC:77160-309-08	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 - KARSOF SYSTEMS LLC (049125501)

Registrant - KARSOF SYSTEMS LLC (049125501)

Establishment

Name	Address	ID/FEI	Business Operations
KARSOF SYSTEMS LLC		049125501	manufacture(77160-309)