

**75% ETHYL ALCOHOL GEL SANITIZER- alcohol liquid**  
**Midland Products 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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**75% Ethyl Alcohol Gelled Formula - CONSUMER**

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

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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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**



Water, Acrylates Copolymer, Fragrance, Aminoethyl Propanol



**Package Label - Principal Display Panel**



NDC: 77136-500-75		<b>Drug Facts</b>	
<h1 style="margin: 0;">Alcohol Antiseptic 75%</h1> <h2 style="margin: 10px 0 0 0;">Hand Sanitizer Gel</h2>  <p style="margin: 10px 0 0 0;">Vol: 275 gal (1040.98L)</p> <p style="margin: 10px 0 0 0;">MADE IN USA </p>		<b>Active Ingredient(s)</b>	<b>Purpose</b>
		Ethyl Alcohol 75% v/v.....	Antiseptic
		<b>Use(s)</b>	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
		<b>Warnings</b>	For external use only. Flammable. Keep away from heat or flame
		<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 eye, rinse eyes thoroughly with water. Stop use and ask a doctor 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>	Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol
		Manufactured for:	
		Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200	



NDC: 77136-500-55		<b>Drug Facts</b>	
<h1 style="margin: 0;">Alcohol Antiseptic 75%</h1> <h2 style="margin: 10px 0 0 0;">Hand Sanitizer Gel</h2>  <p style="margin: 10px 0 0 0;">Vol: 55 gal (208.19L)</p> <p style="margin: 10px 0 0 0;">MADE IN USA </p>		<b>Active Ingredient(s)</b>	<b>Purpose</b>
		Ethyl Alcohol 75% v/v.....	Antiseptic
		<b>Use(s)</b>	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
		<b>Warnings</b>	For external use only. Flammable. Keep away from heat or flame
		<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 eye, rinse eyes thoroughly with water. Stop use and ask a doctor 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>	Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol
		Manufactured for:	
		Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200	

NDC: 77136-500-05		<b>Drug Facts</b>
<h1>Alcohol Antiseptic 75%</h1> <h2>Hand Sanitizer Gel</h2>  <p>Vol: 5 gal (18.92L)</p> <p>MADE IN USA</p> 	<b>Active Ingredient(s)</b> Ethyl Alcohol 75% v/v .....	<b>Purpose</b> .....Antiseptic
	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
	<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
	<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
	<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eye, 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> • 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.	
	<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	<b>Inactive Ingredients:</b> Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol	
	Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200	

NDC: 77136-500-10		<b>Drug Facts</b>
<h1>Alcohol Antiseptic 75%</h1> <h2>Hand Sanitizer Gel</h2>  <p>Vol: 1 gal (3.78L)</p> <p>MADE IN USA</p> 	<b>Active Ingredient(s)</b> Ethyl Alcohol 75% v/v .....	<b>Purpose</b> .....Antiseptic
	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
	<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
	<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
	<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eye, 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> • 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.	
	<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	<b>Inactive Ingredients:</b> Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol	
	Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200	

NDC: 77136-500-16		<b>Drug Facts</b>
<h1>Alcohol Antiseptic 75%</h1> <h2>Hand Sanitizer Gel</h2>  <p>Vol: 16 fl.oz (473.1 ml)</p> <p>MADE IN USA</p> 	<b>Active Ingredient(s)</b> Ethyl Alcohol 75% v/v .....	<b>Purpose</b> .....Antiseptic
	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
	<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
	<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
	<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eye, 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> • 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.	
	<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	<b>Inactive Ingredients:</b> Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol	
	Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200	

NDC: 77136-500-08		<b>Drug Facts</b>	
<h1>Alcohol Antiseptic 75%</h1> <h2>Hand Sanitizer Gel</h2>  <p>Vol: 8 fl.oz (236.5 ml)</p> <p>MADE IN USA</p> 	<b>Active Ingredient(s)</b> Ethyl Alcohol 75% v/v .....	<b>Purpose</b> .....Antiseptic	
	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	<b>Warnings</b> 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 eye, 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.	
	<b>Directions</b> • 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.	<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	<b>Inactive Ingredients:</b> Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200		

NDC: 77136-500-02		<b>Drug Facts</b>	
<h1>Alcohol Antiseptic 75%</h1> <h2>Hand Sanitizer Gel</h2>  <p>Vol: 2 fl.oz (59 ml)</p> <p>MADE IN USA</p> 	<b>Active Ingredient(s)</b> Ethyl Alcohol 75% v/v .....	<b>Purpose</b> .....Antiseptic	
	<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	<b>Warnings</b> 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 eye, 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.	
	<b>Directions</b> • 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.	<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	<b>Inactive Ingredients:</b> Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200		

59 mL NDC: 77136-500-02

236.5 mL NDC: 77136-500-08

473.1 mL NDC: 77136-500-16

3785.4 mL NDC: 77136-500-10

18927.1 mL NDC: 77136-500-05

208197.6 mL NDC: 77136-500-55

1040988.2 mL NDC: 77136-500-75

## 75% ETHYL ALCOHOL GEL SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77136-500
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4.5 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.14 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77136-500-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/15/2020	
2	NDC:77136-500-08	236.5 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/15/2020	
3	NDC:77136-500-16	473.1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/15/2020	
4	NDC:77136-500-10	3785.4 mL in 1 JUG; Type 0: Not a Combination Product	04/15/2020	
5	NDC:77136-500-05	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	04/15/2020	
6	NDC:77136-500-55	208197.6 mL in 1 DRUM; Type 0: Not a Combination Product	04/15/2020	
7	NDC:77136-500-75	1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2020	

**Labeler** - Midland Products LLC (138382226)

### Establishment

Name	Address	ID/FEI	Business Operations
Midland Products LLC		138382226	manufacture(77136-500) , label(77136-500)