# 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	Drug Facts		
	Active Ingredient(s)	Purpose	
	Ethyl Alcohol 75% v/v	Antisepti	
	Use(s)		
Alcohol Antiseptic 75%	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		
Hand Cantilan Cal	• on open skin wounds		
Hand Sanitizer Gel	When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thorough	hly 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		
MIDLAND	• Place enough product on hands to cover all surfaces. Rub hands together until dry.		
PRODUCTS	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)		
Vol: 275 gal (1040.98L)	Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol		
MADE IN USA	Manfufactured for:		
	Midland Products LLC 18600 Graphic Ct.		
	Tinley Park, IL 60477		
	Phone: 708-444-8200		
NDC: 77136-500-55	Drug Facts	aler light	
	Active Ingredient(s)	Purpose	
	Ethyl Alcohol 75% v/v	Ant isept	
01 1 11 1 1 1 1000	Use(s)		
Alcohol Antiseptic 75%	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are	not available.	
Alcohol Alltischtic 13/0	Warnings		
	For external use only. Flammable. Keep away from heat or flame		
	Do not use		
	• in children less than 2 months of age		
Hand Canitinan Cal	• on open skin wounds		
Hand Sanitizer Gel	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.	2	
	Directions		
MIDI AND	Place enough product on hands to cover all surfaces. Rub hands together until dry.		
PRODUCTS	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)		
Vol: 55 gal (208.19L)	Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol		
MADE IN USA	Manfufactured for:		
	Midland Products LLC 18600 Graphic Ct.		
	Tinley Park, IL 60477		

N DC: 77136-500-05	Drug Facts		
	Active Ingredient(s)	Purpose	
	Ethyl Alcohol 75% v/v	Antisep	
	Use(s)		
<b>Alcohol Antiseptic 75%</b>	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Alcohol Alltiscptic 7570	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		
Hand Sanitizer Gel	When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water		
Haria Samitizer Ger	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		
MIDLAND	• P lace enough product on hands to cover all surfaces. Rub hands together until dry.		
PRODUCTS	• Supervise children under 6 years of age when using this product to avoid swallowing.		
	Other Information		
	• Store between 15-30C (59-86F)		
V 1 = 1 (40 co)	Avoid freezing and excessive heat above 40C (104F)		
<b>Vol: 5 gal (18.92L)</b> ADE IN USA	Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol		
ADE IN USA	Mantufactured for: Midland Products LLC	Manfufactured for:	
8888	18600 Graphic Ct.		
	Tinley Park, IL 60477		
	Phone: 708-444-8200	Tiv.	
NDC: 77136-500-10	Drug Facts		
	Active Ingredient(s)	Purpos	
	Ethyl Alcohol 75% v/v	Ant isep	
	Use(s)		
<b>Alcohol Antiseptic 75%</b>	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
Alcohol Alltiscptic 73/0	Warnings		
	For external use only. Flammable. Keep away from heat or flame		
	Do not use		
	• in children less than 2 months of age		
Hand Sanitizer Gel	• on open skin wounds		
nanu Sannuzer Ger	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.		
	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.		
WIIDI VANID			
PRODUCTS	Supervise children under 6 years of age when using this product to avoid swallowing.		
PRODUCTS	COURT AN INC. TOUR		
PRODUCTS	Supervise children under 6 years of age when using this product to avoid swallowing.  Other Information  Store between 15-30C (59-86F)		
PRODUCTS	Other Information		
Vol: 1 gal (3.78L)	Other Information  *Store between 15-30C (59-86F)		
	Other Information  Store between 15-30C (59-86F)  Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfuractured for:		
	Other Information  •Store between 15-30C (59-86F)  •Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfurfactured for: Midland Products LLC		
	Other Information  Store between 15-30C (59-86F)  Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfuractured for:		
	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC  18600 Graphic Ct.		
MADE IN USA	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC  18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200		
	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC  18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200  Drug Facts	Purnos	
MADE IN USA	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s)	100000	
MADE IN USA	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s)  Ethyl Alcohol 75% v/v.		
NADE IN USA NDC: 77136-500-16	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s)  Ethyl Alcohol 75% v/v.  Use(s)	Antisep	
MADE IN USA	Other Information  *Store between 15-30C (59-86F)  • Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s)  Ethyl Alcohol 75% v/v	Antisep	
NDC: 77136-500-16	Other Information  •Store between 15-30C (59-86F)  •Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley P ark, IL 60477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s) Ethyl Alcohol 75% v/v.  Use(s)  Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  Warnings	Antisep	
NDC: 77136-500-16	Other Information  •Store between 15-30C (59-86F)  •Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfurfactured for: Midland Products LLC 18800 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s) Ethyl Alcohol 75% v/v	Antisep	
NADE IN USA NDC: 77136-500-16	Other Information  •Store between 15-30C (59-86F)  •Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley P ark, IL 60477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s) Ethyl Alcohol 75% v/v.  Use(s)  Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  Warnings	Antise	
MADE IN USA  NDC: 77136-500-16	Other Information  *Store between 15-30C (59-86F)  Avoid freezing and excessive heat above 40C (104F)  Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol  Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200  Drug Facts  Active Ingredient(s)  Ethyl Alcohol 75% v/v.  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	Purpos:Ant isept	

Directions

Other Information

## Hand Sanitizer Gel



MADE IN USA



• Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Vol: 16 fl.oz (473.1 ml) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200

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.

• Place enough product on hands to cover all surfaces. Rub hands together until dry.

 $\bullet \, \text{Supervise children under 6} \, \text{years of age when using this product to avoid swallowing}.$ 

NDC: 77136-500-08	Drug Facts	
	Active Ingredient(s) Purpo	
	Ethyl Alcohol 75% v/v	
	Use(s)	
Alcohol Antiseptic 75%	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	
<b>Hand Sanitizer Gel</b>	• 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.	
	Directions	
MIDI AND	• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
PRODUCTS	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)	
Vol: 8 fl.oz (236.5 ml)	Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol	
IADE IN USA	Manfufactured for:	
	Midland Products LLC	
SOLON.	18500 Graphic Ct.	
	Tinley Park, IL 60477 Phone: 708-444-8200	

Active Ingredient(s)

# **Alcohol Antiseptic 75%**

# **Hand Sanitizer Gel**



Vol: 2 fl.oz (59 ml)



Ethyl Alcohol 75% v/v	Antiseptic
Use(s)	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and v	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 eye, rinse eyes	sthoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	60 - 90
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center ri	ght 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, Aminomethyl Propanol	
Manfufactured for:	
Midland Products LLC	
18600 Graphic Ct.	
Tinley Park, IL 60477	

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				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77136-500	
Route of Administration	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)		

P	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)	

Revised: 7/2020 Midland Products LLC