#### 80% 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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# 80% Ethyl Alcohol Gel

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 80% 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**

Water, Acrylates Copolymer, Fragrance, Aminoethyl Propanol

#### Package Label - Principal Display Panel

N DC: 77136-700-75	Drug Facts			
	Active Ingredient(s) Purpos			
	Ethyl Alcohol 80% v/v	Antisepti		
	Use(s)			
Alcohol Antiseptic 80%	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.			
Alconol Antiseptic 0070	Warnings			
	For external use only. Flammable. Keep away from heat or flame			
	Do not use			
	in children less than 2 months of age			
Hand Constinue 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.			
	Directions			
MIDLAND	Place enough product on hands to cover all surfaces. Rub hands together until dry.			
PRODUCTS	<ul> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>			
	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 ProductsLLC			
	18600 Graphic Ct.			
	Tinley Park, IL 60477			
	Phone: 708-444-8200			
NDC: 77136-700-55	Drug Facts	103		
	Active Ingredient(s)	Purpose		
	Ethyl Alcohol 80% v/v	Antisepti		
	Use(s)			
Alcohol Antiseptic 80%		lable.		
	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not ava			
Alconol Antiscptic 0070	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not ava Warnings			
Alconol Antiscptic 00/0				
Alconol Antiscptic 00/0	Warnings			
	Warnings For external use only. Flammable. Keep away from heat or flame			
•	Warnings For external use only. Flammable. Keep away from heat or flame Do not use			
Hand Sanitizer Gel	Warnings           For external use only. Flammable. Keep away from heat or flame           Do not use           • in children less than 2 months of age			
•	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			
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Hand Sanitizer Gel	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 eyesthoroughly with           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)			
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Hand Sanitizer Gel	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 thoroughly with           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 handstogether 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, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol           Manfufactured for:			
Hand Sanitizer Gel	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 thoroughly with           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 handstogether 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, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol			
Hand Sanitizer Gel	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 eyesthoroughly with           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: Water, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol           Manfufactured for:           Midland ProductsLLC			

NDC: 77136-700-05	Drug Facts	61 - C		
		Purpose		
	Ethyl Alcohol 80% v/v	Antisepti		
Alashal Autisoutis 000/	Use(s)			
Alcohol Antiseptic 80%	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 Cardillar 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.			
	Directions  Place enough product on hands to cover all surfaces. Rub hands together until dry.			
MIDLAND	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: 5 gal (18.92L)	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			
N DC: 77136-700-10	Drug Facts	5 <b>1</b>		
	Active Ingredient(s)	Purpose		
		Antisepti		
	Use(s)			
Alcohol Antiseptic 80%	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.			
Alconol Antiscptic 0070	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	• 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.			
Hand Samuzer Oct	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)			
Vol: 1 gal (3.78L)	Avoid freezing and excessive heat above 40C (104F)			
MADE IN USA	Inactive Ingredients: Water, AcrylatesCopolymer, Fragrance, AminomethylPropanol Manfufactured for:			
	Midland Products LLC			
	18600 Graphic Ct. Tinley Park, IL 60477			
	Phone: 708-444-8200			
		64		
NDC: 77136-700-16	Drug Facts	8		
		Purpose		
		Ant isept		
Alashal Anticantia 000/	Use(s)			
Alcohol Antiseptic 80%	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			
Lland 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.			
	Directions			
MIDLAND	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.			
PRODUCTS	Other Information			
FRODUCTS				
PRODUCTS	• Store between 15-30C (59-86F)			
Vol: 16 oz (473.1ml)	Store between 15-30C (59-86F)     Avoid freezing and excessive heat above 40C (104F)			
Vol: 16 oz (473.1ml) MADE IN USA	• Store between 15-30C (59-86F)			
	Store between 15-30C (59-86F)     Avoid freezing and excessive heat above 40C (104F)     Inactive Ingredients: Water, AcrylatesCopolymer, Fragrance, AminomethylPropanol Manfufactured for: Midland Products LLC			
	Store between 15-30C (59-86F)     Avoid freezing and excessive heat above 40C (104F)     Inactive Ingredients: Water, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol Manfufactured for:			

N DC: 77136-700-08	Drug Facts				
	Active Ingredient(s) Purpos				
	Ethyl Alcohol 80% v/v				
	Use(s)				
Alcohol Antiseptic 80%	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.				
Alconol Antiscptic 0070	Warnings				
	For external use only. Flammable. Keep away from heat or flame				
	Do not use				
	in children less than 2 months of age				
Hand Constitute 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.				
	Directions				
MIDLAND	<ul> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> </ul>				
PRODUCTS	Supervise children under 6 years of age when using this product to avoid swallowing.				
	Other Information				
	Store between 15-30C (59-86F)				
	<ul> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>				
Vol: 8 oz (236.5ml)	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				
N DC: 77136-700-02	Drug Facts	205			
	Active Ingredient(s)	Purpose			
	Ethyl Alcohol 80% v/v	Ant isept			
	Use(s)				
Alcohol Antiseptic 80%	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.				
Alconol Antiscptic 00/0	Warnings				
	For external use only. Flammable. Keep away from heat or flame				
	For external use only. Flammable. Keep away from heat or flame				
	For external use only. Flammable. Keep away from heat or flame Do not use				
Hand Sanitizer Gel	For external use only. Flammable. Keep away from heat or flame Do not use  • in children less than 2 months of age	h water.			
Hand Sanitizer Gel	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	h water.			
Hand Sanitizer Gel	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	h water.			
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Hand Sanitizer Gel	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         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	h water.			
Hand Sanitizer Gel	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 wit 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 handstogether until dry.	h water.			
Hand Sanitizer Gel	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 wit 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 handstogether until dry. Supervise children under 6 years of age when using this product to avoid swallowing.	h water.			
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Vol: 2 oz (59ml)	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         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)	h water.			
MIDLAND	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         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 handstogether 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, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol         Manfufactured for:	h water.			
Vol: 2 oz (59ml)	For external use only. Flammable. Keep away from heat or flame     Do not use     in children less than 2 months of age     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 eyesthoroughly wit     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: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol     Marfufactured for:     Midland Products LLC	h water.			
Vol: 2 oz (59ml)	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         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 handstogether 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, AcrylatesCopolymer, Fragrance, Aminomethyl Propanol         Manfufactured for:	h water.			

59 mL NDC: 77136-700-02

236.5 mL NDC: 77136-700-08

473.1 mL NDC: 77136-700-16

3785.4 mL NDC: 77136-700-10

18927.1 mL NDC: 77136-700-05

208197.6 mL NDC: 77136-700-55

1040988.2 mL NDC: 77136-700-75

80% ETHYL ALCOHOL GEL SANITIZER					
alcohol liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77136-700		
Route of Administration	TOPICAL				
<b>Active Ingredient/Active Moi</b>	ety				

	Ingredient Name Basis o			f Strength		Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHO			-	80	mL in 100 mL			
Iı	nactive Ingr	e die nts						
			Ingredient Name				Strength	
FI	RAGRANCE LI	EMON OR	<b>C2001060</b> (UNII: K1725A7G95)					
M	ETHACRYLIC	ACID - ET	THYL ACRYLATE COPOLYMER (4500 MPA.S) (UN	II: T967IEU43	C)	4.5	mL in 100 mL	
A	MINO METHYI	PROPAN	<b>OL</b> (UNII: LU49E6626Q)			0.1	4 mL in 100 mL	
W	ATER (UNII: 0	59QF0KO	) R)					
Р	ackaging							
#	Item Code		Package Description		Marketir Start Da	-	Marketing En Date	
1	NDC:77136- 700-02	59 mL in	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 05/18/2020					
2	NDC:77136- 700-08	236.5 mL	236.5 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 05/18/2020					
3	NDC:77136- 700-16	473.1 mL	473.1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product 05/18/2020					
4	NDC:77136- 700-10	3785.4 m	3785.4 mL in 1 JUG; Type 0: Not a Combination Product 05/18/2020					
5	NDC:77136- 700-05	18927.1 r	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product 05/18/2020					
6	NDC:77136- 700-55	208197.6 mL in 1 DRUM; Type 0: Not a Combination Product 05/18/2020						
7	NDC:77136- 700-75							
	<b>Aarketing</b>	Inform	nation					
N	iui keung	5			g Start Date M		Aarketing End Date	
	U	tegory	Application Number or Monograph Citation	Marketing	Start Date	Mar	keting End Date	

# Labeler - Midland Products LLC (138382226)

Establishment					
Name	Address	ID/FEI	Business Operations		
Midland Products LLC		138382226	manufacture(77136-700), label(77136-700)		

Revised: 7/2020

Midland Products LLC