

80% ALCOHOL HAND SANITIZER- ethyl alcohol hand sanitizer 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.

WHO 80% Ethyl Alcohol Hand Sanitizer

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

glycerin, hydrogen peroxide, purified water USP

WHO 80% Alcohol Principal Display Panel

NDC: 77136-300-75		Drug Facts	
<p>Alcohol Antiseptic 80% Topical Solution</p> <p>Hand Sanitizer Gel Non-Sterile Solution</p>  <p>Vol: 275 gal (1040.98L)</p> <p>MADE IN USA</p> 		Active Ingredient(s)	Purpose
		Ethyl Alcohol 80% v/v.....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 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			
<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: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol			
Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200			

NDC: 77136-300-55		Drug Facts	
<p>Alcohol Antiseptic 80% Topical Solution</p> <p>Hand Sanitizer Gel Non-Sterile Solution</p>  <p>Vol: 55 gal (208.19L)</p> <p>MADE IN USA</p> 		Active Ingredient(s)	Purpose
		Ethyl Alcohol 80% v/v.....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 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			
<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: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol			
Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200			

NDC: 77136-300-05

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Gel Non-Sterile Solution



Vol: 5 gal (18.92L)

MADE IN USA



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/v

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

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.

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

Manufactured for:

Midland Products LLC
18600 Graphic Ct.
Tinley Park, IL 60477
Phone: 708-444-8200

NDC: 77136-300-10

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Gel Non-Sterile Solution



Vol: 1 gal (3.78L)

MADE IN USA



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/v

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

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.

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

Manufactured for:

Midland Products LLC
18600 Graphic Ct.
Tinley Park, IL 60477
Phone: 708-444-8200

NDC: 77136-300-16

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Gel Non-Sterile Solution



Vol: 16 oz (473.1ml)

MADE IN USA



Drug Facts

Active Ingredient(s)

Ethyl Alcohol 80% v/v

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

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.

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

Manufactured for:

Midland Products LLC
18600 Graphic Ct.
Tinley Park, IL 60477
Phone: 708-444-8200

NDC: 77136-300-08		Drug Facts				
<h1 style="text-align: center;">Alcohol Antiseptic 80%</h1> <h2 style="text-align: center;">Topical Solution</h2> <h3 style="text-align: center;">Hand Sanitizer Gel</h3> <h4 style="text-align: center;">Non-Sterile Solution</h4>		<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Active Ingredient(s)</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 80% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active Ingredient(s)	Purpose	Ethyl Alcohol 80% v/v	Antiseptic
		Active Ingredient(s)	Purpose			
Ethyl Alcohol 80% v/v	Antiseptic					
 <p style="text-align: center;">Vol: 8 oz (236.5ml)</p> <p>MADE IN USA </p>		<p>Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use</p> <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds <p>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.</p> <p>Directions</p> <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. <p>Other Information</p> <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) <p>Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol</p> <p>Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200</p>				

NDC: 77136-300-02		Drug Facts				
<h1 style="text-align: center;">Alcohol Antiseptic 80%</h1> <h2 style="text-align: center;">Topical Solution</h2> <h3 style="text-align: center;">Hand Sanitizer Gel</h3> <h4 style="text-align: center;">Non-Sterile Solution</h4>		<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Active Ingredient(s)</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 80% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active Ingredient(s)	Purpose	Ethyl Alcohol 80% v/v	Antiseptic
		Active Ingredient(s)	Purpose			
Ethyl Alcohol 80% v/v	Antiseptic					
 <p style="text-align: center;">Vol: 2 oz (59ml)</p> <p>MADE IN USA </p>		<p>Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use</p> <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds <p>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.</p> <p>Directions</p> <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. <p>Other Information</p> <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) <p>Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol</p> <p>Manufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200</p>				

59mL NDC: 77136-300-02

236.5mL NDC: 77136-300-08

473.1mL NDC: 77136-300-16



3785.4 mL NDC: 77136-300-10

18927.1 mL NDC: 77136-300-05



208197.6 mL NDC: 77136-300-55

1040988.2 mL NDC: 77136-300-75

354.8ml NDC: 77136-300-12

NDC: 77136-300-12		Drug Facts	
<h1>Alcohol Antiseptic 80%</h1> <h2>Topical Solution</h2> <h3>Hand Sanitizer Gel</h3> <h3>Non-Sterile Solution</h3>  <p>Vol: 12 fl oz (354.8 ml)</p> <p>MADE IN USA</p> 		Active Ingredient(s)	Purpose
		Ethyl Alcohol 80% v/v.....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 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			
<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			
Manufactured for:			
Midland Products LLC			
18600 Graphic Ct.			
Tinley Park, IL 60477			
Phone: 708-444-8200			

709.7ml NDC: 77136-300-24

NDC: 77136-300-24		Drug Facts	
<h1>Alcohol Antiseptic 80%</h1> <h2>Topical Solution</h2> <h3>Hand Sanitizer Gel</h3> <h3>Non-Sterile Solution</h3>  <p>Vol: 24 fl oz (709.7 ml)</p> <p>MADE IN USA</p> 		Active Ingredient(s)	Purpose
		Ethyl Alcohol 80% v/v.....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 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			
<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			
Manufactured for:			
Midland Products LLC			
18600 Graphic Ct.			
Tinley Park, IL 60477			
Phone: 708-444-8200			

80% ALCOHOL HAND SANITIZER

ethyl alcohol hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77136-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77136-300-10	3785.4 mL in 1 JUG; Type 0: Not a Combination Product	05/18/2020	
2	NDC:77136-300-05	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	05/18/2020	
3	NDC:77136-300-55	208197.6 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	
4	NDC:77136-300-75	1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/18/2020	
5	NDC:77136-300-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/18/2020	
6	NDC:77136-300-08	236.5 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/18/2020	
7	NDC:77136-300-16	473.1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/18/2020	
8	NDC:77136-300-12	354.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
9	NDC:77136-300-24	709.7 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Midland Products LLC (138382226)

Establishment

Name	Address	ID/FEI	Business Operations
Midland Products LLC		138382226	manufacture(77136-300) , label(77136-300)