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.

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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.

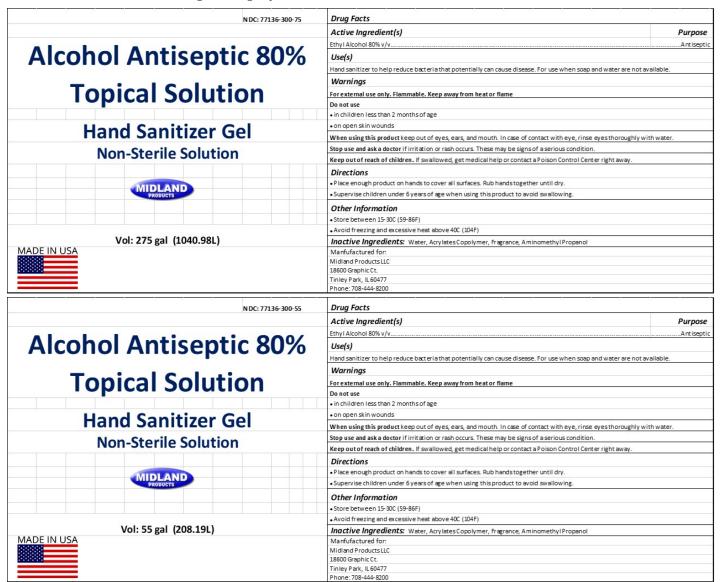
Other information

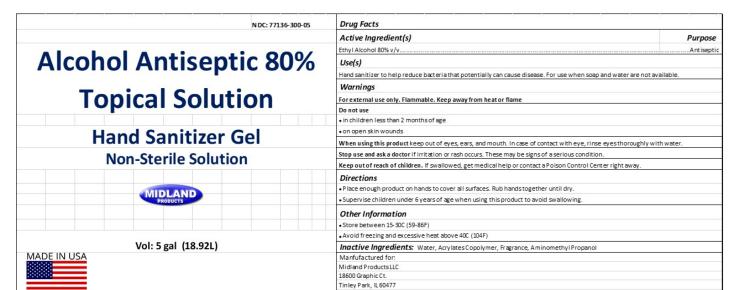
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

WHO 80% Alcohol Principal Display Panel





Phone: 708-444-8200

Drug Facts

NDC: 77136-300-10

NDC: 77136-300-16

Alcohol Antiseptic 80% Topical Solution

> Hand Sanitizer Gel Non-Sterile Solution



Vol: 1 gal (3.78L)



 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

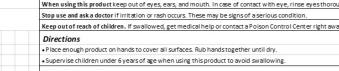
Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer Gel **Non-Sterile Solution**



Vol: 16 oz (473.1ml)



 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)

Manfufactured for Midland Products LLC

Tinley Park, IL 60477

MADE IN USA

Active Ingredient(s) Purpose Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available Warninas For external use only. Flammable. Keep away from heat or flame • 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 Place enough product on hands to cover all surfaces. Rub hands together until dry. Manfufactured for Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200

Drug Facts Active Ingredient(s) Purpose

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

Use(s)

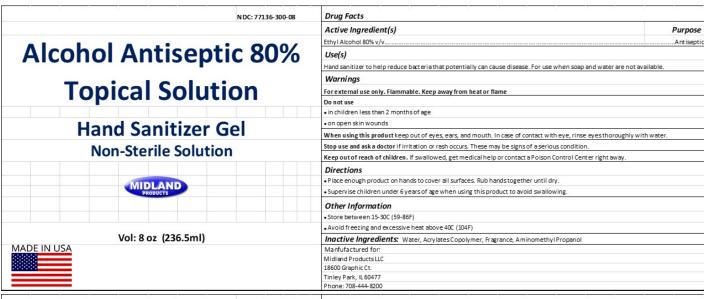
• in children less than 2 months of age

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

Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol

18600 Graphic Ct.

Phone: 708-444-8200



Purpose

NDC: 77136-300-02 **Drug Facts** Active Ingredient(s) **Alcohol Antiseptic 80%** Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available Warninas **Topical Solution** For external use only. Flammable. Keep away from heat or flame • 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. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Non-Sterile Solution 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: 2 oz (59ml) 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

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 | |
|--------------------------|---|--|
| | Active Ingredient(s) Purpos | |
| | Ethyl Alcohol 80% v/v | |
| Alcohol Antiseptic 80% | Use(s) | |
| Alcohol Alltiscptic 0070 | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| | Warnings | |
| Topical Solution | For external use only. Flammable. Keep away from heat or flame | |
| Topical Solution | Do not use | |
| | • in children less than 2 months of age | |
| Hand Canitinas 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. | |
| Non-Sterile Solution | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| Non-Sterile Solution | 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. | |
| PRODUCTS | Other Information | |
| | • Store between 15-30C (59-86F) | |
| | Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 12 fl oz (354.8 ml) | Inactive Ingredients: Glycerin, Hydrogen Peroxide, Purified Water USP | |
| MADE IN USA | Manfufactured for: | |
| | Midland Products LLC | |
| 200000 | 18600 Graphic Ct. | |
| | Tinley Park, IL 60477 | |
| | Phone: 708-444-8200 | |

709.7ml NDC: 77136-300-24

| NDC: 77136-300-24 | Drug Facts | |
|--------------------------|---|--|
| | Active Ingredient(s) Purpose | |
| -1 1 1 - 1 | Ethyl Alcohol 80% v/v | |
| Alcohol Antiseptic 80% | Use(s) | |
| Alcohol Alltiscptic 0070 | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| | Warnings | |
| Topical Solution | For external use only. Flammable. Keep away from heat or flame | |
| Topical Solution | Do not use | |
| | • in children less than 2 months of age | |
| Hand Canitinas 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. | |
| Non-Sterile Solution | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| Non-Sterile Solution | 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. | |
| PRODUCTS | Other Information | |
| | • Store between 15-30C (59-86F) | |
| | Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 24 fl oz (709.7 ml) | Inactive Ingredients: Glycerin, Hydrogen Peroxide, Purified Water USP | |
| MADE IN USA | Manfufactured for: | |
| | Midland Products LLC | |
| 888888 | 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 PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
|---------------------------------------|--------------------|
| WATER (UNII: 0590F0K00R) | |

| 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) | |

Revised: 5/2020 Midland Products LLC