

GEL HAND SANITIZER- alcohol gel

Willamia Dis tilling

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.

Gel 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

Antimicrobial, 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)
- May discolor certain fabrics or surfaces.

Inactive ingredients

water, glycerin, thickener, ph balancer, fragrance

Package Label - Principal Display Panel

89ml NDC 74747-004-01

| Drug Facts | |
|--|----------------|
| Active ingredient(s) | Purpose |
| Ethyl Alcohol 80% v/v..... | Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| 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 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) ⊗ May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

**80% Ethyl Alcohol
Gel Solution**

**Gel Hand Rub
Non-sterile Solution**

3 ounces

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

237ml NDC 74747-004-02

Gel Hand Sanitizer

| | |
|--|---------------------------------|
| Drug Facts | |
| Active ingredient(s) Ethyl Alcohol 80% v/v..... | Purpose Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| Warnings For external use only. Flammable, Keep away from heat or flame. | |
| Do not use <input checked="" type="checkbox"/> in children less than 2 months of age <input checked="" type="checkbox"/> on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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: <input checked="" type="checkbox"/> Place enough product on hands to cover all surfaces. Rub hands together until dry. <input checked="" type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other Information: <input checked="" type="checkbox"/> Store between 15-30C (59-86F) <input checked="" type="checkbox"/> May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

80% Ethyl Alcohol Gel Solution

Gel Hand Rub Non-sterile Solution

8 ounces

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

4473ml NDC 74747-004-03

Gel Hand Sanitizer

| | |
|--|---------------------------------|
| Drug Facts | |
| Active ingredient(s) Ethyl Alcohol 80% v/v..... | Purpose Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| Warnings For external use only. Flammable, Keep away from heat or flame. | |
| Do not use <input checked="" type="checkbox"/> in children less than 2 months of age <input checked="" type="checkbox"/> on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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: <input checked="" type="checkbox"/> Place enough product on hands to cover all surfaces. Rub hands together until dry. <input checked="" type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other Information: <input checked="" type="checkbox"/> Store between 15-30C (59-86F) <input checked="" type="checkbox"/> May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

80% Ethyl Alcohol Gel Solution

Gel Hand Rub Non-sterile Solution

16 ounces

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

946ml NDC 74747-004-04

Gel Hand Sanitizer

| Drug Facts | |
|--|----------------|
| Active ingredient(s) | Purpose |
| Ethyl Alcohol 80% v/v..... | Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| Warnings For external use only. Flammable, Keep away from heat or flame. | |
| Do not use <input checked="" type="checkbox"/> in children less than 2 months of age <input checked="" type="checkbox"/> on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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: <input checked="" type="checkbox"/> Place enough product on hands to cover all surfaces. Rub hands together until dry. <input checked="" type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other Information: <input checked="" type="checkbox"/> Store between 15-30C (59-86F) <input checked="" type="checkbox"/> May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

80% Ethyl Alcohol Gel Solution

Gel Hand Rub Non-sterile Solution

32 ounces

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

33667ml NDC 74747-004-05

Gel Hand Sanitizer

| Drug Facts | |
|--|----------------|
| Active ingredient(s) | Purpose |
| Ethyl Alcohol 80% v/v..... | Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| Warnings For external use only. Flammable, Keep away from heat or flame. | |
| Do not use <input checked="" type="checkbox"/> in children less than 2 months of age <input checked="" type="checkbox"/> on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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: <input checked="" type="checkbox"/> Place enough product on hands to cover all surfaces. Rub hands together until dry. <input checked="" type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other Information: <input checked="" type="checkbox"/> Store between 15-30C (59-86F) <input checked="" type="checkbox"/> May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

80% Ethyl Alcohol Gel Solution

Gel Hand Rub Non-sterile Solution

128 ounces

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

1041l NDC 74747-004-06

Gel Hand Sanitizer

| | |
|--|---------------------------------|
| Drug Facts | |
| Active ingredient(s) Ethyl Alcohol 80% v/v..... | Purpose Antimicrobial |
| Use(s) Hand Sanitizer to help reduce bacteria on skin. | |
| Warnings For external use only. Flammable, Keep away from heat or flame. | |
| Do not use <input checked="" type="checkbox"/> in children less than 2 months of age <input checked="" type="checkbox"/> on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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: <input checked="" type="checkbox"/> Place enough product on hands to cover all surfaces. Rub hands together until dry. <input checked="" type="checkbox"/> Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other Information: <input checked="" type="checkbox"/> Store between 15-30C (59-86F) <input checked="" type="checkbox"/> May discolor certain fabrics or surfaces | |
| Inactive ingredients Water, Glycerin, Thickener, Ph balancer, Fragrance | |

80% Ethyl Alcohol Gel Solution

Gel Hand Rub Non-sterile Solution

275 gallons

**Willamia Distilling
Buffalo, NY 14213
Flammable Liquid-3**

| GEL HAND SANITIZER | | | | |
|---|----------------|---|----------------------|--------------------|
| alcohol gel | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74747-004 | |
| 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 |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:74747- | 80 mL in 1 BOTTLE, PLASTIC, Type 0; Not a Combination Product | 09/11/2020 | |

| | | | | |
|---|------------------|--|------------|--|
| 1 | 004-01 | 89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/09/2020 | |
| 2 | NDC:74747-004-02 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/09/2020 | |
| 3 | NDC:74747-004-03 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/09/2020 | |
| 4 | NDC:74747-004-04 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/09/2020 | |
| 5 | NDC:74747-004-05 | 3667 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/09/2020 | |
| 6 | NDC:74747-004-06 | 1041000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 09/09/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 09/09/2020 | |

Labeler - Willamia Distilling (117476529)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Willamia Distilling | | 117476529 | manufacture(74747-004) |

Revised: 9/2020

Willamia Distilling