

HAND SANITIZER- alcohol liquid
Gervasi 1700 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.

Hand sanitizer

Alcohol 80 % v/v

Antiseptic

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat or flame

- In children less than 2 months of age
- On open skin wounds

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 40 C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Hand Sanitizer 533mL
Hand Sanitizer 3785mL
Hand Sanitizer 946mL

NDC 74123-001-03



Drug Facts

| Active Ingredient | Purpose |
|--------------------------|----------------|
| Alcohol 80% v/v..... | Antiseptic |

Uses

To help reduce bacteria that can potentially 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 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 to avoid swallowing.

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

Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

Manufactured by Gervasi Vineyard
1700 55th Street NE • Canton, OH 44721 • gervasivineyard.com

NDC 74123-001-02



GERVASI

**HAND
SANITIZER**

TOPICAL SOLUTION

**ALCOHOL ANTISEPTIC 80%
NON-STERILE SOLUTION**

1 GALLON (3785mL) • NOT FOR RESALE

Drug Facts

Active Ingredient

Alcohol 80% v/v.....

Purpose

Antiseptic

Uses

To help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

Warnings

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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

Manufactured by Gervasi Vineyard

1700 55th Street NE • Canton, OH 44721 • gervasivineyard.com

NDC 74123-001-01



GERVASI

**HAND
SANITIZER**

TOPICAL SOLUTION

ALCOHOL ANTISEPTIC 80%
NON-STERILE SOLUTION

18 FL OZ (533mL) • NOT FOR RESALE

Drug Facts

Active Ingredient

Alcohol 80% v/v.Antiseptic

Purpose

Uses

To help reduce bacteria that can potentially 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

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Label

HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74123-001 |
| 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) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:74123-001-01 | 533 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:74123-001-02 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:74123-001-03 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/20/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - Gervasi 1700 LLC (010606034)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Gervasi 1700 LLC | | 010606034 | manufacture(74123-001) |