**HAND SANITIZER- alcohol solution**
**Fresh Sanitizer, 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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**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from heat or flame. Do not consume.

**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)
- May discolor fabrics.

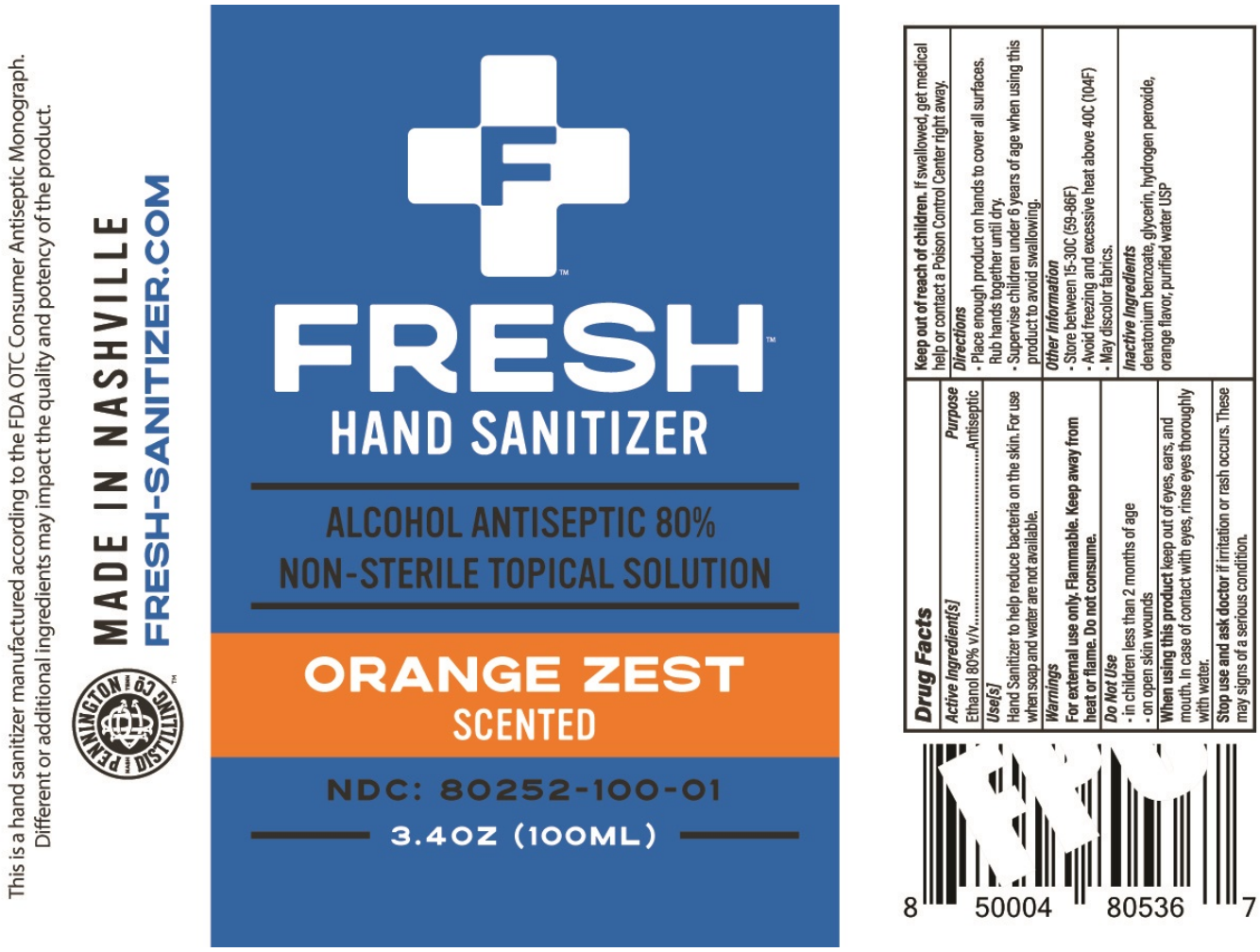
**Inactive ingredients**

denatonium benzoate, glycerin, hydrogen peroxide, orange flavor, purified water USP

**Package Label - Principal Display Panel**

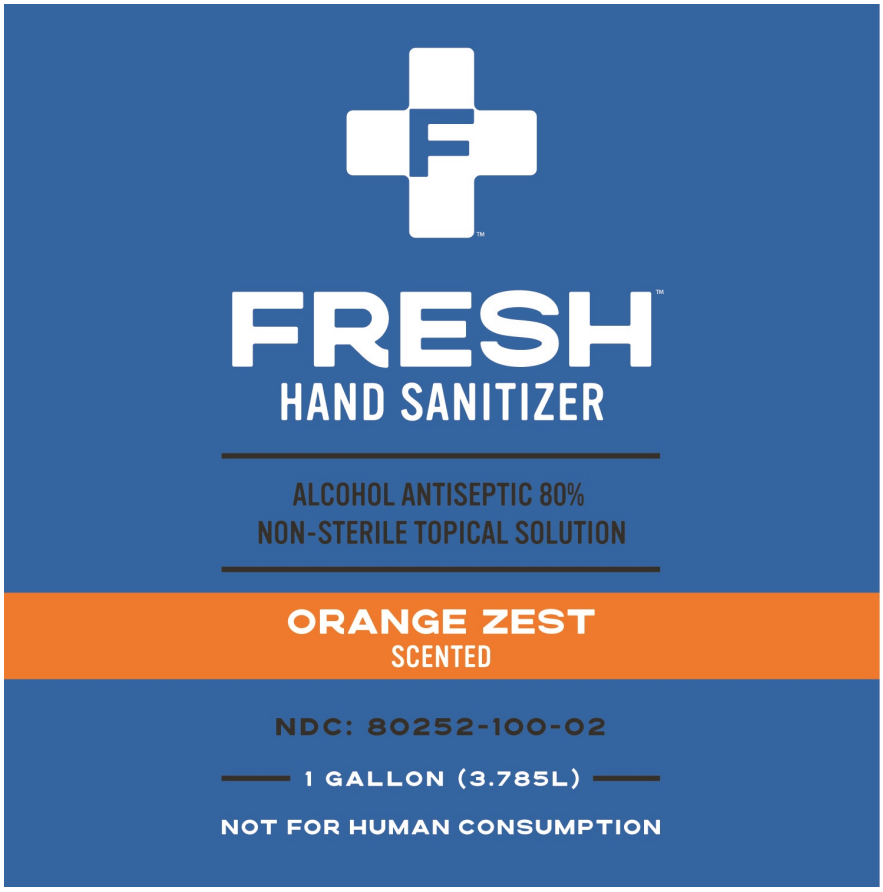
100 mL

NDC: 80252-100-01




3785 mL or 3.785L or 1 Gallon

NDC: 80252-100-02




**Drug Facts**

| | Purpose |
|---|---|
| *Active Ingredient[s]* Ethanol 80% v/v | Antiseptic |

***Use[s]***
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This is a hand sanitizer manufactured according to the FDA OTC Consumer Antiseptic Monograph. Different or additional ingredients may impact the quality and potency of the product.

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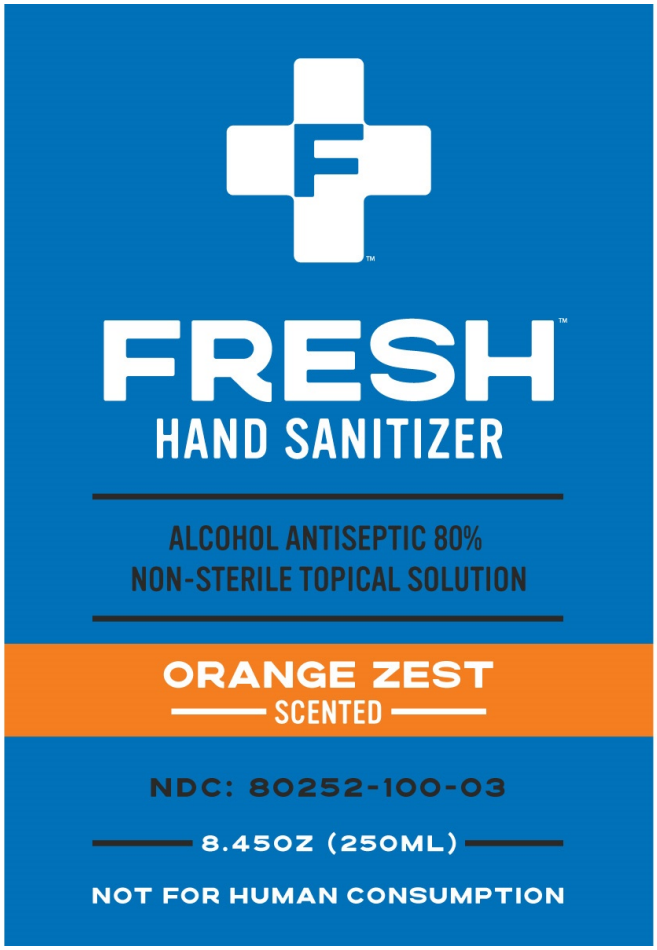
250mL

NDC: 80252-100-03

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# HAND SANITIZER

alcohol solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80252-100 |
| **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** |
| **DENATONIUM BENZOATE** (UNII: 4YK5Z54AT2) | 0.000411 g in 100 mL |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 1.421 mL in 100 mL |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | 0.1251 mL in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | 18.4539 mL in 100 mL |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:80252-100-01 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2020 | |
| **2** | NDC:80252-100-02 | 3785 mL in 1 CONTAINER; Type 0: Not a Combination Product | 10/01/2020 | |
| **3** | NDC:80252-100-03 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 10/01/2020 | |

## Labeler - Fresh Sanitizer, LLC (130701925)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Fresh Sanitizer, LLC | | 130701925 | manufacture(80252-100) |

Revised: 10/2020 Fresh Sanitizer, LLC