**HAND SANITIZER- isopropyl alcohol gel**
**Sugarleaf Labs, Inc.**

*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)**

Isopropyl Alcohol 70% 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.

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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**

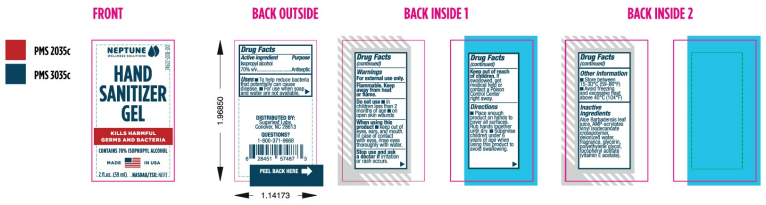
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Aloe Barbadensis leaf juice, AMP-acrylates vinyl isodecanoate crosspolymer, deionized water, fragrance, glycerin, polyethylene glycol, tocopheryl acetate (vitamin E acetate).

**Package Label - Principal Display Panel**

33.8 fl. oz. (1.1 qt.) / 1 L NDC: 74627-008-11




2 fl. oz. (60 ml) NDC: 74627-008-00

# HAND SANITIZER

isopropyl alcohol gel

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:74627-008 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 70 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **GLYCERIN** (UNII: PDC6A3C0OX) | 0.5 mL in 100 mL |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | 0.3 mL in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | 26.8 mL in 100 mL |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | 1.7 mL in 100 mL |
| **.ALPHA.-TOCOPHEROL ACETATE, DL-** (UNII: WR1WPI7EW8) | 0.1 mL in 100 mL |
| **ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%)** (UNII: 2N8MDB79NA) | 0.3 mL in 100 mL |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:74627-008-11 | 1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/20/2020 | |
| **2** | NDC:74627-008-00 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/20/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|

| | | | |
|---|---|---|---|
| OTC monograph not final | part333A | 08/20/2020 | |

## Labeler - Sugarleaf Labs, Inc. (105464061)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Shotwell Hydrogenics, LLC | | 108985732 | manufacture(74627-008) , pack(74627-008) , label(74627-008) |

Revised: 8/2020 Sugarleaf Labs, Inc.