**HAND SANITIZER- alcohol gel**
**Biological Health Group**

*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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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 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.

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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.

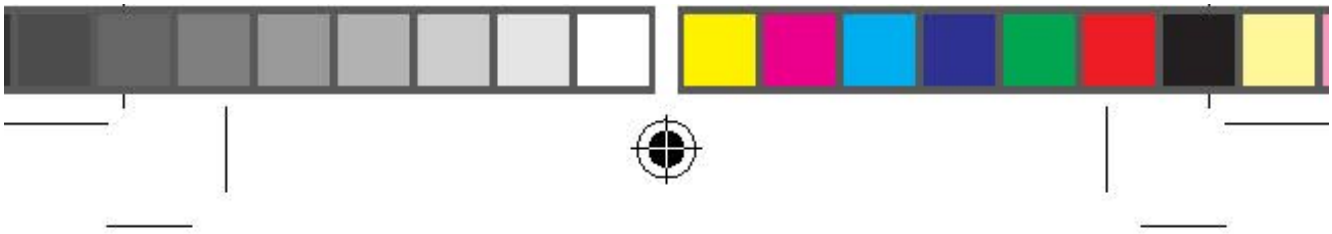
**Other information**

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

**Inactive ingredients**

Aloe Vera Juice, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Aminoethyl Propanol, Carbomer

**Package Label - Principal Display Panel**



NDC: 88888-888-88

PROSANA®
skin & body

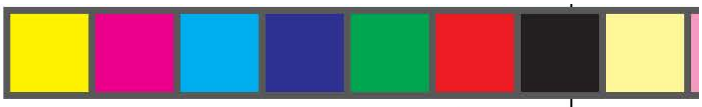
HAND
SANITIZER
GEL

with Aloe & Vitamin E

6 FL. OZ. (177 ML)

Kills 99.99% of Germs





# Drug Facts

| Active Ingredient | Purpose |
|---|---|
| Ethanol (70%) | Antiseptic |

***Use(s)***

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***Other Information***

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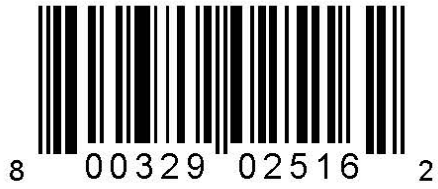
- Avoid freezing & excessive heat above 40C (104F)

***Inactive Ingredients***

Aqua, Aloe Barbadensis (Aloe Vera) Leaf Juice, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate (Vitamin E), Aminoethyl Propanol, Carbomer

Made in Canada. Distributed by Universal Companies
Abingdon, VA. 800-558-5571 **UniversalCompanies.com**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# HAND SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69711-803 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety |
|---|

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | |
| **AMINOMETHYL PROPANEDIOL** (UNII: CZ7BU4QZJZ) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER 940** (UNII: 4Q93RCW27E) | |
| **.ALPHA.-TOCOPHEROL, DL-** (UNII: 7QWA1RIO01) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69711-803-01 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 03/30/2020 | |

## Marketing Information

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

## Labeler - Biological Health Group (079767886)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Deserving Health | | 202617023 | manufacture(69711-803) |

Revised: 5/2020 Biological Health Group