

**HAND SANITIZER ISOPROPYL ALCOHOL ANTISEPTIC 70% TOPICAL GEL- isopropyl alcohol gel**  
**Solugen, 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.*

-----  
**Hand Sanitizer Isopropyl Alcohol Antiseptic 70% Topical Gel**

This is a hand sanitizer manufactured according to the part333A of the OTC monograph. The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentag formulation)

- a. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.5% v/v).
- c. Hydroxymethyl Cellulose (1.3% v/v) .
- d. Sterile distilled water or boiled cold water.

**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.

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 40C (104F)

**Inactive ingredients**

glycerin, methylcellulose, purified water USP

**Hand Sanitizer Isopropyl Alcohol Antiseptic 70% Topical Gel**



LOT #: \_\_\_\_\_

**Hand Sanitizer Liquid**

**Isopropyl Alcohol Antiseptic 70% Topical Gel**

**Hand Sanitizer**

**Non-sterile Solution**



|  |                              |
|--|------------------------------|
| <b>Drug Facts</b>  |                              |
| <b>Active ingredient(s)</b><br>Isopropyl alcohol 70% v/v   | <b>Purpose</b><br>Antiseptic |
| <b>Use(s)</b><br>Health care personnel hand rub to help reduce bacteria that potentially can cause disease.  |                              |
| <b>Warnings</b><br>For external use only. Flammable. Keep away from heat or flame.<br>Do not use:<br>• in children less than 2 months of age<br>• on open skin wounds.<br>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.<br>Stop use and ask a doctor if irritation or rash occurs. There may be signs of a serious condition.<br>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. |                              |
| <b>Directions</b><br>• Place enough product on hands to cover all surfaces. Rub hands together until dry.<br>• Supervise children under 6 years of age when using this product to avoid swallowing.  |                              |
| <b>Other information</b><br>• Store between 15-30C (59-86F)<br>• Avoid freezing and excessive heat above 40C (104F)  |                              |
| <b>Inactive ingredients</b> glycerin, methylcellulose, purified water USP  |                              |

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

**Net Weight:**  
DOT: UN1993, 3, III, Flammable Liquid, 0.8, 3 (n-propanol, isopropanol)  
Percent Active Alcohol: 70 % (v/v)

14549 Minetta St. Houston, TX 77035  
PHONE: (713) 380-2134

18927000 ml NDC: 71158-004-01

**HAND SANITIZER ISOPROPYL ALCOHOL ANTISEPTIC 70% TOPICAL GEL**

isopropyl alcohol gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71158-004 |
| <b>Route of Administration</b> | 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         |
|--|------------------|
| HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1) | 1.3 mL in 100 mL |
| WATER (UNII: 059QF0KO0R)                   |                  |
| GLYCERIN (UNII: PDC6A3C0OX)                | 1.5 mL in 100 mL |

**Packaging**

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71158-004-01 | 18927000 mL in 1 TANK; Type 0: Not a Combination Product                                 | 08/31/2020           |                    |
| 2 | NDC:71158-004-02 | 1249000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 08/31/2020           |                    |
| 3 | NDC:71158-004-03 | 208198 mL in 1 DRUM; Type 0: Not a Combination Product                                   | 08/31/2020           |                    |
| 4 | NDC:71158-004-04 | 18927 mL in 1 DRUM; Type 0: Not a Combination Product                                    | 08/31/2020           |                    |
| 5 | NDC:71158-004-05 | 3785 mL in 1 PAIL; Type 0: Not a Combination Product                                     | 08/31/2020           |                    |
| 6 | NDC:71158-004-09 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product                                   | 08/31/2020           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 08/31/2020           |                    |

**Labeler** - Solugen, Inc. (057475094)**Establishment**

| Name          | Address | ID/FEI    | Business Operations    |
|---------------|---------|-----------|------------------------|
| Solugen, Inc. |         | 057475094 | manufacture(71158-004) |

**Establishment**

| Name          | Address | ID/FEI    | Business Operations    |
|---------------|---------|-----------|------------------------|
| Solugen, Inc. |         | 117507685 | manufacture(71158-004) |