

# **ANTISEPTIC GEL HANDWASH- antiseptic gel handwash liquid**

## **SafeSpace Co.**

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### **Hand Sanitizer PLD template II**

#### **Active Ingredient**

Ethyl Alcohol 67% v/v.....Antiseptic

#### **purpose**

Antiseptic

#### **Uses**

- Handwash to help decrease bacterial on the skin.
- Recommended for repeated use.

#### **Warnings**

- Flammable. Keep away from fire or flame.
- For external use only.

#### **do not use**

- In the eyes

#### **When Using**

- Do not use in or near the eyes.
- If contact occurs, flush eyes with water for 15 minutes. Consult physician if irritation persists.
- If swallowed, seek medical assistance or consult a poison control center immediately.

#### **Stop Use**

- Stop use and ask a doctor if: Irritation develops. If condition persists for more than 72 hours consult a doctor.
- Keep out of reach of children.
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#### **Directions for Use**

- Place a palmful ( 5 grams) of product in one hand,.
- Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes).
- Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist and rub into the skin until dry (approximately 30 seconds).

- Will air dry in 15 seconds.
- Store below 95 ° F.
- Close spout to avoid evaporation.

Water, triethanolamine, fragrance, acrylic polymer

| Drug Facts  |                |
|---|----------------|
| <b>Active ingredient</b>  | <b>Purpose</b> |
| Ethyl Alcohol 67% v/v   | Antiseptic     |
| <b>Uses</b>   |                |
| <ul style="list-style-type: none"> <li>• Handwash to help decrease bacteria on the skin.</li> <li>• Recommended for repeated use.</li> </ul>  |                |
| <b>Warnings</b>   |                |
| <ul style="list-style-type: none"> <li>• Flammable. Keep away from fire or flame.</li> <li>• For external use only.</li> </ul>  |                |
| <b>Do not use</b>   |                |
| <ul style="list-style-type: none"> <li>• In the eyes.</li> </ul>  |                |
| <b>When using this product</b>  |                |
| <ul style="list-style-type: none"> <li>• Do not use in or near the eyes. If contact occurs, flush eyes with water for 15 minutes. Consult physician if irritation persists.</li> <li>• If swallowed, seek medical assistance or consult a poison control center immediately.</li> </ul>   |                |
| <b>Stop use and ask a doctor if</b>   |                |
| <ul style="list-style-type: none"> <li>• Irritation develops. If condition persists for more than 72 hours consult a doctor. Keep out of reach of children.</li> </ul>  |                |
| <b>Directions</b>   |                |
| Place a 'palmful' (5 grams) of product in one hand.   |                |
| <ul style="list-style-type: none"> <li>• Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes).</li> <li>• Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds).</li> <li>• Will air dry in 15 seconds.</li> </ul> |                |
| <b>Other information</b>  |                |
| Store below 95°F. • Close spout to avoid evaporation.   |                |
| <b>Inactive ingredients</b>   |                |
| Water, Triethanolamine, Fragrance, Acrylic Polymer.   |                |

NDC 81471-693-01

**SafeSpace**™

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Made in USA

600004540

## ANTISEPTIC GEL HANDWASH

antiseptic gel handwash liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81471-693 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  |  | Basis of Strength  | Strength             |                    |
|--|--|--|----------------------|--------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) |  | ALCOHOL  | 67 mL in 100 mL      |                    |
| <b>Inactive Ingredients</b>                            |  |  |                      |                    |
| Ingredient Name  |  | Strength   |                      |                    |
| CARBOMER 940 (UNII: 4Q93RCW27E)                        |  |  |                      |                    |
| TROLAMINE (UNII: 9O3K93S3TK)                           |  |  |                      |                    |
| WATER (UNII: 059QF0KO0R)                               |  |  |                      |                    |
| <b>Packaging</b>                                       |  |  |                      |                    |
| #  | Item Code                                | Package Description  | Marketing Start Date | Marketing End Date |
| 1  | NDC:81471-693-01                         | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/30/2020           |                    |
| <b>Marketing Information</b>                           |  |  |                      |                    |
| Marketing Category                                     | Application Number or Monograph Citation | Marketing Start Date   | Marketing End Date   |                    |
| OTC Monograph Drug                                     | 505G(a)(3)                               | 01/30/2020   |                      |                    |

**Labeler** - SafeSpace Co. (962024704)

| <b>Establishment</b>       |         |           |                        |
|----------------------------|---------|-----------|------------------------|
| Name                       | Address | ID/FEI    | Business Operations    |
| QuestSpecialty Corporation |         | 103840377 | manufacture(81471-693) |

Revised: 12/2024

SafeSpace Co.