

**HAND SANITIZER- alcohol gel**  
**Pacific Star 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 75% 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.

**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**

carbomer, fragrance, glycerin, water


**Package Label - Principal Display Panel**

500mL NDC: 79174 -100-04

|   |
|---|
| <b>Drug Facts (continued)</b>   |
| <b>Directions</b><br><ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul> |
| <b>Other information</b><br><ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>   |
| <b>Inactive ingredients</b> carbomer, fragrance, glycerin, water  |

Exp. Date: \_\_\_\_\_  
 Lot No.: \_\_\_\_\_

DISTRIBUTED BY:  
 Pacific Star, LLC  
 9434 Ashwood Lane  
 Fishers, IN 46038  
 (800) 484-1719  
 Made in China




|   |                              |
|---|------------------------------|
| <b>Drug Facts</b>   |                              |
| <b>Active ingredient[s]</b><br>Alcohol 75% v/v.....   | <b>Purpose</b><br>Antiseptic |
| <b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |                              |
| <b>Warning[s]</b> For external use only. Flammable. Keep away from heat or flame.   |                              |
| <b>Do not use</b><br><ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul> |                              |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.         |                              |
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.                                 |                              |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.                       |                              |

## HAND SANITIZER

alcohol gel

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:79 174-100 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 75 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) |          |
| CARBOMER 940 (UNII: 4Q93RCW27E)                       |          |
| GLYCERIN (UNII: PDC6A3C0OX)                           |          |
| WATER (UNII: 059QF0K00R)                              |          |

### Packaging

| # | Item Code         | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|-------------------|--|----------------------|--------------------|
| 1 | NDC:79 174-100-01 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product   | 03/30/2020           |                    |
| 2 | NDC:79 174-100-02 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020           |                    |
| 3 | NDC:79 174-100-03 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020           |                    |
| 4 | NDC:79 174-100-04 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020           |                    |
| 5 | NDC:79 174-100-05 | 3780 mL in 1 BOTTLE; 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** - Pacific Star LLC (117556007)

## Establishment

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Guangzhou Maycare Cosmetics Factory |         | 554531547 | manufacture(79174-100) |

Revised: 6/2020

Pacific Star LLC