

# HAND SANITIZER- alcohol gel

## QUANZHOU BESTHOPE HOUSEHOLD PRODUCTS CO.,LTD.

*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.*

### 50049-010 Hand Sanitizer

#### Active Ingredient

Ethyl Alcohol 75%

#### Purpose

Antiseptic

#### Use

For Hand Sanitizing

- For external use only
- Flammable. Keep away from fire or flame
- When using this product
- Keep out of eyes. In case of contact with eyes, flush thoroughly with water
- 1 Avoid contact with open skin
- Do not inhale or ingest
- Stop use and ask a doctor
- If skin irritation or redness develops
- Keep out of reach of children. Children under 6 years of age use only under adult supervision

#### Directions

Wet hands thoroughly with product and allow to dry without wiping  
Not recommended for infants

#### Inactive ingredients

Alcohol, Water (Aqua), Glycerin, Butylene Glycol, Carbomer, Aminomethyl Propanol, Aloe Barbadensis Leaf Extract.



**HAND SANITIZER**  
alcohol gel

| Product Information                                       |                  |   |                      |                    |
|---|------------------|---|----------------------|--------------------|
| Product Type  |                  | HUMAN OTC DRUG  | Item Code (Source)   | NDC:50049-010      |
| Route of Administration                                   |                  | 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           |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |                  |   |                      |                    |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q)                    |                  |   |                      |                    |
| WATER (UNII: 059QF0K00R)                                  |                  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                               |                  |   |                      |                    |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                         |                  |   |                      |                    |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)                        |                  |   |                      |                    |
|   |                  |   |                      |                    |
| Packaging   |                  |   |                      |                    |
| #   | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
| 1   | NDC:50049-010-01 | 100 in 1 CARTON   | 07/04/2020           |                    |
| 1   |                  | 45 mL in 1 BOTTLE; Type 0: Not a Combination Product    |                      |                    |
| 2   | NDC:50049-010-02 | 60 in 1 CARTON  | 07/04/2020           |                    |
| 2   |                  | 75 mL in 1 BOTTLE; Type 0: Not a Combination Product    |                      |                    |
| 3   | NDC:50049-010-03 | 24 in 1 CARTON  | 07/04/2020           |                    |
| 3   |                  | 187.5 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 4   | NDC:50049-010-04 | 12 in 1 CARTON  | 07/04/2020           |                    |
| 4   |                  | 375 mL in 1 BOTTLE; Type 0: Not a Combination Product   |                      |                    |
|   |                  |   |                      |                    |
| Marketing Information                                     |                  |   |                      |                    |
| Marketing Category  |                  | Application Number or Monograph Citation                | Marketing Start Date | Marketing End Date |
| OTC monograph not final                                   |                  | part333E  | 06/04/2020           |                    |
|   |                  |   |                      |                    |

| Labeler - QUANZHOU BESTHOPE HOUSEHOLD PRODUCTS CO.,LTD. (529121531) |         |           |                        |
|---|---------|-----------|------------------------|
| Establishment   |         |           |                        |
| Name  | Address | ID/FEI    | Business Operations    |
| QUANZHOU BESTHOPE HOUSEHOLD PRODUCTS CO.,LTD.                       |         | 529121531 | manufacture(50049-010) |

Revised: 7/2020

QUANZHOU BESTHOPE HOUSEHOLD PRODUCTS CO.,LTD.