

ANTIBACTERIAL HAND SANITIZER- alcohol gel
JIANGMEN SHUIZIRUN SANITARY ARTICLES 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.

Drug Facts

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Use

Hand sanitizer to help decrease bacteria on the skin.

When water, soap and towel are not available

Recommended for repeated use.

Warnings

For external use only.

Flammable, keep away from fire or flame

Do not apply around eyes.

Do not use in ears and mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

Keep out of reach of children.

children must be supervised in use of this product.

Directions

Pump as needed into your palms and thoroughly spread on both hands.

Rub into skin until dry.

Inactive ingredients

Pure Water, Triethanolamine, Glycerin, Disodium EDTA, Carbomer

Other Information

Store at 20 ° (68 to 77 °).

May discolor fabrics.

Packaging

Antibacterial Hand Sanitizer

1.8 fl. oz. (54ml)

| | |
|--|--|
| Drug Facts | <i>Hand Sanitizer</i> 1.8 fl. oz. (54 ml) |
| Active Ingredient Purpose Ethyl Alcohol 62% Antiseptic | |
| Use • hand sanitizer to help decrease bacteria on the skin • when water, soap & towel are not available • recommended for repeated use | |
| Warnings For external use only Flammable. Keep away from fire or flame Do not apply around eyes. Do not use in ears & mouth When using this product, avoid contact with eyes. In case of contact flush eyes with water. Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours Keep out of reach of children. Children must be supervised in use of this product. | |
| Directions • pump as needed into your palms and thoroughly spread on both hands • rub into skin until dry | |
| Other information • store at 20 °C (68 °F to 77 °F). • may discolor fabrics | |
| Inactive Ingredients Purified water, triethanolamine, glycerine, Disodium EDTA, carbomer | |
| Made in China | |

ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71734-309 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 62 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71734-309-01 | 54 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/02/2020 | |
| 2 | NDC:71734-309-02 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/02/2020 | |
| 3 | NDC:71734-309-03 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/02/2020 | |
| 4 | NDC:71734-309-04 | 238 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/02/2020 | |
| 5 | NDC:71734-309-05 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/02/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 05/02/2020 | |

Labeler - JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD. (544530534)

Registrant - JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD. (544530534)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD. | | 544530534 | manufacture(71734-309) |

Revised: 5/2020

JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.