**ANNIE- alcohol gel**
**ANNIE INTERNATIONAL, 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.*

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**Active Ingredient**

Alcohol 75%

**Purpose**

Antiseptic

**Use**

Hand Sanitizer to help reduce bacteria on the skin

**Warnings**

Flammable. Keep away from fire or flame

For external use only.

**When using this product**

do not use it near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if**

irritation or rash appears and lasts

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply the sanitizer to the palm of one hand and rub all over hands until your hands are dry
- Children under 6 years of age should be supervised when using

**Other information**

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

**Inactive ingredients**

Water (Aqua), Glycerin, Carbomer, Propylene Glycol, Sodium Hydroxide, Parfum (Fragrance), Aloe Barbadensis Leaf Extract

**Principal Display Panel**

NDC 75629-075-03

annie®

MOISTURIZING HAND SANITIZER GEL WITH ALOE VERA

Kills 99.9% of Most Germs

3.38 OZ (100mL)


NDC 75629-075-09

annie®

MOISTURIZING HAND SANITIZER GEL WITH ALOE VERA

Kills 99.9% of Most Germs

9.5 OZ (280mL)


NDC 75629-075-16

annie®

MOISTURIZING HAND SANITIZER GEL WITH ALOE VERA

Kills 99.9% of Most Germs

16.91 OZ (500mL)


**ANNIE**

alcohol gel

**Product Information**

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:75629-075 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:75629-075-03 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/24/2020 | |
| **2** | NDC:75629-075-09 | 280 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/29/2020 | |
| **3** | NDC:75629-075-17 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/24/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 04/24/2020 | |

## Labeler - ANNIE INTERNATIONAL, INC (874227903)

## Registrant - ANNIE INTERNATIONAL, INC (874227903)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Huizhou Bomei Cosmetic Co., Ltd. | | 546012568 | manufacture(75629-075) |

Revised: 4/2020 ANNIE INTERNATIONAL, INC