

**HAND SANITIZER GEL- ethyl alcohol solution**  
**SPIRIT PHARMACEUTICALS 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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**HAND SANITIZER SOLUTION**

***Drug Facts***

***Active ingredient***

Ethyl alcohol 70%

***Purpose***

Antiseptic

***Uses***

- hand sanitizer to help reduce bacteria on the skin that potentially can cause disease
- recommend for repeated use

***Warnings***

**For external use only. Flammable. Keep away from heat and flame.**

- Do not use**
- in children less than 2 months of age
  - on open skin wounds

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**When using this product**

- keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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**Stop use and ask a doctor if** irritation or rash appears and lasts. 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.
- Children under 6 years of age should be supervised when using this product

### ***Other information***

- Store between 15°-30°C (59°86°F)
- Avoid freezing and excessive heat above 40°C (104°F)
- may discolor certain fabrics or surfaces

### ***Inactive ingredients***

benzalkonium chloride, fragrance, glycerin, hydrogen peroxide, isopropyl myristate, propylene glycol, tocopheryl acetate, water

### **Questions or comments?**

**1-888-333-9792**

Manufactured by: APL

P.O. Box 7771, Ajman, UAE

Under License From

MODD PERFUMES & COSMETICS

10 Cameron Road, Seven Kings

London, IG3 8LA

United Kingdom

For external use only

Made in U.A.E.

Distributed By:

Spirit Pharmaceuticals LLC

Ronkonkoma, NY 11779

### **PRINCIPAL DISPLAY PANEL**

HANDY

HAND-SANITIZER SOLUTION

EFFECTIVELY KILLS 99.9% OF THE  
MOST COMMON GERMS/ BACTERIA

70%

ALCOHOL CONTENT

WITH

VITAMIN E & MOISTURIZERS

PLEASANT FRAGRANCE

STAY PROTECTED

16.9 FL. OZ. (500 ml)

MODD



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MODD



70% ALCOHOL SOLUTION

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64860-3

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## HAND SANITIZER GEL

ethyl alcohol solution

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-4082 |
| 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 |
|--|----------|
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)      |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                   |          |
| <b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)          |          |
| <b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)        |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)           |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                      |          |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68210-4082-5 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/01/2020           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 07/01/2020           |                    |

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2022

SPIRIT PHARMACEUTICALS LLC