

ANTISEPTIC HAND SANITIZER EXTRA STRENGTH GEL- ethyl alcohol gel
Commonwealth Homes, 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.

ANTISEPTIC HAND SANITIZER GEL

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- on children less than 2 months of age
- on open wounds

When using this product do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre right away

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store under 105°F

Inactive ingredients

Hydroxyethyl cellulose, Isopropyl myristate, Propylene glycol, Water

Questions?

1-937-848-2098

You can also report serious side effects to this phone number. Mon - Fri 9.00am - 5.00 pm

Manufactured by: Commonwealth Homes Inc, Centerville, Ohio, 45370

Made in the USA

Packaging

**ANTISEPTIC
HAND SANITIZER
GEL**

1 Gallon (3.79 L)

| Drug Facts | |
|--|----------------|
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Manufactured by: Commonwealth Homes Inc, Centerville, Ohio, 45370
Made in the USA
Lot No: 73802-101-01
Expiry: 73802-101-01

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ANTISEPTIC HAND SANITIZER EXTRA STRENGTH GEL

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73802-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|---------|--------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 L in 1 L |
|--|---------|--------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73802-101-01 | 3.79 L in 1 CONTAINER; Type 0: Not a Combination Product | 03/28/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/28/2020 | |

Labeler - Commonwealth Homes, Inc. (127801525)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|------------|------------------------|
| Commonwealth Homes, Inc. | | 12780 1525 | manufacture(73802-101) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| Integrity Specialty Products | | 608975228 | manufacture(73802-101) |

Revised: 6/2020

Commonwealth Homes, Inc.