

COVIGEL- ethyl alcohol liquid
Flavorcraft Industries 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.

CoviGel Hand Sanitizer 1.25ml

This is a gel hand sanitizer manufactured using only United States Pharmacopoeia (USP) grade ingredients in the preparation of the product.

Active Ingredient(s)

Alcohol 80% v/v.

Purpose

Purpose: Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. 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.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

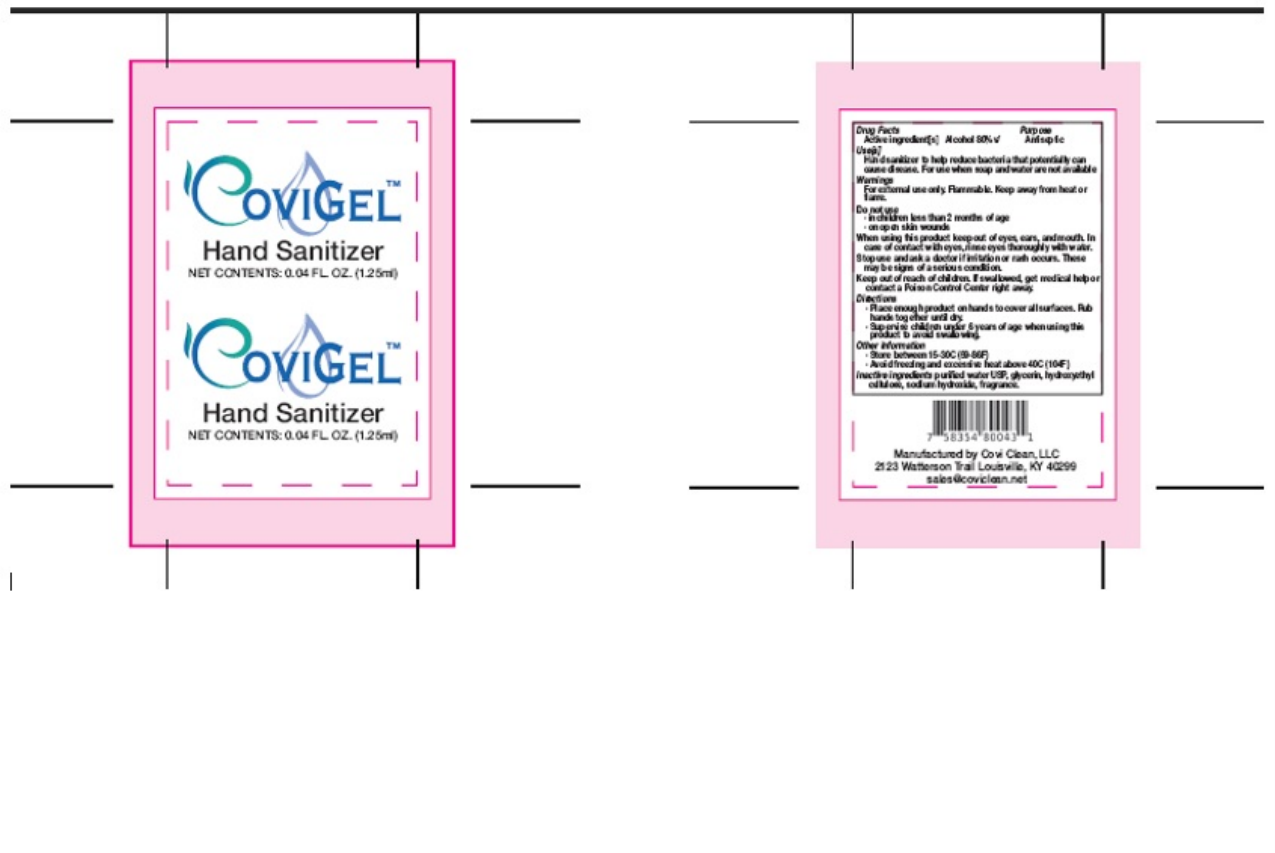
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP, glycerin, hydroxyethyl cellulose, sodium hydroxide, fragrance.

CoviClean 1.25ml

1.25ml NDC, 74593-003-01



COVIGEL

ethyl alcohol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74593-003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-------------------|
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | 0.03 mL in 100 mL |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | 0.97 mL in 100 mL |

| | | | | |
|-----------------------------|------------------|---|----------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | | | 1.2 mL in 100 mL | |
| WATER (UNII: 059QF0KO0R) | | | 17.85 mL in 100 mL | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:74593-003-01 | 1.25 mL in 1 POUCH; Type 0: Not a Combination Product | 06/01/2020 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part333A | 06/01/2020 | |
| | | | | |

Labeler - Flavorcraft Industries Inc (621632921)

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| MaxPax LLC | | 017038858 | pack(74593-003) |

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Flavorcraft LLC | | 621632921 | manufacture(74593-003) |

Revised: 6/2020

Flavorcraft Industries Inc