

CPR HAND SANITIZER- ethyl alcohol gel
FGD, 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.

CPR Hand Sanitizer (250 gals)

Active ingredient

Ethyl Alcohol 70%

Purpose

Antimicrobial

Uses

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. Highly flammable liquid and vapor. Causes serious eye irritation. Keep away from heat or flame.

Do Not Use

- If you are allergic to any of the ingredients
- In children less than 2 months of age
- On open skin wounds

When using this product

When using this product avoid contact with eyes, ears, and mouth.

In case of contact with eyes, rinse eyes thoroughly with water.

Stop use or ask a doctor if

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 (1-800-222-1222) right away.

- Keep away from heat/sparks/open flame/hot surfaces.
- No Smoke. Keep container tightly closed.
- Avoid breathing vapors/mist/spray.
- Contaminated work clothing should not be allowed out of the workplace.
- Wear protective eye protection/face protection.
- Store in a well-ventilated place. Keep cool.
- Dispose of contents/container to a licensed treatment, storage or disposal facility (TSRF)

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73787-116 |
| 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) | |
| GUARAPROLOSE (1300 MPAS AT 1%) (UNII: 1530WMS90S) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73787-116-01 | 946353 mL in 1 DRUM; Type 0: Not a Combination Product | 05/12/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 05/12/2020 | |

Labeler - FGD, LLC (111927555)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Goodwin Co. | | 806987483 | manufacture(73787-116) |

Revised: 1/2021

FGD, LLC