**HAND SANITIZER- alcohol gel**
**Fareva Morton Grove, 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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a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (77%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerin

c. FRAGRANCE (PARFUM)
d. ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
e. ALOE BARBADENSIS LEAF JUICE

f. AMINOMETHYL PROPANOL

g. RED 4 (CI 14700)

h. CITRIC ACID

i. SODIUM BENZOATE

j. POTASSIUM SORBATE

**Active Ingredient(s)**

Alcohol 78% v/v. Purpose: Antiseptic

**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 and redness develops and persists.

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**

Acrylates/C10-30 Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Citric Acid, Fragrance, Glycerin, Potassium Sorbate, Red 4 (CI 14700), Sodium Benzoate, Water

**Package Label - Principal Display Panel**

50 mL NDC: 72686-188-05


**HAND SANITIZER**

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72686-188 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 78 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **AMINOMETHYLPROPANOL** (UNII: LU49E6626Q) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **FRAGRANCE JUNIPERBERRY ORANGE ORC2000843** (UNII: 2KS3NF08B2) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER INTERPOLYMER TYPE A (55000 CPS)** (UNII: 59TL3WG5CO) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **ALOE** (UNII: V5VD430YW9) | |
| **FD&C RED NO. 4** (UNII: X3W0AM1JLX) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72686-188-05 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 12/15/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 12/15/2020 | |

## Labeler - Fareva Morton Grove, Inc. (116752326)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Fareva Morton Grove, Inc | | 116752326 | manufacture(72686-188) , analysis(72686-188) , label(72686-188) , pack(72686-188) , relabel(72686-188) , repack(72686-188) |

Revised: 12/2020 Fareva Morton Grove, Inc.