

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.

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (78%, 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. Glycerol
- c. Hydroxypropyl cellulose
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 78% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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

glycerin, hydroxypropyl cellulose, water

Package Label - Principal Display Panel

135 mL NDC: 72686-180-06

1/4

1/4



InstantGEL™ PURE



Alcohol GEL
Hand Sanitizer
Dye-Free
Perfume-Free

4.5 fl oz
(135 mL)

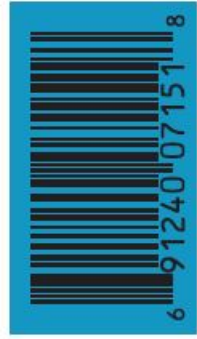


| Drug Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Ethyl alcohol 78%v/v | Antiseptic |
| Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use ■ for when soap and water are not available | |
| Warnings For external use only | |
| Flammable: Keep away from fire or flame. | |
| When using this product ■ Keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin, ■ Do not inhale or ingest. | |
| 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 Center right away. | |
| Directions ■ Wet hands thoroughly with product and allow to dry without wiping. ■ For children under 6, use only under adult supervision. ■ Not recommended for infants. | |
| 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. ■ Harmful to wood finishes and plastics. | |
| Inactive ingredients Glycerin, Hydroxypropylcellulose, Water (Aqua) | |

PRINT HEIGHT 5-1/2
TUBE LENGTH 6-3/8

Stock #: IGP4FLOZ
4000007311

Manufactured for:
SC Johnson Professional USA, Inc.
Charlotte, NC 28217
1-800-248-7190
www.scjp.com



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HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72686-180 |
| 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 |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72686-180-06 | 135 mL in 1 TUBE; Type 0: Not a Combination Product | 06/15/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/15/2020 | |

Labeler - Fareva Morton Grove, Inc. (116752326)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|--|
| Fareva Morton Grove, Inc. | | 116752326 | manufacture(72686-180) , analysis(72686-180) , label(72686-180) , pack(72686-180) , relabel(72686-180) , repack(72686-180) |

Revised: 6/2020

Fareva Morton Grove, Inc.