

HAND SANITIZER- ethanol gel
Fifth Generation, 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.

Hand sanitizer

Ethanol 80% v/v

Antiseptic

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

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

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

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 40 C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Hand Sanitizer

200 mL 73982-000-01

100 mL 73982-000-00

375 mL 73982-000-02

3785 mL 73982-000-03

11356mL 73982-000-04

18927 mL 73982-000-05

208197 mL 73982-000-06



HAND

CLEANSE **CLEANSER**



FOR HANDS ONLY
DO NOT DRINK

MANUFACTURED AND BOTTLED BY FIFTH GENERATION INC. 80% ALC. BY VOL.

LOVE, *Tito's*

Alcohol Antiseptic 80%
Topical Solution
Hand and Surface Cleanser

Non-sterile Solution

Drug Facts

Active ingredient[s]

Purpose

Ethyl Alcohol 80% v/v.....Antiseptic

Use[s]

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

Warnings

For external use on hands and surfaces only. Flammable. Keep away from heat or flame.

Do not use

- on children less than 2 months of age
- on open skin wounds
- on polished wood, painted surfaces, leather, rayon fabrics, or acrylic plastics

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.
- Apply to surfaces as needed. Let air dry.

Other information

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

Inactive ingredients water, hydrogen peroxide, glycerin, tert-butyl alcohol, denatonium benzoate

Please email HandQA@titosvodka.com for questions or concerns.

Expiration Date: 04/2021

Batch ID: X11114

HAND SANITIZER

ethanol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73982-000 |
| 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 |
|--|-----------------|
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TERT-BUTYL ALCOHOL (UNII: MD83SFE959) | |
| DENATONIUM BENZOATE (UNII: 4YK5Z54AT2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:73982-000-01 | 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 2 | NDC:73982-000-00 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 3 | NDC:73982-000-02 | 375 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 4 | NDC:73982-000-03 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 5 | NDC:73982-000-04 | 11356 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 6 | NDC:73982-000-05 | 18927 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |
| 7 | NDC:73982-000-06 | 208197 mL in 1 DRUM; Type 0: Not a Combination Product | 03/27/2020 | |
| 8 | NDC:73982-000-07 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/27/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/27/2020 | |

Labeler - Fifth Generation, Inc. (961445723)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Fifth Generation, Inc. | | 961445723 | manufacture(73982-000) |

Revised: 8/2020

Fifth Generation, Inc.