

**HAND SANITIZER- ethanol cloth
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

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- 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 80% 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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3 mL NDC: 00000-000-00

HAND 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

Produced by Fifth Generation, Inc. in Austin, TX.

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

Expiration Date: 04/2021

Batch ID: X11114

HAND SANITIZER

ethanol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73982-002
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
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GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73982-002-20	2000 in 1 BOX	03/30/2020	
1		3 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:73982-002-10	1000 in 1 BOX	03/30/2020	
2		3 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:73982-002-30	3000 in 1 BOX	03/30/2020	
3		3 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Fifth Generation, Inc. (961445723)

Establishment

Name	Address	ID/FEI	Business Operations
Fifth Generation, Inc.		961445723	manufacture(73982-002)

Revised: 4/2020

Fifth Generation, Inc.