# DRIPPN PURE NATURE HAND SANITIZER- ethyl alcohol 70% gel iGermx 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.

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## **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 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) (70%, 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 0.1854%
- c. Hydrogen peroxide (0.125% v/v).
- d. Water 36.95%
- e. Carbopol 0.824%
- f. Aloe Vera 0.515%
- g. Peppermint 0.215%
- h. AMP 0.1524%
- i. Menthol 0.0515%
- i. Blue 0.00824%

## **Active Ingredient(s)**

Alcohol 70% 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.

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# **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 0.1854% Hydrogen peroxide (0.125% v/v). Water 36.95% Carbopol 0.824% Aloe Vera 0.515% Peppermint 0.215% AMP 0.1524% Menthol 0.0515% Blue 0.00824%

# Package Label - Principal Display Panel

80740-003-04 1 BOTTLE 236 ml

## Kills 99.99% of germs fast. No need to wash, rinse or dry.

- · Ultra-Moisturizing Aloe Vera
- · Leaves hands soft, refreshed & hygienically clean
- · Quick & convenient

Suitable for use when outdoors, while travelling, before food preparation, and after restroom use.

DIRECTIONS: Apply 1-2 pumps to palm. Spread and rub over back of hands and finger tips. Allow hands to air dry.

CAUTION: Keep out of reach of children, For external use only. Do not swallow. Avoid eyes. If irritation occurs, wash affected area and discontinue use.

Do not use on inflamed or broken skin.

Do not store in direct sunlight.

Store below 50°C

MAIN INGREDIENTS: 100% Plant Based 70% Ethyl Alcohol

Inactive Ingredients: Water, Glycerin, Hydroxyethyl Cellulose, Fragance.

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Designed by DRIPPIN in Texas





# PURE NATURE HAND SANITIZER Your Well-Being Starts Here The Third County Hand County Hand

### 80740-003-01 1 BOTTLE 1 L

## Kills 99.99% of germs fast. No need to wash, rinse or dry.

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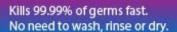
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discontinue use.

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## 80740-003-03 1 BOTTLE 473 ml

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# DRIPPN PURE NATURE HAND SANITIZER

ethyl alcohol 70% gel

# **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:80740-003

Route of Administration TOPICAL

# Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)ALCOHOL0.7 mL in 1 mL

Inactive Ingredients					
Ingredient Name	Strength				
GLYCERIN (UNII: PDC6A3C0OX)	$0.1854\;mL\;$ in $1mL$				
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.5 mL in 1 mL				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	$0.824\ mL$ in $1\ mL$				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	$0.1524\ mL$ in $1\ mL$				
PEPPERMINT OIL (UNII: AV092KU4JH)	0.215 mL in 1 mL				
WATER (UNII: 059QF0KO0R)	$0.37\ mL$ in $1\ mL$				
MENTHOL (UNII: L7T10EIP3A)	$0.0515 \ mL$ in $1 \ mL$				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.00824 mL in 1 mL				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80740-003- 01	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 20			
2	NDC:80740-003- 02	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 20			
3	NDC:80740-003- 03	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 20			
4	NDC:80740-003- 04	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 20			
5	NDC:80740-003- 05	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2020			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	11/0 1/20 20				

# Labeler - iGermx LLC (117603473)

Revised: 9/2020 iGermx LLC