

INPURE HAND SANITIZER- hand sanitizer gel
YEGREENA CO., LTD.

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.

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

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

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

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

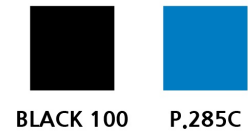
Inactive ingredients

Water, Citrus Limon (Lemon) Fruit Extract, Carbomer, Glycerin, Aminomethyl Propanol, Aloe Barbadensis Leaf Juice, Citrus Paradisi Seed, Camellia Sinensis Leaf Extract, Sodium Hyaluronate

Other information

- Store between 15-30C (59-86F)
- May discolor certain fabrics or surfaces.

Package Label - Principal Display Panel



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Inpure Hand Sanitizer

It simply sanitizes your hands without water
Alcohol Antiseptic 80% | Topical Solution | Non-sterile Solution

PREMIUM HAND SANITIZER

[16.9 fl.oz. (500 mL)]

Inpure Hand Sanitizer

Drug Facts	
Active Ingredient	Purpose
Ethyl alcohol 80% v/v	Antiseptic
Use: Hand sanitizer to help reduce bacteria on the skin.	
Warnings:	
For external use only. Flammable. Keep away from fire or flame.	
When using this product do not use in or near the eyes. In case of contact, 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.	
Other information:	
Store between 15-30°C (59-86°F)	
Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients: Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Camellia Sinensis Leaf Extract, Carbomer, Citrus Limon (Lemon) Fruit Extract, Citrus Paradisi Seed, Glycerin, Sodium Hyaluronate, Water	

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MANUFACTURER: YEGREENA Co., Ltd.
39, Aenggogae-ro 621beon-gil, Namdong-gu, Incheon, Korea [MADE IN KOREA]
EXPIRATION DATE: Marked on the bottom of the product www.yegreenacos.com

INPURE HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78417-101
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
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
WATER (UNII: 059QF0K00R)	
LEMON OIL (UNII: I9GRO824LL)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78417-101-10	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

Labeler - YEGREENA CO., LTD. (690405240)

Establishment

Name	Address	ID/FEI	Business Operations
YEGREENA CO., LTD.		690405240	manufacture(78417-101)

Revised: 6/2020

YEGREENA CO., LTD.