

## **PURI-CLEAN ADVANCED HAND SANITIZER- isopropyl alcohol gel**

### **Prime Enterprises**

*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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### **Puri-Clean Advanced 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. Isopropyl Alcohol (75%, 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)**

Isopropyl 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, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

Active Ingredients	Purpose
Ethyl Alcohol 70% w/v	Antiseptic

**Use** ■ For hand washing to decrease bacteria on the skin.

**Warnings**  
For external use only.

**Flammable:** Do not use near heat, flame or while smoking.

**When using this product** ■ keep out of eyes. If product gets into eyes, rinse with water to remove. Avoid contact with broken skin. Do not inhale or ingest.

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

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

**Directions**  
■ Wet hands thoroughly with product and allow to dry without wiping.  
■ For children under 6, use only under adult supervision.

**Other information**  
■ Do not store above 104° F.  
■ May discolor some fabrics, wood finishes and plastics.

**Inactive ingredients**  
Aloe Barbadosensis Leaf Juice, Aminomethyl Propanol, Carbomer, Glycerin, Isopropyl Myristate, Tocopherol, Water

**Questions and comments** info@makrobeauty.com

\*Kills common germs that may cause illness.  
Distributed by: Makro Beauty, LLC, Miramar, Florida 33027  
Made in USA • From US and imported ingredients

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## PURI-CLEAN ADVANCED HAND SANITIZER

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0331
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0331-5	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

**Labeler** - Prime Enterprises (101946028)

**Registrant** - Prime Enterprises (101946028)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0331) , analysis(58443-0331) , label(58443-0331) , pack(58443-0331)