

**CORNELLS- alcohol gel**  
**Premier Cosmetics**

*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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**Active Ingredient**

Isopropyl Alcohol 70% v/v.

**Purpose**

Antiseptic

**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.

**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<sup>0</sup>C (59-86<sup>0</sup>F)
- Avoid freezing and excessive heat above 40<sup>0</sup>C (104<sup>0</sup>F)

**Inactive ingredients**

Aqua, Glycerin, Propylene Glycol, Isopropyl Myristate, Aminomethyl Propanol, Carbomer, Fragrance, Tocopheryl Acetate, Aloe barbadensis Leaf Extract.

**Package Label - Principal Display Panel**

Label 65 mL

**CORNELLS**  
WELLNESS

**ISOPROPYL ALCOHOL 70%  
KILLS 99.9% OF GERMS**

**INSTANT HAND  
SANITIZER**

ADVANCED FORMULA

Cornells Instant Hand Sanitizer is a 70% Isopropyl Alcohol based rub developed for hand disinfection.



**ANTISEPTIC/DISINFECTANT**  
with Moisturizers & Vitamin E

**65ml e 2.19 fl.oz**

**INSTANT HAND SANITIZER** **CORNELLS**  
WELLNESS

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b> Isopropyl alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Spray 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.	
<b>Other information</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> Aqua, Glycerin, Propylene Glycol, Isopropyl Myristate, Aminomethyl Propanol, Carbomer, Fragrance, Tocopheryl Acetate, Aloe barbadensis Leaf Extract.	

Made in Dubai, U.A.E. Mfd. by PCI  
An ISO 9001: 2015 and ISO 22716: 2007  
GMP Certified Company.  
Dubai • London • Milan • New York • Paris



6 294015 139723



Label 480 mL

**CORNELLS**  
WELLNESS

**INSTANT HAND SANITIZER**



**ISOPROPYL ALCOHOL 70%  
KILLS 99.9% OF GERMS**

**ADVANCED FORMULA**  
**GEL**  
ANTISEPTIC/DISINFECTANT

**480ml e 16.2 fl.oz**

**CORNELLS**  
WELLNESS

**INSTANT HAND SANITIZER**  
**ISOPROPYL ALCOHOL 70%**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b> Isopropyl alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> Aqua, Glycerin, Propylene Glycol, Isopropyl Myristate, Aminomethyl Propanol, Carbomer, Fragrance, Tocopheryl Acetate, Aloe barbadensis Leaf Extract.	

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6 294015 139662



Label 500 mL



Label 1000 mL



Front Clear on Clear



Back PP White

**CORNELLS**  
alcohol gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 117-001
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78 117-001-01	65 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	
2	NDC:78 117-001-02	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	
3	NDC:78 117-001-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	
4	NDC:78 117-001-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/02/2020	

**Labeler** - Premier Cosmetics (557941540)

## Establishment

Name	Address	ID/FEI	Business Operations
Premier Cosmetics		557941540	manufacture(78 117-001)

